ROMADKA Jennifer * DCBS

From: Patricia Clark <[redacted]
Sent: Tuesday, November 26, 2024 12:05 AM
To: WINKEL Karen J * DCBS
Subject: Public comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Karen Winkel,
I am writing to express my deep concern regarding the proposed rules on gender affirming care. According to the current rule HB2002, medical insurers are to provide coverage for “medically necessary” cases prescribed by a licensed provider in consultation with the medical community.
I understand that the Insurance Commissioner is proposing rules that define “accepted standard of care” as outlined by WPATH-8, requiring adherence to their protocols for gender affirming treatment.
It seems limiting and unethical to allow one advocacy body to determine medical standard of care for this population. In addition, it appears that there were no licensed medical or health professionals included on the advisory committee who drafted these proposed rules for the Insurance Commissioner. Is it not the role of the Commissioner to regulate financial institutions, not make decisions regarding medical care?
Similarly, it seems biased and unethical to require that all health professionals be trained by the WPATH-8.
Lastly, any rule regarding gender affirming care must also provide and clearly state provisions for individuals seeking to detransition. It is my understanding that this latter point is not well addressed.
As a clinical psychologist, I have worked with clients with gender dysphoria, a psychiatric condition defined in the Diagnostic snd Statistical Manual of Mental Disorders, edition 5. Throughout the years, I have consulted with psychiatrists and fellow psychologists regarding this disorder and know that any treatment must be open, flexible and individualized for the client, and only be provided by medical and healthcare professionals. Forcing providers to strictly adhere to and train in the protocols of one body, the WPATH-8, with its own agenda, is an injustice to the clients we serve. The WPATH-8 should not be establishing “accepted standard of care” for gender affirming treatment and the Insurance Commissioner must not approve this.
Sincerely,
Dr. Patricia Clark

Sent from my iPhone

ROMADKA Jennifer * DCBS

From: Kara Connelly [redacted] >
Sent: Tuesday, November 26, 2024 4:46 PM
To: WINKEL Karen J * DCBS
Cc: EMERSON Lisa * DCBS; HALL Brooke M * DCBS
Subject: Rulemaking for HB2002
Attachments: Connelly Public Comment- HB2002 rulemaking_.docx

Thank you for your time and consideration.

Best,
Kara Connelly, MD

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Kara Connelly, MD, Pediatric Endocrinologist, Medical Director of a pediatric gender clinic**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Kara Connelly and I am an Oregon healthcare provider working/living in Oregon. I am a pediatric endocrinologist and a medical director of a pediatric gender clinic. I have been treating gender diverse youth and young adults for 13 years, and have seen the positive impact that this medically necessary, lifesaving care has on young people's ability to reduce minority stress, experience alignment in their mind and body, and reach their full potential as adults.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care, version 8 (SOC8). This written testimony will highlight the following key points:

Key points:

1. Large scale (of tens of thousands of individuals) studies about benefits of access to gender affirming care during adolescence AND harm of lack of access to care DO exist

2. Research methods used in gender affirming care are widely accepted & used in other areas of medicine, particularly in pediatrics

3. The Cass Review, published by the United Kingdom, does not recommend a ban on care and agrees with points the WPATH SOC 8 makes

4. The Cass Review has many methodological flaws in the way the data was used & interpreted

5. Clinical practice guidelines and standards of care consider evidence but also benefits & harms of treatment vs no treatment as well as patient/family values & preferences

6. The development of WPATH SOC8 utilized a comprehensive & expansive process including systematic literature reviews & Delphi process for approval

Numerous peer reviewed research papers in well-respected academic journals demonstrate the positive impact of medical care for gender diverse youth on mental health and well-being. The number of studies that evaluate the efficacy of medical care for gender diverse adolescents is significant, and they rely on applying a variety of commonly used research methods including:

- prospective observational and retrospective cross-sectional studies comparing individuals who receive treatment to those who do not, and

- longitudinal studies that follow individuals over a period of time.

These are all research methods that are widely used in the field of medicine for evaluation of treatments, particularly in the field of pediatrics.

We do not have time in this forum to discuss all relevant studies, but wanted to highlight a few while also providing supplemental materials:

First, a study published in 2022 of more than 27,000 transgender and nonbinary adults revealed lower lifetime odds of suicidality for those who were able to access gender-affirming care during adolescence compared to those who could not access care until adulthood.

Another study published in October 2024 demonstrated that a large sample of gender diverse youth showed very high levels of satisfaction and low levels of regret with puberty blockers and hormone treatment.

Finally, a study of over 20,000 transgender adults found that access to pubertal suppression and gender-affirming hormones during adolescence resulted in lower odds of depression and lifetime suicidal ideation.

The WPATH SOC8 recognizes the benefits of accessing medical support for some gender diverse adolescents and has developed the standards of care in order to guide clinicians in developing individualized care plans with families.

In addition to discussing outcomes, I want to acknowledge that many questions have come up around a report titled the “Cass Review” and its implications on the provision of medical care for transgender youth.

This review process was overseen by a pediatrician named Dr. Hillary Cass, commissioned by the United Kingdom’s National Health Service, who produced a final report in April 2024. The 4-year review aimed to address the failure to provide timely, competent, and high-quality care to transgender youth in the UK.

Unfortunately, in the short time since its release, the Cass Review has been used to justify restrictions on healthcare for transgender youth. However, nowhere in the 388 page document does the Cass Review recommend a ban against medical care for gender diverse youth.

The Cass Review was informed by several systematic reviews of literature and summarizes the findings of the reviews as demonstrating “weak evidence” in support of gender affirming care. However, many methodological flaws have been identified in the analysis of the National Health Service’s data and the systematic reviews conducted, which have called into question the validity of this analysis.

If considered during rule-making, we want to note that the Cass Review makes statements that are consistent with the models of care described in guidelines developed by WPATH and the Endocrine Society.

Namely that medical care is appropriate for some transgender youth and should be provided in a holistic, comprehensive, and individualized manner – which is consistent with the approach in all of Oregon’s pediatric gender clinics.

In developing guidelines that provide recommendations on clinical care, panels of experts consider the evidence of a treatment’s efficacy, alongside of:

- the benefits and harms of both treatment and no treatment,
- patients’ values and preferences, and
- the resources required to offer treatment.

This is precisely why evidence quality is not synonymous with clinical recommendations.

The WPATH SOC 8 was developed based on a review of prior standards, definition of topics needed to be added or expanded upon and systematic literature reviews. Approval of each recommendation followed the Delphi process, meaning that at least 75% of SOC8 members needed to agree with each statement.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community and turning to WPATH standards will ensure that Oregonians continue to receive the highest-quality, evidence-based care based on the most current research and clinical practices.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002

- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

- Transparency for the patient if requested related to adverse benefit determinations

- Alignment with network adequacy standards

- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation have the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Kara Connelly, MD

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Dr. Jennifer Cork [redacted]
Sent: Tuesday, November 26, 2024 12:52 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Dr. Jennifer Cork, DSW, LCSW and I am an Oregon mental health provider and disability rights advocate who specializes in treating neurodivergent (autism, ADHD, IDD) clients in the mental health setting. Due to the fact that transgender individuals are 3 to 6 times more likely to be autistic than the general population, I treat a number of transgender and gender diverse individuals in my therapy practice.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I am dual licensed in another state where gender affirming care is not allowed for minors and not covered by Medicaid for any age individual and have seen first hand the negative impacts of denying evidenced based, gender affirming care can have on my clients' mental health. This is backed up by research that has shown that gender affirming care literally saves lives.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Again, this is live-saving care, especially for transgender individuals with other intersecting identities, such as my autistic clients, or those who belong to other vulnerable minority populations.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Dr. Jennifer Cork
Salem, OR 97304-4253

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Fwd: Oregon Transgender Cverage
Date: Monday, November 18, 2024 11:42:15 AM
Attachments: 20241015131826340_2024.10.15 - Ala. Amicus Br. iso TN FINAL.pdf

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[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

>> Hello , I am writing to you as Ann endocrinologist and someone deeply concerned with children . Using WPAth Soc 8 guidelines would be a terrible error. I think it woukd tu you in legal jeopardy for malpractice suits. It is clear that WOath is basically an advocacy group. They know that multiple systematic reviews show very low quality evidence for medIcalizing gender care for kids. This includes the Cass review out of the UK. wPath sponsored some of its own systematic reviews out of Johns Hopkins and they didn't publish them because they confirmed the low level of evidence. Read the Amicus brief from Alabama I have included it basically takes apart the idea the Soc 8 is a reasonable standard of Care. I urge you not to use WPath guidelines. I also urge you not to cover the medical transition of children. I previously testified on this on your Medicaid committee.
>> Roy Eappen MDCM , FRCP(c) FACP, FACE
>> Assistant Ptofessor of Medicne
>> McGill University
>> Montreal Quebec
>> Canada
>>>
>>>
>>> https://www.supremecourt.gov/DocketPDF/23/23-477/328275/20241015131826340_2024.10.15%20-%20Ala.%20Amicus%20Br.%20iso%20TN%20FINAL.pdf
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No. 23-477

In the Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

JONATHAN SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, *et al.*,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

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Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

From: [redacted]
To: HALL Brooke M * DCBS; EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002
Date: Friday, November 22, 2024 11:43:45 PM

TO: Oregon Division of Financial Regulation

FROM: Dr. Katie Eichner, Licensed Psychologist and Owner, Fierce Compassion Psychotherapy LLC

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Katie Eichner and I am an Oregon Licensed Psychologist working and living in Portland (OR 2934). I provide outpatient psychotherapy services to Oregon residents and specialize in work with the transgender population. I also conduct assessments and provide letters in support of gender affirming care.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have worked with trans folks who have been denied coverage for needed gender affirming care procedures and seen the devastating impact on their mental health; for instance, a trans man whose health insurance (provided through company headquarters in another state) refused to provide coverage for top surgery. The insurance company ignored my appeal letter describing the medical necessity of the

procedure. While he waited to save up money to pay for his own medically necessary surgery, he continued to self-medicate with substances in order to mitigate his extreme dysphoria, experienced extreme social isolation due to the impact of dysphoria on his willingness to be perceived by others and leave the house, and experienced severe depressive symptoms. After he received the surgery, his functioning greatly improved, he stopped abusing substances, he reconnected with community, and his depression was alleviated. Gender affirming care is an essential part of healthcare.

I have also seen how some insurers currently avoid being in compliance with Oregon law (e.g., by refusing to bill OHP for gender affirming procedures listed in the WPATH standards), and how taxing this is for my clients who must choose between pursuing long bureaucratic fights for coverage, paying out of pocket in some hope they might be reimbursed, or forgoing care entirely and living with the ongoing misery and psychological anguish of extreme dysphoria.

I want to share appreciation for the following that are in the proposed rule:

· Determining a standard of care in rule for insurers to be in compliance with HB2002

· Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

· Transparency for the patient if requested related to adverse benefit determinations

· Alignment with network adequacy standards

· Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

There is of course more research needed into gender affirming care; the transgender community is underserved and underresearched as a marginalized population. This in no way negates the values of the WPATH standards of care, and I am glad to know they are specifically referenced in HB2002. The WPATH standards are the most up to date and cutting edge guidance we have available to guide us in supporting this vulnerable community, as policymakers and as healthcare providers. Oregon's

healthcare coverage is pioneering in supporting the most marginalized among us. HB2002 will help ensure that Oregon continues to require that insurers provide care for those marginalized folks who need it most; by making sure that folks without the time or resources, who are fighting to survive day to day, pay their bills, and navigate discrimination do not have to take on health insurers to make sure they are in compliance with Oregon law around gender affirming care.

My work as a psychologist will be made easier by this rule. If I no longer need to support my trans clients around their concern and distress about attempting to secure coverage for procedures, we can focus instead on alleviating their symptoms, helping them thrive and build community, and appreciating the many joys of living in this state.

Gender affirming care is lifesaving care. I have seen folks who are denied it come closer and closer to ending their own lives, and seen folks who receive it go on to thrive in ways they previously could neither access nor imagine.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Dr. Katie Eichner

Licensed Psychologist

--
Katie Eichner, Ph.D
[redacted]
Katie Eichner, Ph.D
Licensed Psychologist
[redacted]
(503) 427-8514
Pronouns: she/they

From: [redacted]
To: WINKEL Karen J * DCBS
Cc: [redacted]
Subject: Public Comment on 2025 Gender-Affirming Treatment Rule
Date: Friday, November 22, 2024 6:51:53 AM
Attachments: image001.png

You don't often get email from [redacted]. Learn why this is important

Karen,

You should not waste your time with this rule. As soon as President Trump is back in office then he is going to ensure that all "gender affirming care" is banned. If you do not believe me, then watch this short video and hear it from President Trump's lips yourself: (Note: He talks first about the safety of children and then about insurances that apply to both children and adults.)

https://youtu.be/Pzf0-FAucy0

"Gender affirming care" can not be eradicated soon enough! Not only because it damages individuals, their families and society, but also because it supplants medically-indicated psychological counseling to help a person to accept and love their (birth) sex.

As an aside, placing personal pronouns next to your name tells the world you have allowed yourself to be indoctrinated into a cult. I suggest you remove them, at least by the time President Trump is back in office. In case you're not aware, AOC has already removed hers!
https://x.com/RepAOC

Sharon Fair, PT, PsyD, PhD
[redacted]
904-735-2558
[redacted] FL 32177
Wellness Society

> ----- Forwarded Message -----
> **From:** WINKEL Karen J * DCBS <karen.j.winkel@dcbs.oregon.gov>
> **To:**
> **Sent:** Thursday, November , 2024 at
> **Subject:** RE: Public Comment on 2025 Gender-Affirming Treatment Rule
>
> Dear ,
>
> This confirms we received your public comment and is now part of the rulemaking record.

Thank you,

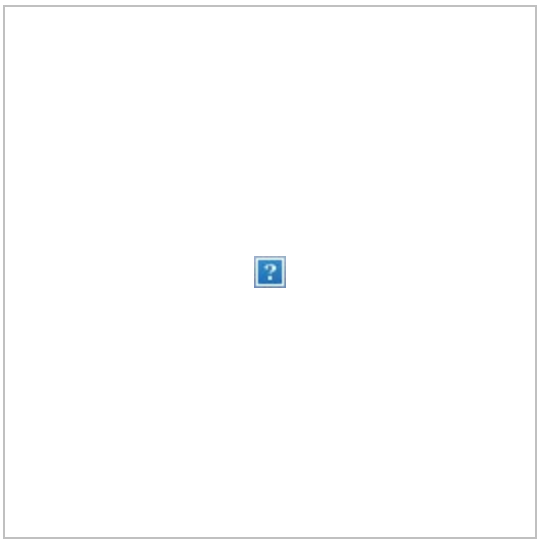
Karen Winkel (she/her/hers)

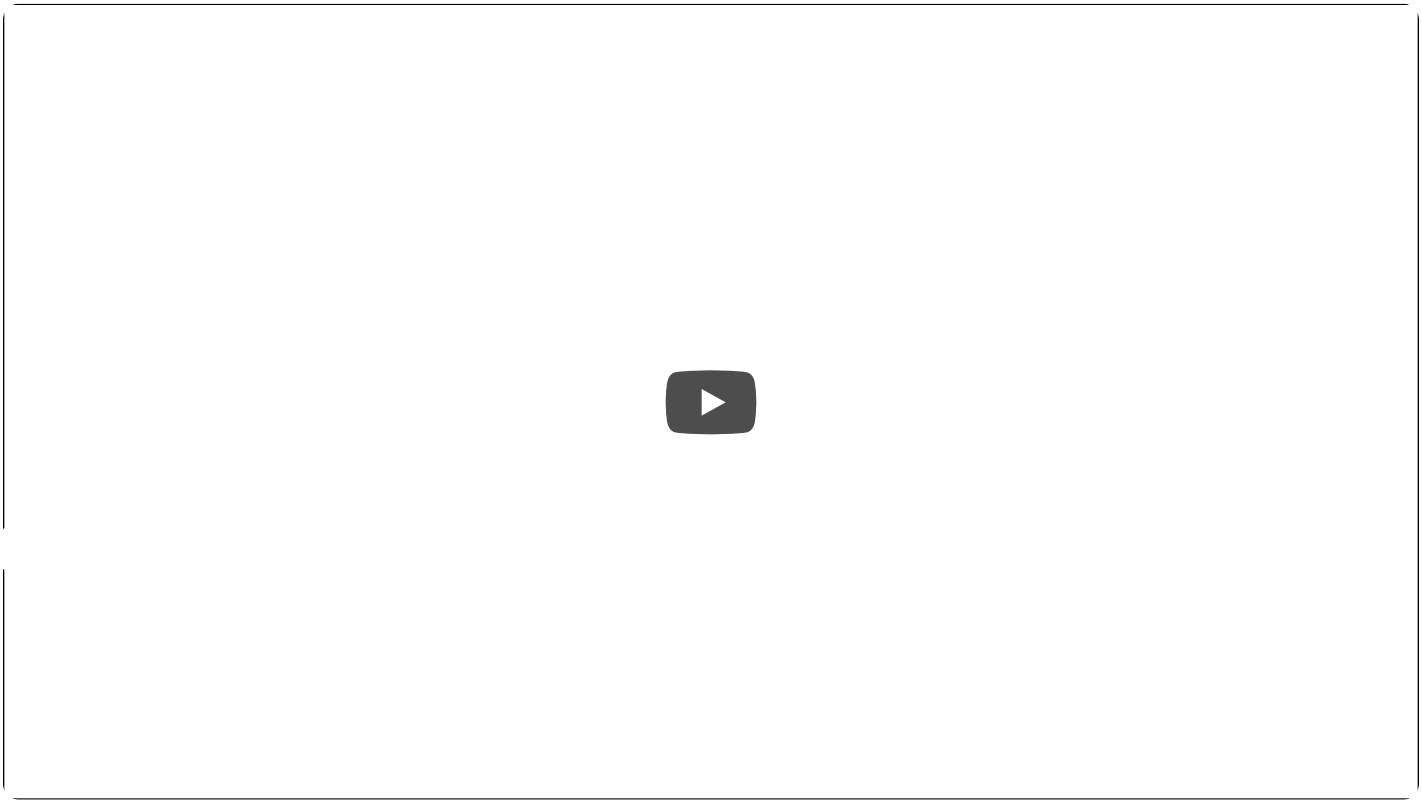
Rules Coordinator

DCBS | Division of Financial Regulation

Karen.J.Winkel@dcbs.oregon.gov

Phone: 503-947-7694





2024 United States elections
The Electoral College has confirmed Donald Trump as president-elect.

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Will President Trump's plans end Transgender? Take a listen!

Sharon Fair, PT, PsyD, PhD
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Wow! Take a listen to President Trump's plans that may effectively END the influence of transgender ideology on the USA society. A summary of a few of his statements: Codify into law the historical definitions of men and women (and boys and girls), financial retributions to the victims of "gender affirming care," legal action and penalties against pharmaceutical companies who have s … ...more

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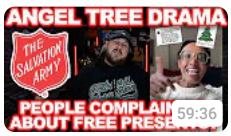

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From: [redacted]
To: HALL Brooke M * DCBS; EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: Support for the proposed rules re HB2002
Date: Friday, November 22, 2024 12:09:23 PM

Dear Ms. Hall, Ms. Emerson, and Ms. Winkel:

I write to express my strong support for the proposed rules re implementing HB2002, which ensure access to medically necessary gender-affirming care for transgender and gender-diverse individuals. These rules represent a critical step forward in promoting evidence-based, equitable healthcare in Oregon.

Gender-affirming care is supported by extensive research and clinical guidelines, including the World Professional Association for Transgender Health's Standards of Care, Version 8. Such care has been shown to significantly improve mental health outcomes, reduce psychological distress, and enhance quality of life for individuals experiencing gender dysphoria.

The proposed rules appropriately address barriers to care by prohibiting blanket exclusions, mischaracterization of medically necessary procedures as cosmetic, and unnecessary cost-sharing mechanisms. These changes are essential to ensure that care is both accessible and equitable for all who need it.

It is vital that treatments such as facial gender-affirming surgery, tracheal shaves, and hair electrolysis are recognized as not merely cosmetic; they are medically necessary components of care for many individuals. By requiring coverage for these treatments, the rules ensure that transgender and gender-diverse individuals can access the full spectrum of care recommended by their healthcare providers.

Adopting these rules will not only protect the health and well-being of transgender and gender-diverse individuals but also reaffirm Oregon's leadership in advancing human rights and healthcare equity. I urge you to finalize and implement these rules without delay.

Thank you for your dedication to this important issue. Please let me know if additional information or support would be helpful.

Sincerely,

Kris Fury, PsyD
Psychologist Resident
Pronouns: She, Her, Hers

Clinical Supervisor: Jon Frew, PhD, ABPP - [redacted]

Main: (503) 622-8964
Direct: (503) 567-8763
Fax: (503) 715-5469
[redacted]
www.portlandmh.com
Portland Mental Health & Wellness Patient Portal
Telehealth Link: https://meet.google.com/tzg-vxdu-kea

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lauren Herbert [redacted] >
Sent: Monday, November 25, 2024 5:40 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Lauren Herbert, and I am an Oregon retired pediatrician.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I retired from my practice in general pediatrics last summer. During my practice, I saw teens receive gender-affirming care and have a significant improvement in their moods and their self-esteem. They received their evaluation through OHSU, gender clinic, where I was impressed by the care with which the providers evaluated, counseled, and treated the teens.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lauren Herbert
Eugene, OR 97403-1737

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Kae Hixson <[redacted]>
Sent: Monday, November 25, 2024 8:19 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Dr. Kae Hixson and I am a Licensed Oregon mental health provider. I have provided gender affirming care in Oregon for two decades.

I am asking you to support this proposed rule as written. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My experience is that gender affirming healthcare is life-preserving, life-affirming, and absolutely medically necessary. The way this rule is written, proposed, and ultimately, adopted will improve healthcare in Oregon.

I want to share appreciation for the following that are in the proposed rule:
· Determining a standard of care in rule for insurers to be in compliance with HB2002
· Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
· Transparency for the patient if requested related to adverse benefit determinations
· Alignment with network adequacy standards
· Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Most importantly, the fear-mongering, disinformation, and anti-trans advocates are wrong about gender affirming care. We now have several, independent, peer-reviewed research studies that show that regret for gender affirming care for children, teens, and adults is very rare. Very recently, as the principal author of a study in JAMA Pediatrics, Kristina Olson (from Princeton) published research summarized here: "220 youths who had accessed puberty blockers or hormones were detailed by the youth and/or their parents as part of an ongoing decade-long study of transgender youth. At a mean of 4.86 years after beginning blockers and 3.40 years after beginning hormones, they reported very high levels of satisfaction and low levels of regret; the overwhelming majority (97%) continued to access gender-affirming medical care."

Even closer to home, the Gender Affirming Surgery clinic at OHSU studied almost 2,000 individuals who received gender affirming care from 2016 to 2021 and found only 6 patients who had regret or de-transitioned.

The scientific evidence and stories of trans Oregonians are clear: this is life affirming medical care and HB 2002 as originally proposed allows access to medically necessary, equitable health care for transgender Oregonians. Please remember my testimony when you finalize this draft into rule.

Thank you.

Sincerely,
Kae Hixson
Portland, OR 97220-3149

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Del Knight <[redacted]>
Sent: Saturday, November 23, 2024 10:13 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

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Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Del Knight, PsyD. I am an Oregon Licensed Professional Counselor specializing in working with transgender communities. Additionally, I am the Program Manager of the Affirm Two-Spirit, Trans, Nonbinary (2STNB) Program at Portland Mental Health and Wellness, which provides clinical supervision to transgender pre-licensed clinicians who specialize in delivering gender-affirming mental health care to transgender patients.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

In my work with transgender patients, I have conducted over 100 gender-affirming surgery assessments. I have witnessed firsthand the life-changing impact for transgender patients of having access to medically necessary gender-affirming care and procedures. Additionally, as a transgender individual who was able to receive gender-affirming care myself, I know personally about the mental health benefits of feeling more congruent in my body, clothing, and social interactions.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Members of transgender communities are historically under-resourced and often not afforded the means to access medically necessary gender-affirming procedures not otherwise covered by their insurance. HB2002 expanded access to

many medically necessary gender-affirming procedures that were previously not covered. In my 11 years working with transgender communities, I have witnessed grief and hopelessness in my patients, especially BIPOC, low-income, and trans women whose medically necessary gender-affirming procedures were kept out of reach by insurance restrictions. Conversely, with the passing of HB2002, these same conversations with patients about the medically necessary gender-affirming procedures they would now have access to are accented by feelings of hope, joy, and tremendous relief for these same intersectional communities.

By supporting HB2002 in its current form, you help me concretely support my patients in not losing hope, joy, and relief while protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Del Knight
Portland, OR 97205-3200

From: [redacted]
To: HALL Brooke M * DCBS
Cc: EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: Re: HB2002 Rulemaking Comments
Date: Friday, November 22, 2024 4:09:00 PM
Attachments: Oregon Division of Financial Regulation.pdf

> Some people who received this message don't often get email from [redacted]. Learn why this is important

Hello again,

I have attached my comments below. Please let me know if you have any questions.

Best,
Dr. Kat Kosmos, PsyD
Licensed Psychologist

On Fri, Nov 22, 2024 at 1:45 PM Kat Kosmos <[redacted]> wrote:

> Thank you!
>
> Best,
> Kat
>
> On Fri, Nov 22, 2024 at 12:02 PM HALL Brooke M * DCBS <Brooke.M.HALL@dcbs.oregon.gov> wrote:
>
> > Hello Dr. Kosmos,
> >
> > Yes, you can submit your comment letter and send it to Karen, Lisa and I via email. We will include you comment in the record and take it under consideration.
> >
> > Thank you,
> >
> > Brooke
> >
> > ---
> >
> > **From:** Kat Kosmos [redacted]>
> > **Sent:** Friday, November 22, 2024 11:58 AM
> > **To:** HALL Brooke M * DCBS <brooke.m.hall@dcbs.oregon.gov>; EMERSON Lisa * DCBS <lisa.emerson@dcbs.oregon.gov>; WINKEL Karen J * DCBS <Karen.J.Winkel@dcbs.oregon.gov>
> > **Subject:** HB2002 Rulemaking Comments
> >
> > > Some people who received this message don't often get email from [redacted] Learn why this is important
> >
> > Hi there,
> >
> > My name is Dr. Kosmos and I wanted to check the process for submitting comments in regards to the HB2002 rulemaking process- Would I be submitting

my comments via email to these emails? My understanding is there has been representation around dismantling important gender affirming care rights that are currently in place and I want to make sure that decisions are being made with evidence based information.

Thank you for your time,
Dr. Kosmos

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: Dr. Kat Kosomos, PsyD. Kosmos Psychology.

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Kosmos and I'm a licensed psychologist in the state of Oregon. I am writing to express concern over anti-trans rhetoric that is being expressed in the rulemaking process of HB2002. The research around gender affirming care is clear in that it saves lives across age groups. In an age of misinformation, it is imperative to be familiar with the evidence based research around this important care.

Sinead Murano-Kinney (2024) summarized the importances well by stating:

> Calling gender-affirming care "lifesaving" (Matouk and Wald 2022) may sound like hyperbole, but when trans youth can't access this care, they're at greater risk of depression and suicidality (Turban et al. 2020). Attempts to restrict access to this medically necessary care rely on misinformation regarding the safety and efficacy of the medications provided to trans youth. Anti-trans extremists exploit the public's unfamiliarity with trans youth and the relative inaccessibility of medical literature to the public, falsely characterizing trans youth as a new phenomenon, citing fake diagnoses (Ashey 2018; Tennehill 2018; Turban et al. 2023; Turban, Dolotina, et al. 2022) of "rapid onset gender dysphoria" (Fenway Health 2023) and making false claims that this evidence-based healthcare is "experimental". But, it's fear, not scientific fact (Sun and Ashely 2023), that underpins these attacks on transition-related healthcare.

Access to gender affirming care saves lives. This cannot be understated. Trans youth are already at a disproportionately higher risk of depression and suicidality. In 2024, National Institutes of Health (NIH) stated that transgender and nonbinary youth report more than four times greater rates of suicide attempts compared to their cisgender peers and gender identity acceptance from others can reduce the risk for these youths (Price and Green, 2022). This acceptance must be demonstrated in all systems they find themselves in, including seeing their state protecting them and their community. Specifically, trans and nonbinary youth who receive gender-affirming hormones or puberty blockers had 60% lower odds of depression and 73% lower odds of self-harm or suicidal thoughts (Tordoff, et. al. 2022).

Other misinformation around the discourse of gender affirming care include side effects with puberty blockers. One argument that is commonly associated with the prolonged use of puberty blockers include reduced bone mineral density. While it is true that research suggests there is a risk of individuals experiencing a reduction in bone mineral density, it fails to reflect that this

reduction is significantly different then what their cisgender peers experience throughout their adolescence (Nos, et al., 2022). This is why best practices in providing gender affirming care includes regularly monitoring patients receiving care. In other words, continued and frequent access to medical care ensures monitoring of any side effects. The answer is not to limit health care access to these life-saving services.

Another common and dangerous argument against gender affirming care suggests that individuals regret gender affirming care and eventually “detransition.” Up-to-date research suggests otherwise. Nearly all transgender youth (>95%) who are properly diagnosed and treated continue to identify as transgender as they grow up (Olson, et al. 2022; van der Loos, 2022). Regret is extremely rare; several recent systematic reviews of thousands of transgender patients found that rates of regret were around 1%, which is much lower than many common procedures (Butos, 2021; Thorton, 2024). For instance, joint replacements reveal regret rates as high as 30%, yet we are not suggesting that these services be taken away or restricted (Szabo, 2018).

The gravity of this topic cannot be distilled entirely down to a letter or comment. I have attempted to capture relevant evidence-based information as a means to counter misinformation around the topic of gender affirming care for transgender and nonbinary youth, knowing that I could continue at great lengths. Instead, I will reiterate what I’ve already demonstrated: HB2002 saves lives.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Gender-affirming care is lifesaving care.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Thank you for your time and consideration,

Dr. Kat Kosmos, PsyD
Licensed Psychologist

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From: [redacted]
To: HALL Brooke M * DCBS; WINKEL Karen J * DCBS; EMERSON Lisa * DCBS
Subject: HB2002 public comment
Date: Monday, November 25, 2024 5:01:39 PM
Attachments: HB2002 Rulemaking public comment letter Kramer esigned.pdf

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You don't often get email from [redacted] Learn why this is important

Please see attached letter.
Thank you!

--
Ari Kramer, Psy.D.
Dr. Kramer uses he/him pronouns
Licensed Clinical Psychologist in Oregon and Illinois
Empowering Therapy and Consulting LLC
(503) 433-2649
http://www.empoweringtherapyandconsulting.com
"Not everything that is faced can be changed, but nothing can be changed until it is faced." --James Baldwin

November 25, 2024

Gender Affirming Treatment Rulemaking Committee: HB2002
Oregon Division of Financial Regulation

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Ari Kramer (he/him pronouns), and I am a licensed clinical psychologist living and working in Oregon. My practice specializes in gender affirming mental health care for transgender (both binary and non-binary) adults. This includes conducting mental health assessments for the purpose of determining best course of care including providing letters of support for appropriate candidates for gender affirming surgery, as well as providing ongoing psychotherapy for clients. I have been providing psychological assessment and treatment for clients seeking gender affirming care for the past 8 years. As part of my training, I underwent an interdisciplinary training course through WPATH which gave me insight into both the medical and mental health guidelines for treatment. In addition to maintaining active WPATH membership, I regularly obtain continuing education on topics related to gender diversity to provide affirming, up to date expertise in the field of transgender mental healthcare. I follow WPATH SOC8 (Standards of Care Version 8) well-researched guidelines in making determinations on providing letters of support. I follow the numerous empirically supported studies and clinical professional organization positions on providing gender affirming mental treatment. I consider doing this work to be part of my ethical responsibility as a psychologist, as well as a great honor to care for the emotional wellbeing of members of the transgender community.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

While Oregon has provided access to gender affirming care on a broad level, there have still been numerous gaps in care that have left patients vulnerable and unable to obtain services needed. Even with insurers in Oregon covering services, there has been significant variance in which insurance companies cover which procedures, with some deemed as “cosmetic” and not covered, or requiring specific language needed in provider letters and pre-authorization that is not standardized, not publicized to members or providers, or sets a significantly higher threshold than what is consistent with current WPATH guidelines. For many transgender women, surgeries deemed “cosmetic” are ones that would allow them to pass in public, thereby reducing dysphoria caused by an internal gender incongruence as well as an external incongruence in how others are

perceiving them. For many women, both trans and cis, determining safety in public takes a significant toll on mental health including higher rates of anxiety and depression. For transgender women facing safety concerns and increased rates of harassment and assault in public, being able to be perceived accurately as a woman is not a matter of cosmetic choice, it is a lifesaving medical necessity.

Further, while there are several well-qualified surgeons in Oregon, waitlists for surgery are often measured in years, rather than months. Many insurance networks do not allow for out-of-network care even when waitlist time creates an undue burden on transgender patients. I have worked with multiple clients who have moved out of state in order to obtain necessary services rather than wait several years for a consultation, which leads to a loss of Oregonians who feel welcome and cared for in the state, as well as decreases the revenue of gender affirming care providers here. This lack of access when provider network adequacy is not met would be considered unacceptable for other medically necessary surgeries. It is only because insurance companies are not truly putting gender affirming surgical procedures on par with other types of lifesaving care that this is thought of as standard.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of these gaps. I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law. From an 'on the ground' provider perspective, these rules are what makes the difference between a theoretical mandate for allowing gender affirming care, and actual access to care for Oregonians. Given the power insurance carriers have in determining coverage, it is vital that these policies are created with empirically supported worldwide professional standards of care, and with the mental and physical health of transgender Oregonians in mind, not just what is easiest for insurance companies.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please take into account actual transgender patients and those of us who specialize in transgender medicine and mental health when you finalize this draft into rule. Thank you for your continued work to support Oregonians.

Sincerely,

Ari Kramer, Psy.D.

From: [redacted]
To: HALL Brooke M * DCBS; WINKEL Karen J * DCBS; EMERSON Lisa * DCBS
Subject: Re: HB2002 public comment
Date: Monday, November 25, 2024 7:05:55 PM
Attachments: HB2002 Rulemaking public comment letter Kramer esigned secure.pdf

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> You don't often get email from [redacted]. Learn why this is important

Hi there,
I realize this is after the deadline, but I am hoping that my initial letter can be replaced with this secured copy of what I sent prior to the deadline. I had not realized that I had not certified the original pdf signature on the initial document. This was the only change made. Thank you so much!
Warmly,
Dr. Ari Kramer

On Mon, Nov 25, 2024 at 4:58 PM Ari Kramer <[redacted]> wrote:

> Please see attached letter.
> Thank you!
>
> --
> Ari Kramer, Psy.D.
> Dr. Kramer uses he/him pronouns
> Licensed Clinical Psychologist in Oregon and Illinois
> Empowering Therapy and Consulting LLC
> (503) 433-2649
> http://www.empoweringtherapyandconsulting.com
> *"Not everything that is faced can be changed, but nothing can be changed until it is faced." --James Baldwin*
>

--
Ari Kramer, Psy.D.
Dr. Kramer uses he/him pronouns
Licensed Clinical Psychologist in Oregon and Illinois
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"Not everything that is faced can be changed, but nothing can be changed until it is faced." --James Baldwin

Because email is not a secure form of communication, confidentiality cannot be guaranteed. Additionally, there may be delays in the times that messages sent by email are received or replies can be made. Please note that information contained in this email message is for the sole use of the intended recipient. Any unauthorized review, use, disclosure or distribution is prohibited. In case of emergency, call 911 for emergency assistance or go to the nearest emergency room. National Suicide Prevention Lifeline 1-800-273-TALK (8255); Trans Lifeline (Trans and Gender Expansive Suicide Prevention Hotline) 1-877-565-8860; The Trevor Project (LGBTQ Suicide Prevention Hotline)1-866-488-7386.

From: [redacted]
To: EMERSON Lisa * DCBS; HALL Brooke M * DCBS; WINKEL Karen J * DCBS
Subject: Public comment on Gender-Affirming Treatment (HB 2002) RAC
Date: Saturday, November 23, 2024 6:48:35 PM
Attachments: Outlook-y34f5sar.png
wpath soc 8.docx

> Some people who received this message don't often get email from [redacted]. Learn why this is important

Hello all,

I'm a pediatric endocrinologist who cares for gender diverse youth and I would like to submit written testimony for HB 2002. I hope I'm directing it to the correct place!

Document attached

Thank you,
Charlene Lai

Charlene Lai, MD (she/her)
Pediatric Endocrinology
Assistant Professor
Ambulatory Medical Director for DCH 7th floor Pediatric Medical Specialties
Doernbecher Children's Hospital
Oregon Health & Science University
Book time to meet with me

Dear Esteemed Members of the Oregon Legislature,

As a pediatric endocrinologist who provides care to gender-diverse youth, I am writing to strongly advocate for the adoption of the most updated World Professional Association for Transgender Health (WPATH) Standards of Care as the guideline for health insurance companies in Oregon when determining coverage for gender-affirming care. Currently the most updated version is Standards of Care Version 8 (SOC 8). These evidence-based guidelines reflect the most current, rigorous research and the consensus of international experts in the field. For my patients, access to gender-affirming care is not only life-changing but often life-saving, helping them thrive both physically and emotionally.

WPATH SOC 8 integrates decades of clinical expertise, research, and patient-centered care principles. SOC 8 specifically addresses the needs of adolescent youth and non binary youth. It is supported by an extensive body of peer-reviewed evidence and considers the medical, psychological, and social aspects of care. By endorsing WPATH SOC 8, Oregon can ensure that health insurers base their decisions on the highest standard of care, promoting equity, reducing unnecessary denials, and protecting the health and well-being of transgender youth and adults.

Thank you for your commitment to advancing inclusive healthcare policies. I urge you to prioritize the adoption of WPATH SOC 8 as the guiding framework for insurance coverage decisions in Oregon.

Sincerely,

Charlene Lai, MD

From: [redacted]
To: WINKEL Karen J * DCBS
Cc: [redacted]
Subject: Public Comment Opposing 2025 Gender-Affirming Treatment Rules (Revised VS)
Date: Sunday, November 24, 2024 5:26:43 PM

> You don't often get email from [redacted]. Learn why this is important

To whom it may concern:

Democratic lawmakers must read this law in its entirety and not just blindly follow party lines. If one does not read the whole law, and you assume that this law is protecting gender-diverse youth then you haven't been paying attention to multiple media articles and prestigious medical journals out of Europe and even the United States. Passing this law simply bc you are a Democrat is supporting archaic medical guidelines and poor to lowest quality research regarding both medical and surgical interventions for gender-diverse youth.

As you know, the State of Oregon relies on self-ID, and psych evaluations at the OHSU pediatric trans clinic and the psych evaluations are "for insurance approval only" as I was told when my daughter was referred to OHSU at age 14. A social worker did a short phone call with my daughter and that social worker made an appointment for an endocrinologist prior to the psychologist's evaluation "so we can get your kiddo on his meds asap!" My daughter was referred to the OHSU pediatric trans clinic in 2021 by Dr. Richard Ly, MD, a pediatric psychiatrist and he based his diagnosis of gender dysphoria on self-identification, she only had one of the 8 criteria in the DSMV but that didn't matter to him even though 6 out of 8 criteria are required for a gender dysphoria diagnosis. Our family was supportive of my daughter's trans identity but we wanted to be cautious bc this identity seemingly came out of the blue during Covid lockdown when she was doing online school, I didn't know she was watching Tiktok videos about how cool it is to be a trans boy and if your parents question anything cut them out of your lives bc they are bigots (according to the Trevor Project). The trans ID didn't make sense so we were mistakenly led to believe that OHSU does an extremely thorough psych evaluation and is cautious about writing a kid a script for T.

I was told by multiple physicians and therapists that at age 14 we as parents can not question or say no to testosterone ("bc it's like ignoring cancer"). I am a down-ballot lifelong Democrat who is in favor of high-quality health care for trans adults, my father was a trans medicine pioneer before becoming boarded in ER medicine. My dad and I immediately started researching everything we could find on this topic including the side effects of testosterone on natal girls and there are serious side effects that no physician we spoke with was aware of, this is downright lazy medical care bc Drs know how to look up side effects and they shouldn't make up fake completed suicide stats to blackmail parents into agreeing to hormones and or surgery. I was told over and over again that there is a 42% chance of COMPLETED SUICIDE if I did not agree to testosterone for my 14-year-old. I found the study they were quoting, it was done via an anonymous survey from a San Franciscan newspaper and they paid participants, mean age 25 who said: "they'd had a suicide attempt in their lifetimes". This bogus study did not differentiate between post or pre-medicalization. This is bunk science. We've read almost every study and none have a control group (unless you count 6 kids as a control JAMA Peds!) This is not normal in medicine, trust me, I've talked to cardiologists, urologists, psychiatrists, ER docs, Hospitalists, etc. Most American physicians are not members of the AMA and consider it a waste of money or simply a lobbying group. So when

anyone claims the AMA supports surgical and medical interventions for gender-diverse youth they haven't been talking to the majority of boarded and licensed physicians and surgeons.

OHSU knows it, and so does anyone else who reads the NYTS paper of record. I outsmarted OHSU bc I had connections and an excellent psychologist who understands how to do psych evaluations, she set up the first gender clinic at Boston Children's Hospital and set up OHSU's program. That psychologist understands how to address all psychiatric co-morbidities and works with families and listens to parents. My daughter is now 17 and identifies as a girl. Did you know that sometimes teens follow trends and sometimes teens are influenced by social media? Oregon could be at the forefront of gender care instead you are choosing to keep our kids' treatments in dark ages and have chosen profit margins over the overall health and fertility of our gender-diverse youth. You are basing this law on zero robust studies or evidence and now we know that puberty blockers and cross-sex hormones have serious long-term side effects including possible sterilization.

According to multiple news sources including NPR, I found out that one puberty blocker implant (Supprelin LA) now costs $96k per year. The older drug cost $4400. Why would the Oregon Health Plan and insurance only cover the more expensive drug? Because there are rebates and kickbacks from the drug companies and prestigious medical centers like OHSU are allowed to charge full list price and keep the profits. I think we figured out the biggest motivation for prestigious medical centers to ignore the latest reviews of the scientific literature out of multiple European countries, it's called FOLLOW THE MONEY! I know of one nurse practitioner at a different prestigious medical center on the West Coast who does puberty blocker implants all day long and brings in millions of dollars in profits a year for the hospital. NPs & docs also waits until the psychologist leaves or just bypass the minimal psych evaluation and put the insurance code: Endocrine Disorder Not Otherwise Specified in lieu of a gender dysphoria insurance code, this is no ethical lawmakers. It should be considered insurance fraud, but since when have ethics mattered to gender clinics in the USA? Do they think that Americans don’t have object permanence or we don’t read the international news?

This bill is going into law and the Democrats voted in favor of this, you are all culpable of pushing for-profit medical care for gender-diverse youth based on politics and not what is best medical practices and I hope you all read the US vs Skrmetti Amicus Brief from the Alabama Attorney General so you can see how the Biden administration, Rachel Levine, MD and the American Academy of Pediatrics decided to remove all age limits for surgeries (except phalloplasty) for minors and Admiral Levine, MD actively pressured WPATH to remove those surgical age limits that surgeons like Dr. Blaire Peters performs on kids at OHSU. Shame on Oregon physicians & surgeons who have forgotten their oath to first not harm. I thought the Democrats were the party science. No, you are now the party of weaponized empathy and a strange unscientific ideology that should have no place in American medicine.

Sincerely, Noelle Lamberton & Ronald Lamberton, MD

From: [redacted]
To: HALL Brooke M * DCBS; EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: Public Comment in Support of HB2002 and Gender-Affirming Care
Date: Friday, November 22, 2024 10:59:48 AM

Dear Ms. Hall, Ms. Emerson, and Ms. Winkel,

I am writing to express my strong support for the proposed rules implementing HB2002, which ensure access to medically necessary, gender-affirming care for transgender and gender-diverse individuals. These rules represent a critical step forward in promoting equitable, evidence-based healthcare in Oregon.

Gender-affirming care is supported by extensive research and clinical guidelines, including the World Professional Association for Transgender Health's Standards of Care, Version 8. This care has been shown to significantly improve mental health outcomes, reduce psychological distress, and enhance quality of life for individuals experiencing gender dysphoria.

The proposed rules appropriately address barriers to care by prohibiting blanket exclusions, mischaracterization of medically necessary procedures as cosmetic, and unnecessary cost-sharing mechanisms. These changes are essential to ensure that care is both accessible and equitable for all who need it.

It is also vital to recognize that treatments such as facial gender-affirming surgery, tracheal shaves, and hair electrolysis are not merely cosmetic but are medically necessary components of care for many individuals. By requiring coverage for these treatments, the rules ensure that transgender and gender-diverse individuals can access the full spectrum of care recommended by their healthcare providers.

Adopting these rules will not only protect the health and well-being of transgender and gender-diverse individuals but also reaffirm Oregon's leadership in advancing human rights and healthcare equity. I urge you to finalize and implement these rules without delay.

Thank you for your dedication to this important issue. Please let me know if additional information or support would be helpful.

Sincerely,

Brad Larsen, PsyD
Licensed Psychologist & Founder
Pronouns: He, Him, His

Main: (503) 622-8964
Direct: (503) 715-5468
Fax: (503) 715-5469

[redacted]
www.portlandmh.com
Portland Mental Health & Wellness Patient Portal
Telehealth Link: https://meet.google.com/jnp-borb-oih?authuser=0

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-Affirming Treatment Rule HB2002
Date: Tuesday, November 26, 2024 12:40:37 PM
Attachments: SEGM public comment.pdf

> You don't often get email from [redacted]. Learn why this is important

Dear Karen,

I am writing today on behalf of the Society for Evidence-Based Gender Medicine (SEGM) to express our concerns about a new proposed rule on “gender-affirming treatment.” We are deeply concerned with the Oregon Insurance Commissioner’s plans to establish the treatment guidelines of the World Professional Association for Transgender Health’s (WPATH) as the official standard of care for gender-dysphoric and questioning patients under Oregon law.

Although WPATH calls its treatment guidelines “Standards of Care” (SOC), they do not represent the community standard of care. In fact, the credibility of WPATH SOC8, and their competency to establish "medical necessity" under state law is currently the subject of multiple ongoing legal disputes. Recent legal discovery revealed several deeply problematic practices pursued by WPATH SOC8 authors, which indicate that SOC8 is not an evidence-based guideline. Please see our attached letter for detailed explanations.

Julia Mason MS MD FAAP
Pediatrician at Calcagno Pediatrics, Gresham Oregon
Board member SEGM

SEGM
SOCIETY FOR EVIDENCE BASED GENDER MEDICINE

November 25, 2024

Email: Karen.J.Winkel@dcbs.oregon.gov

Subject: Public Comment on 2025 Gender-Affirming Treatment Rule

I am writing today on behalf of the Society for Evidence-Based Gender Medicine (SEGM) to express our concerns about a new proposed rule on "gender-affirming treatment." SEGM is a registered nonprofit organization dedicated to promoting evidence-based care for gender-dysphoric children, adolescents, and young adults. SEGM has collaborated with prominent leaders in gender and evidence-based medicine worldwide, and has commissioned several systematic reviews of evidence into the practice of youth gender transitions. Our expertise is evidence evaluation.

We are deeply concerned with the Oregon Insurance Commissioner's plans to establish the treatment guidelines of the World Professional Association for Transgender Health's (WPATH) as the official standard of care for gender-dysphoric and questioning patients under Oregon law. Although WPATH calls its treatment guidelines "Standards of Care" (SOC), they do not represent the community standard of care. In fact, the credibility and competency of WPATH's SOC8 to establish "medical necessity" under state law is currently the subject of multiple ongoing legal disputes. For this reason, we urge you to consider the following information and review whether WPATH's SOC8 should be used as Oregon's standard of care.

Documents recently produced as the result of legal discovery revealed several deeply problematic practices pursued by WPATH SOC8 authors, including:

- **Suppression of scientific evidence**. As reported by the British Medical Journal investigative reporting, WPATH commissioned and then suppressed dozens of systematic reviews of evidence that were supposed to provide the basis for SOC8. As court documents indicate, the research was suppressed because it showed weak—and in some cases non-existent—evidence base for WPATH's recommendations.

  The suppressed evidence affected at least six SOC8 chapters, including Assessment, Primary Care, Endocrinology, Surgery, and Reproductive Medicine (see Appendix A for more detail). Specific to the Endocrinology section, which outlines recommendations for hormone interventions for gender-dysphoric youth, only three of 13 questions in the registered protocol have been addressed in a published systematic review, while the evidence for 10 of 13 questions remains suppressed.

- **Manufacturing medical necessity**. The court documents show that WPATH SOC8 was written with a specific goal to assert medical necessity for virtually any procedure desired by the patient. The documents show that SOC8 authors openly discussed their plans to use

SOC8 to compel the "obtuse and unhealthy system of healthcare coverage" to provide reimbursement for a broad range of "gender-affirming" procedures by ensuring that it contains the language that would allow "any 'goodwilling' clinician" to deliver on the patient wishes. The documents also show that SOC8 was written as a tool for attorneys to defend the use of these procedures in court.

Legal disclosures reveal that in order to assert "medical necessity," WPATH SOC8 replaced the original language of "*wishing* these treatments" with "*in need of* these treatments" (see Appendix B for more detail).

Among the procedures asserted as "medically necessary" by WPATH SOC8 are:

- Penile-preserving vaginoplasty (surgeries that allow male patients to have both a penis and a neovagina)
- Orchiectomy and penectomy (removal of testes and penis) for male patients who identify as eunuchs
- Uterine transplantation for male patients
- Mastectomy for teenage girls (including "nonbinary" mastectomies that preserve some breast tissue and reposition the nipples for a more masculine chest appearance for teens who don't identify either male or female).

- **Removal of minimum age requirements under political pressures.** Legal discovery also show that WPATH leadership contravened its own Delphi consensus process and unilaterally removed minimum ages for all endocrine interventions and for most surgeries. The court disclosures reveal that these last-minute changes were brought about through political pressures exerted upon WPATH leadership, which it was unable to withstand. Some authors of WPATH were well aware that this violates the process integrity, stating "we can never say that the adolescent chapter passed Delphi." Even the guidelines' lead author noted that "its [sic] disappointing that politics always trumps common sense and what is best for patients" (see Appendix C for more detail).

  As SOC8 currently stands, the following interventions can be provided at any age:

  - Mastectomies for female adolescents
  - Removal of testicles and penis and construction of vaginoplasties for male adolescents
  - Cross-sex hormones for patients of either sex

The full list of age minimums that was removed past-publication is still available online as a correction, although WPATH additionally went to great length to remove this correction notice as well. As court documents show, the inconspicuous removal of the age minimums was a key goal.

WPATH's treatment guidelines have a troubling history of violating the principles of evidence-based medicine. The previous guideline version, SOC7, was found to be "incoherent" and not fit for implementation by a 2021 systematic review. The current version, SOC8, was evaluated in a more recent 2024 systematic review and also scored very low, particularly in the domains of rigor of development, applicability, and editorial independence. Like its predecessor SOC7, SOC8 was also not recommended for implementation.

A growing number of progressive European countries that share Oregon's commitment to equality and inclusion, such as Sweden, Finland, and the UK, no longer follow WPATH's recommendations for young gender dysphoric people. After completing independent systematic reviews of evidence and rigorously reviewing the practice of youth gender transition, these countries established their own treatment guidelines and policies that prioritize evidence, care quality, and patient safety over politics.

In conclusion, Oregon's gender-dysphoric young people deserve access to the highest quality, evidence-based care. The use of WPATH's SOC8 as Oregon's standard of care would make the state an outlier, and, we believe, risk the care quality and safety of Oregon's most vulnerable patients.

Sincerely,

Julia Mason, MD

Appendix A: Suppression of scientific evidence

1. WPATH document listing the systematic evidence reviews that were commissioned by WPATH and completed by Johns Hopkins University (JHU) (Boe v. Marshall, Doc 560-17 p.38 of 93) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX167-560-17-JHU-2.pdf :

> Since the start of the contract between WPATH and JHU Dr Robinson and her team have provided systematic literature reviews for the development of statements of the following chapters: Assessment, Primary Care, Endocrinology, Surgery, Reproductive Medicine, and Voice Therapy. Dr Robinson and team have also provided guidance regarding the methodology of the SOC8 and feedback for some of the statements.

2. Email from Dr. Robinson from JHU noting that WPATH restricted JHU's efforts to publish their reviews (Boe v. Marshall, Doc 560-23: p. 23 of 42) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX173-560-23-HHS-5-REDACTED.pdf :

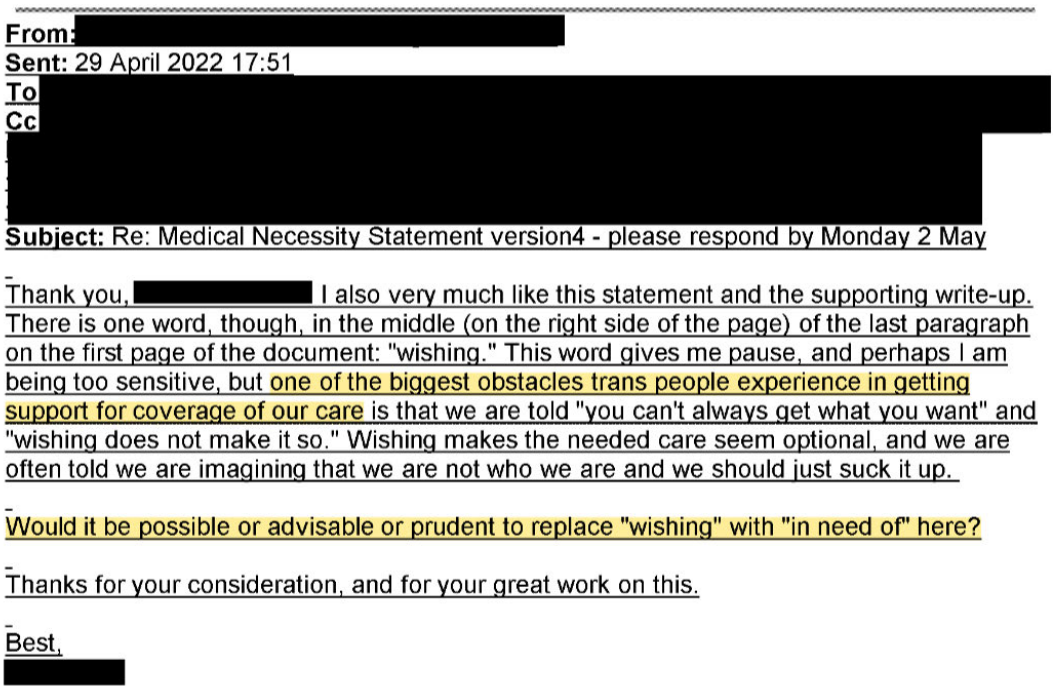
From: Karen Robinson [redacted]
Sent: Monday, August 31, 2020 4:57 PM
To: Chang, Christine (AHRQ/CEPI) <[redacted]; Ritu Sharma <[redacted]>; Lisa Wilson [redacted]
Subject: Re: Ongoing review on gender-affirming surgeries: duplication with EPC program nomination

Christine -

I'm sorry I failed to get back to you. I have been distracted and I am not sure what we will end up publishing in a timely manner as we have been having issues with this sponsor trying to restrict our ability to publish.

Appendix B: Manufacturing medical necessity

1. WPATH changed the wording from "wish" to "need" (Boe v. Marshall, Doc. 700-10, p. 28 of 86) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX181-700-10-WPATH-8-REDACTED-560-31.pdf :



From: [redacted]
Sent: 29 April 2022 17:51
To [redacted]
Cc [redacted]
Subject: Re: Medical Necessity Statement version4 - please respond by Monday 2 May

Thank you, [redacted] I also very much like this statement and the supporting write-up. There is one word, though, in the middle (on the right side of the page) of the last paragraph on the first page of the document: "wishing." This word gives me pause, and perhaps I am being too sensitive, but one of the biggest obstacles trans people experience in getting support for coverage of our care is that we are told "you can't always get what you want" and "wishing does not make it so." Wishing makes the needed care seem optional, and we are often told we are imagining that we are not who we are and we should just suck it up.

Would it be possible or advisable or prudent to replace "wishing" with "in need of" here?

Thanks for your consideration, and for your great work on this.

Best,
[redacted]

2. WPATH worded “medical necessity” to be “expansive” so that “insurance regulatory bodies” could use it “as evidence for medical necessity in coverage decisions” (Boe v. Marshall, Doc. 700-10, p. 44 of 86) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX181-700-10-WPATH-8-REDACTED-560-31.pdf :

On Fri, Aug 27, 2021 at 12:50 PM Dan Karasic [redacted] wrote:

The editors can decide whether or not it needs to be a Delphi statement, and where the discussion of medical necessity should be placed. The statement (or explanatory text) should list medically necessary treatments in an expansive way, and also state that other treatments not listed may also be medically necessary treatments. It should allow for medical necessity to be determined by clinician assessment of the interventions needed for an individual's treatment of their gender incongruence.

The concept of medical necessity is so critical for provision of healthcare to trans people in the US-- prisons are required to provide medically necessary care, state laws require medically necessary care to be provided, insurance regulatory bodies and independent medical reviewers look at evidence for medical necessity in coverage decisions.

There are important lawsuits happening right now in the US, one or more of which could go to the Supreme Court, on whether trans care is medically necessary vs experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time.

Best,
Dan

Dan Karasic, MD
Professor Emeritus of Psychiatry
UCSF Weill Institute for Neurosciences
Telepsychiatry private practice in California
[redacted]
he/him
[redacted]

3. Acknowledgement that SOC8's Medical Necessity Statement was written to be "a tool for our attorneys" in the U.S. to give them "greater force" in legal settings to compel the "obtuse and unhealthy system of healthcare 'coverage" (Boe v. Marshall, Doc. 700-10, p. 62 of 86) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX181-700-10-WPATH-8-REDACTED-560-31.pdf :

On 2022-01-06 23:01, [redacted] wrote:

Dear [redacted]

Thank you for putting this together; you've done a great job with this. Indeed, it is important that such a statement is part of the actual SOC. And, indeed, the original Medical Necessity Statement was specific to the US because this was where we were experiencing the problem with our obtuse and unhealthy system of healthcare "coverage" and we needed a tool for our attorneys to use in defending access to care here. I have long wanted this (and many of our other policy statements) to become part of the SOC because that gives them greater force. I am very happy to see the medical necessity statement expanded to a more global context, which the ICD-11 has made possible.

Appendix C: Removal of minimum age requirements under political pressures

1. Original pressure to remove minimum ages (Boe v. Marshall, Doc. 700-15, p. 12 of 92) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX186-700-15-WPATH-13-REDACTED-560-36.pdf :

ages and treatment in the adolescent chapter, I need your opinion

From: [redacted]
To: Adolescent SOC8 <adolescentsoc8@wpath.org>
Date: Fri, 29 Jul 2022 12:18:06 -0400
Attachments: age in adolescent chapter.docx (14.1 kB); SUMMARY CRITERIA for adolescents new version.docx (16.67 kB)

Dear all,
I hope you are all well and having a good summer. I know you were hoping not to hear anything related to the SOC-8 anymore, but here we are again.
The whole document (over 500 pages) has now been checked for references etc and sent to the IJTH. We are hoping to get the proofs this week so we need to go through it again and we will have a very small window if we want to change anything.

The issue of ages and treatment has been quite controversial (mainly for surgery) and it has come up again.

We sent the document to Admiral Levine, Minister of Health for the USA, for their views. We had a meeting on Zoom last week as she wanted to give us her feedback. She liked the SOC-8 very much but she was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth and maybe adults too. Apparently the situation In the USA is terrible and she and the Biden administration worried that having ages in the document will make matters worse. She asked us to remove them.

We have the WPATH executive committee in this meeting and we explained to her that we could not just remove them at this stage. So we have been thinking of solutions.

You may remember that ages in the document were a "suggestion" not a "recommendation" as we had no evidence to recommend that, but in the document it has become a "recommendation" as it is part of the criteria.

What is clear is that we don't want to remove the ages from the whole document, in fact, I thought that we needed to have the ages for young people to have access to care in the USA…

One solution we thought will be to make the ages criteria a "suggestion" as it is in the document attached. If we do this, in the overall criteria of the appendix we could also put them as a suggestion (as in the document attached) or remove them from the criteria all together but leave them in the chapter as a "suggestion".

The chairs would like to do this but we want to have your opinion.

As time, is an issue with the proofs coming soon and having to be sent away soon, I would like to get your views as soon as possible (we need this by Monday the 1st of august):

1. Do we leave things as they are in the text and in the criteria?
2. Do we change in both documents and move it to suggest as per the attached documents (changes highlighted)?
3. Do we change it to suggest in the text and remove it from the criteria in the appendix.

Let me know your thoughts

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER BOEAL_WPATH_072114

11

2. WPATH SOC authors' original concern that it is not appropriate to use treatment guidelines for political purposes (Boe v. Marshall, Doc. 700-15, p 33/92) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX186-700-15-WPATH-13-REDACTED-560-36.pdf :

I was never committed to ages, so I'm fine with adjustments to de-emphasize them. However, I know others in the group felt ages were a priority, and I don't want to undermine those perspectives.

- Response from Co-Lead: *I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi.*
- Response from another workgroup member: *I do agree that the Delphi situation is a key consideration. Could they send them through again? It is a large change, which I'm fine supporting, but it is weird because then we can never say that the adolescent chapter passed Delphi*

This feels like a very significant change to make in a very short time frame without proper discussion. I think we need to think about the ramifications. My sense is that the US, along with many other countries, is moving toward putting restrictions on youth seeking medical interventions and making the age requirement MUCH older. If our concern is with legislation (which I don't think it should be - we should be basing this on science and expert consensus if we're being ethical) wouldn't including the ages be helpful? ie, it will be harder for states/countries to enact laws that go against the SOC. Plus, aren't the ages just a recommendation with room for adjusting in unique circumstances? I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda. Maybe I'm missing something.

3. WPATH succumbing to pressures and removing the age minimums (Boe v. Marshall, Doc. 700-16, pp 284-5 of 341) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX187-700-16-WPATH-14-REDACTED-560-37.pdf :

6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.
6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

2. With the aforementioned criteria fulfilled (6.12.a–6.12.g), the following are suggested minimal ages for gender-affirming medical and surgical treatment for adolescents:

- 14 years and above for hormone treatment (estrogens or androgens) unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame.
- 15 years and above for chest masculinization unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame.
- 16 years and above for breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty) as part of gender-affirming treatment unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame.
- 17 and above for metoidioplasty, orchidectomy, vaginoplasty, hysterectomy, and fronto-orbital remodeling as part of gender-affirming treatment unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame.
- 18 years or above for phalloplasty unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame.

Page: 50

Number: 1 Author: walterbouman Subject: Sticky Note Date: 9/5/2022 3:55:00 AM -04'00'
Remove this entire sentence (all highlighted), including all the remaining bullet points with ages.

So, remove: "With the aforementioned criteria fulfilled (6.12.a-6.12.g), the following.....considering the factors unique to the adolescent treatment time frame."

Number: 2 Author: walterbouman Subject: Highlight Date: 9/5/2022 3:52:24 AM -04'00'

4. WPATH acknowledgement of political influence (Boe v. Marshall, Doc. 700-15, p. 26 of 92) https://www.alabamaag.gov/wp-content/uploads/2024/10/SJ.DX186-700-15-WPATH-13-REDACTED-560-36.pdf :

From: Walter Bouman [redacted]
To: [redacted]
Date: Sat, 02 Jul 2022 03:00:41 -0400

Dear [redacted]

dont worry: you did the right thing! Its disappointing that politics always trumps common sense and what is best for patients……

From: [redacted] on behalf of [redacted]
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment
Date: Tuesday, November 26, 2024 4:29:08 PM

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002
FROM: Christina Milano, MD, Associate Professor of Family Medicine

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

I am in my 20th year of practicing family medicine and 19th year of providing gender affirming hormone therapy and related care to Oregonians. I am the Medical Director of major transgender health program in our region that serves thousands of patients. I have been a teacher and collaborator in myriad educational initiatives relating to gender affirming care, and have been coaching and lecturing on the topic to regional, national and international audiences for over a decade. I oversaw Oregon's inaugural gender-affirming ECHO in gender affirming care, created and delivered the advanced hormone therapy segment of the American Academy of Family Practice's on-demand CME module in LGBTQ+ health and facilitate the Oregon-statewide Community of Practice in Gender Affirming Hormone Therapy. As Medical Director of our organization's Transgender Health Program, I authored and disseminated our health system's guidelines for prescribing and managing Gender Affirming Hormone Therapy and participate in all multidisciplinary committee and case review activities pertaining to the care of gender expansive patients of all ages. I was also recently elected to serve on the National Medical Committee of Planned Parenthood, specifically for consultation and review of guidelines pertaining to gender affirming care across all Planned Parenthood affiliates. I am also a researcher in the field of gender affirming care, having published on topics ranging from the impact of testosterone therapy on cervical cytology specimens and preventive health screening activity rates as they compare between cisgender and transgender populations in community health centers.

I am outlining my extensive background in this work to underscore the veracity of my declaration that I have the implicit practice experience with patients (numbering in the thousands), and accountability in my teaching and leadership roles to be attesting to the conscientious and meticulous approach that my colleagues throughout the medical and scientific community engaged in when drafting the most recent Standards of Care (v.8) for the World Professional Association of Transgender Health. My every day is steeped in review of the hundreds of peer-reviewed publications on the minutiae of topics that pertain to the care of transgender individuals, so that I can ensure I am providing the most evidence-based approach to my practice of providing gender-affirming hormone therapy to patients, and in support of the clinical queries I respond to from academic physician colleagues who wish to do the same.

I urge you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field.

Sincerely,
Christina Milano
Portland, OR 97202-1643

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Maliheh Nakhai [redacted] >
Sent: Saturday, November 23, 2024 7:25 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Maliheh Nakhai and I am an Oregon Primary Care Physician.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have had patients who have not been able to access gender affirming treatments, and for most patients this has been severely detrimental to their mental health. For some, the inability to access gender affirming hormones and/or surgeries has actually made it unsafe for them to live in certain places (due to risk of violence) and they have had to move to other locations. Gender affirming care is lifesaving in so many ways!

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Gender affirming care helps decrease suicide and severe mental health crises. Gender affirming care helps people be safer in their communities. Gender affirming care helps people be able to hold jobs and pay taxes.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Maliheh Nakhai
Portland, OR 97218-1348

From: [redacted]
To: HALL Brooke M * DCBS; EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002
Date: Monday, November 25, 2024 8:58:04 AM

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Alyssa Nolde, PsyD Licensed Psychologist**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Alyssa Nolde and I am an Oregon mental health provider working and living in the Portland Metro area. **In my career, I have seen the importance of gender affirming care on the mental health of my patients. Seeing the improvement in someone's well being as they have access to the care they need is a level of fulfillment that I find hard to describe. I have seen the detrimental mental health effects of someone not receiving care, and the thought of Oregon potentially blocking gender affirming care is frightening and appalling to me.**

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Fortunately, in my career thus far, I have not had a patient denied gender affirming procedures. I have however seen the detrimental effects of one of my former patients being denied hormone replacement therapy at an organization in the Portland area. The rate at which this person decompensated was shocking; symptoms of depression, suicidality.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Alyssa Nolde, PsyD

--
Alyssa Nolde, PsyD
Licensed Psychologist; OR 3043

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Skye Passmore <[redacted]>
Sent: Monday, November 25, 2024 12:07 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _Dr. Skye Passmore_____ and I am an Oregon Board certified Family medicine Physician/ gender affirming hormone therapy prescriber/ parent/ citizen and transgender ally.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Skye Passmore
Eugene, OR 97405-1696

From: [redacted]
To: HALL Brooke M * DCBS; EMERSON Lisa * DCBS; WINKEL Karen J * DCBS
Subject: HB2002: Public Comments
Date: Friday, November 22, 2024 12:38:25 PM

You don't often get email from [redacted]. Learn why this is important

Dear Ms. Hall, Ms. Emerson, and Ms. Winkel,

I am writing to express my strong support for the proposed rules implementing HB2002, which ensure access to medically necessary, gender-affirming care for transgender and gender-diverse individuals. These rules represent a critical step forward in promoting equitable, evidence-based healthcare in Oregon.

Gender-affirming care is supported by extensive research and clinical guidelines, including the World Professional Association for Transgender Health's Standards of Care, Version 8. This care has been shown to significantly improve mental health outcomes, reduce psychological distress, and enhance quality of life for individuals experiencing gender dysphoria.

The proposed rules appropriately address barriers to care by prohibiting blanket exclusions, mischaracterization of medically necessary procedures as cosmetic, and unnecessary cost-sharing mechanisms. These changes are essential to ensure that care is both accessible and equitable for all who need it.

It is also vital to recognize that treatments such as facial gender-affirming surgery, tracheal shaves, and hair electrolysis are not merely cosmetic but are medically necessary components of care for many individuals. By requiring coverage for these treatments, the rules ensure that transgender and gender-diverse individuals can access the full spectrum of care recommended by their healthcare providers.

Adopting these rules will not only protect the health and well-being of transgender and gender-diverse individuals but also reaffirm Oregon's leadership in advancing human rights and healthcare equity. I urge you to finalize and implement these rules without delay.

Thank you for your dedication to this important issue. Please let me know if additional information or support would be helpful.

Sincerely,

Mark Reck, PsyD
Licensed Psychologist & Clinical Director
Pronouns: He, Him, His

Main: (503) 622-8964
Direct: (503) 389-5711
Fax: (503) 715-5469
[redacted]
www.portlandmh.com
Portland Mental Health & Wellness Patient Portal
Telehealth Link: https://meet.google.com/asa-bmwu-dkr?authuser=0

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Testimony for HB 2002
Date: Friday, November 22, 2024 8:44:32 AM
Attachments: TO Oregon Division of Financial Regulation - Google Docs.pdf

---

> You don't often get email from [redacted] Learn why this is important

Please see my attached letter as a healthcare provider submitting testimony for HB2002.
Thank you.
Suzanne Scopes, ND
503-753-6533
pronouns: she/her

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: Suzanne Scopes, ND, Naturopathic Physician, private practice and former Outside In Transgender Clinic volunteer medical director

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Suzanne Scopes and I am a healthcare provider working in Portland, Oregon. For more than 20 years, I have specialized in providing gender affirming health care in my private practice. From 2005 to 2015, I volunteered as a provider and medical director in the Transgender Clinic at Outside In, which serves low income and homeless patients seeking gender affirming health care. I have also mentored and taught gender affirming care to other providers. It is from this extensive clinical experience that I have come to know that this care is truly lifesaving health care.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have worked with many patients over the years who have been denied gender affirming care, particularly surgical care to align their bodies with their gender identity. These denials have had devastatingly negative effects on the patient's mental health. Alternatively, when patients have been able to access gender affirming care, their mental health status has improved markedly. Since depression and suicidality due to

discrimination is so prevalent in this population, maintaining access to this care can be literally lifesaving.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

As a gender affirming care provider, I have always been guided by the World Professional Association for Transgender Health published Standards of Care. These have been updated periodically to reflect current research and information. Denials of care by insurers who have no knowledge of these standards of care is unprofessional and causes negative health outcomes.

Discrimination and the consequent negative health outcomes are documented as being considerably worse for transgender people who also identify as people of color, low income or immigrant status. My clinical experience also reflected this unfortunate reality.

Having to spend considerably less time and resources completing prior authorizations and fighting insurance companies to cover care that has been denied, will increase our time to be available for direct patient care.

Sadly, I have had too many of my transgender patients end their own lives or struggle with depression caused by discrimination and hatred. I look forward to a time when patients can reliably access the lifesaving care that they need and that their doctors recommend. This will positively impact health outcomes for transgender Oregonians, particularly those in groups who are already underserved and facing daily discrimination.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Suzanne Scopes, ND

Oregon Licensed Naturopathic Physician

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on Treatment of Gender Dysphoria in Children and Youth
Date: Thursday, November 21, 2024 9:07:16 AM

Dear Ms. Winkel:

I am writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender affirming treatment.

I am a psychiatrist in British Columbia who is well educated about the diagnosis and treatment of children, youth and adults with gender dysphoria. I have been public regarding my concerns about WPATH Standards of Care 8 (SOC8) and the use of gender affirming treatment in children and youth in general. By gender affirming care, I am referring to the use of puberty blockers, cross sex hormones and surgeries with the purpose of altering the bodies to better fit a self identified gender.

Bill HB2002 required insurers to cover "medically necessary" care. Gender affirming care does not meet the definition of medical necessity.

I have presented on the issues regarding gender affirming care to residents and colleagues, and have recently published an article that promotes psychosocial treatment and psychotherapy as first line treatment for gender dysphoria. I will be presenting a webinar on December 3rd on psychotherapy as first line treatment for gender dysphoria. I invite you or anyone in your office to attend.

I have spoken to hundreds of physicians, and aside from the ones who provide gender affirming care, all of them agree that we need to stop medicalized treatments in children and youth once I have provided them with the facts and evidence. However, only a handful of colleagues will speak up publicly, as they fear losing jobs, complaints to regulatory colleges, and being accused of being transphobic.

I think that if Oregon adopts WPATH SOC8 as treatment guidelines, dire harm will result to many children and youth who would have otherwise grown up and become accepting of their sexed bodies. The majority of them will end up gay or lesbian. Instead of being allowed to grow up and discover their sexualities, they are being told they were born in the wrong bodies and that this can be changed. Children and youth simply do not have the capacity to consent to these treatments, or the fact it is impossible to ever change someone's sex. In addition, their self identities are in flux, and still developing, as is their sexuality.

WPATH is an organization that purports to be evidence based. However, the recent unsealing of WPATH internal emails in Alabama is proof that WPATH suppressed evidence and allowed itself to be influenced by the government. Specifically, the publication of systematic reviews WPATH commissioned from Johns Hopkins for SOC8 was suppressed because the results did not support the use of gender affirming care in children and youth. There are now many systematic reviews, all of which show there is low to very low evidence of benefit for gender affirming treatments, and risk of harm. Some of these systematic reviews were published prior to SOC8's publication, yet are not referenced in it.

WPATH is not a medical organization and cannot be trusted to provide any recommendations given their disregard for the science.

These vulnerable youth deserve for Oregon to protect them from harm, not to support medical treatments that have no evidence of efficacy, alter their bodies irreversibly, and often lead to regret once they mature. Many detransitioners have bravely told their stories, and Oregon should listen to them.

Best Regards,

Joanne Sinai
Joanne Sinai, MD, MEd, FRCPC
Psychiatrist
USTAT Clinic
Clinical Associate Professor
University of British Columbia
Department of Psychiatry
Island Health
[redacted]
Victoria, BC
V8W 2K7
phone: 250.519-3544
fax: 250.519-3545

J Can Acad Child Adolesc Psychiatry. 2024 Jul;33(2):145-153. Epub 2024 Jul 1.

Psychodynamic psychotherapy for gender dysphoria is not conversion therapy

Joanne Sinai [1], Peter Sim [2]

Affiliations

PMID: 38952790 PMCID: PMC11201722

Abstract

Over the last ten years, there has been a substantial increase in the number of children and adolescents referred to gender clinics for possible gender dysphoria. The gender affirming model of care, a dominant treatment approach in Canada, is based on low quality evidence. Other countries are realizing this and making psychosocial treatments and/or exploratory psychotherapy a first line of treatment for gender related distress in young patients. Psychodynamic (exploratory) psychotherapy has established efficacy for a range of conditions, and has been used in youth and adults with gender dysphoria. In Canada, the adoption of psychodynamic psychotherapy for gender dysphoria is impeded by some academics who argue that it may violate laws against conversion therapy. Psychodynamic psychotherapy is not conversion therapy and should be made available in Canada as a treatment modality for gender dysphoria.

Keywords: autonomy; conversion therapy; evidence-based treatment; gender affirming care; gender dysphoria; informed consent; psychodynamic psychotherapy for gender dysphoria; transgender children; transgender youth.

Comment in

Urgent need for CACAP position statement on psychotherapy for gender dysphoria.
Savenkov O.
J Can Acad Child Adolesc Psychiatry. 2024 Nov;33(3):162. Epub 2024 Nov 1.
PMID: 39534779 Free PMC article. No abstract available.

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Webinars

Therapy First provides a range of trainings for mental health clinicians working with young people who are questioning their identity. Therapy First members always have free access to the recordings of previous trainings. To explore upcoming webinars, click below.

Psychodynamic Psychotherapy as First Line Treatment for Gender Dysphoria

Dr. Joanne Sinai

Tuesday December 3rd at 8pm EST

In July 2024, the Journal of the Canadian Academy of Child and Adolescent Psychiatry published a paper by Joanne Sinai, a Canadian psychiatrist, and Peter Sim, a retired lawyer, that reviewed the current mental health landscape for gender dysphoria. The paper argued that psychodynamic psychotherapy should be made available as a first-line treatment for gender dysphoria. In this webinar, Sinai will provide an overview of the paper and examine the aspects of psychodynamic psychotherapy that enhance the ability for those with gender dysphoria to develop greater insight and understanding regarding the conscious and unconscious factors that impact their distress. It is only when a greater level of understanding occurs that these patients will be able to exercise their autonomy and provide truly informed consent.

Learning objectives:

- Understand changes in patient profiles of those presenting with gender dysphoria.
- Review the differential diagnosis of gender dysphoria as a symptom of distress

- Discuss the potential benefits of psychodynamic psychotherapy for gender dysphoria, in particular with regard to autonomy and informed consent.

Dr. Joanne Sinai is a Canadian psychiatrist and Clinical Associate Professor at the University of British Columbia. She completed her medical school and psychiatry residency at the University of Toronto. She also has a Master's of Education with a focus on health on health professional education. In Victoria, BC, she works at a psychiatric urgent care clinic and also has a long term psychodynamic psychotherapy practice.

Therapy First has been approved by NBCC as an Approved Continuing Education Provider, ACEP No. 7505. Programs that do not qualify for NBCC credit are clearly identified. Therapy First is solely responsible for all aspects of the programs. This webinar provide 1.5 hours of CE credits.

Book Now

From: [redacted]
To: WINKEL Karen J * DCBS; EMERSON Lisa * DCBS; HALL Brooke M * DCBS
Subject: Public Comment
Date: Monday, November 25, 2024 10:32:06 AM

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Rose Snyder, Ed.M., Psy.D.**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Dr. Rose Snyder and I am an Oregon clinical psychologist working and living in West Linn, OR. I have been in practice for 22 years as a therapist/psychologist and have specialized in working with at-risk youth, trauma, the LGBTQ population, and parenting neurodivergent youth.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have written several letters for insurance approval for gender-affirming care for my clients over the past 5 years. Luckily, each of them have been approved and my clients have been able to have insurance coverage for their gender-affirming care. Had they not, each of them would have been at far greater risk in terms of depression and suicide; in fact, they are were at this type of risk when they began treatment with me. Post-treatment, each of these clients has expressed great relief to have their

bodies match their experienced gender identity.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

This rule will help me continue to be able to do my best job possible as a provider for such clients. They come to me with questions and distress about gender identity and we go through a rigorous exploration to make sure of their best path forward. When it comes to the physical medicine side of things, gender-affirming care can and will continue to be life-saving care for such clients.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Dr. Rose Snyder

Rose Snyder, Ed.M., Psy.D.
www.rosesnyder.org
[redacted]

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002
Date: Wednesday, November 20, 2024 7:57:49 PM
Attachments: Outlook-51rgkivl.png

> You don't often get email from [redacted] Learn why this is important

TO: Oregon Division of Financial Regulation

FROM: Isabelle Trepiccione, MD. Outside In

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Isabelle Trepiccione and I am a primary care doctor working in Portland, OR. I work at Outside In medical clinic where (amongst other things) I provide primary care and gender affirming medical care to transgender and nonbinary clients.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Gender-affirming care is life-saving care and access to gender affirming care can significantly improve the mental health of transgender and nonbinary persons of all ages.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have numerous patients who have dealt with profound depression, anxiety, suicidal ideation for years. Upon realization of their gender identity and access to an affirming environment and affirming medical care, procedural care such as gender affirming mastectomy and vaginoplasty in particular; their prior mental health symptoms resolve or are significantly alleviated.

I want to share appreciation for the following that are in the proposed rule:

· Determining a standard of care in rule for insurers to be in compliance with HB2002

· Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

· Transparency for the patient if requested related to adverse benefit determinations

· Alignment with network adequacy standards

· Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians.

Thank you,

Isabelle

Isabelle Trepiccione, MD
Pronouns: she/her/hers
Family Physician
[redacted] Portland, Or 97205
T 503.535.3860| www.OutsideIn.org

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of myka dubay
Sent: Monday, November 25, 2024 7:48 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Myka Dubay and I am an Oregon labor activist and community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

In 2022 I myself received gender affirming care in Oregon, and despite the protections we already had, my surgery was initially denied. I had to file a grievance and go through the appeal process to be heads — skills I have because of my job, but not everyone does and not everyone knows how to figure out who to talk to in the system for decisions we know are incorrect — and illegal. Patients should not have to read the law to insurance companies who are denying care just to receive that care. If insurance companies want to operate in Oregon, it is imperative they know what the laws are, that they follow them, and that they are held accountable when they do not.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
myka dubay
Portland, OR 97217-6332

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Alan Dubinsky
Sent: Monday, November 25, 2024 8:31 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Alan Dubinsky and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
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- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Alan Dubinsky
Portland, OR 97220-3149

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Please maintain support for gender affirming care
Date: Friday, November 22, 2024 10:32:24 AM

> You don't often get email from [redacted]. Learn why this is important

HB 2002 Support Letter

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Kayla Duncan**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Kayla and I am a community member living in Central Oregon. My youngest kiddo has been exploring gender differences over the past few years and we have sought medical advice and support for this in my community.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Kayla

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Gender Affirming Care
Date: Wednesday, November 20, 2024 12:39:14 PM

> You don't often get email from [redacted]. Learn why this is important

Please do not allow Gender Affirming Care to be considered in the State of Oregon.
It does nothing for the person and does everything for the wallets of those offering the "care".

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Just Say No
Date: Wednesday, November 20, 2024 8:57:38 AM

> You don't often get email from [redacted]. Learn why this is important

I am a lifelong resident of Oregon and want to formally object to any consideration to "Gender Affirming Care".

Studies show this direction does more harm to a human being than good, including suicide rates, mental health implications and overall health.

Please do the right thing.

Jim Dunn

From: [redacted] on behalf of [redacted]
To: WINKEL Karen J * DCBS
Subject: HB2002 Comment of Support
Date: Monday, November 25, 2024 9:49:48 PM

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Karana Dunn and I am an Oregon resident working in renewable storage. I am not trans myself but I am friends with many who identify as trans or non-binary and am very familiar with the challenges they face and why access to gender-affirming healthcare is critical.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:
- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Karana Dunn
Beaverton, OR 97008-7811

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Sarah Dykes [redacted]>
Sent: Monday, November 25, 2024 1:30 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Sarah Dykes, I am currently an Oregon health care provider, and a former educator. I am also the parent of a queer and gender expansive youth. Access to gender affirming care is life saving and critical. I cannot express enough the significance of protecting the dignity and wellbeing of LGBTQIA+ populations and their ability to receive adequate health care and services to thrive. I have witnessed the suffering and negative mental health outcomes of individuals who face barriers to gender affirming care and navigating an already difficult health care system.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Access to gender affirming care is critical and life saving for many of the clients I see in my practice and among youth who I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

As a mental health care provider I have taken a hippocratic oath to do no harm and to provide support and care for all, which includes special training in line with the WPATH guidelines and recommendation to protect and serving marginalized and vulnerable populations for gender affirming care and services. Ensuring insurance coverage and health care access allows me to keep this oath and ethical practice for all.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Sarah Dykes
Portland, OR 97205-1760

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lauren Easterlund [redacted]>
Sent: Monday, November 25, 2024 11:24 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Public Comment - Gender Affirming Care is Mental Health Care

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Lauren Easterlund MSW, CSWA and I am an Oregon Mental Health Provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I work with many transgender clients, and receiving adequate gender affirming Care is essential for their mental well being. Transgender people already face a slew of discrimination from family, peers, jobs, and housing, which contributes to higher risk factors (such as suicide) and mental health needs. Receiving adequate healthcare is a proven protective factor that leads to greater well being, and I have seen that repeatedly in my practice as a mental health provider.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lauren Easterlund
Eugene, OR 97405-1311

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Kathryn Emard [redacted] >
Sent: Monday, November 25, 2024 10:56 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is KATHRYN EMARD and I am an Oregon Mental Health Counselor.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have worked with members of the LGBT community, including Trans clients for the last 5 years and have supported many clients through the process of gender transition. Gender Affirming Care is a necessary and life saving thing. There is already so much gatekeeping and many hoops to jump through for patients who just want to live their lives and express themselves for who they really are. These barriers hurt people. When clients of mine have not had access to Gender Affirming Care the psychological impact has been profound. Patients who are unable to access care experience depression and suicidal ideation. I am extremely concerned about what impacts the current state of politics will bring to the table. We need to be strong as a state in our advocacy and protection of this marginalized and vulnerable group. They deserve the right to live as they are, to be safe, to be supported and to live freely, just as any other Oregonian. Bodily autonomy is a human right.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Oregon should always strive to adhere to the highest standards of care in Trans Health in order to respect and protect marginalized communities. Our most marginalized people will be impacted the most by lack of access, including people of color and people struggling with poverty. I have heard over and over in my career that "Gender Affirming Care saved my life!" What a powerful statement.I have seen the peace and healing that Gender Affirming Care has brought to clients in my care. It is crucial that we protect it.Oregon has always been a light in the world and needs to continue to make a stand, especially in these dark and uncertain times.
.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Kathryn Emard
Lake Oswego, OR 97035-3202

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of April Erdos <[redacted]>
Sent: Tuesday, November 26, 2024 12:01 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is April Erdos and I am an Oregon mental health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

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- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
April Erdos

Portland, OR 97239-2951

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Alec Esquivel <[redacted]>
Sent: Monday, November 25, 2024 1:12 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Alec Esquivel and I am an Oregon transman and advocate. It is now more important than ever that Oregon stands firm against the pending federal attacks on access to health care for transgender persons. Extremists should not be allowed to decide who gets access to life saving care. We must ensure that patients, along with their medical professional teams, have the support and access they need.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

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- Transparency for the patient if requested related to adverse benefit determinations
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- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in life-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians.

Thank you for your time and care with this matter.

Sincerely,
Alec Esquivel
Portland, OR 97220-5261

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Rain Estrada <[redacted]>
Sent: Sunday, November 24, 2024 5:31 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Rain Estrada and I am an Oregon Therapist and I work with transgender clients.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have seen the positive impact of clients being able to access gender-affirming interventions that help them experience more congruence with their gender.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Rain Estrada
Portland, OR 97227-1338

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lydia Evans <[redacted]>
Sent: Monday, November 25, 2024 12:44 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Lydia Evans and I am an Oregon mental health provider. I have seen in my work how crucial gender-affirming care is to the people I work with, for both mental and physical wellbeing.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:
- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lydia Evans
Portland, OR 97202-4203

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Rem Fadich [redacted]>
Sent: Monday, November 25, 2024 6:10 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____Rem___ and I am an Oregon _____community member_____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

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[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Rem Fadich
Portland, OR 97215-1978

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of River Fagan [redacted] >
Sent: Tuesday, November 26, 2024 3:50 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Paul "River" Fagan and I am an Oregon health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Having worked with many trans clients, I have personally seen the devastating and long term mental health problems caused by lack of access to gender-affirming care. I have also been lucky enough to see the positive impact of supportive and affirming care for trans and non-binary clients.

I want to share appreciation for the following that are in the proposed rule:

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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
River Fagan

Portland, OR 97206-4682

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: 2025 Rules for Gender Affirming Care
Date: Friday, November 22, 2024 4:32:49 PM

> You don't often get email from [redacted]. Learn why this is important

I am very concerned about these proposed rules.

They are not based in science. Where is the science that shows puberty blockers and surgery changes the chromosomal structure of a human from that of birth?

A child's brain is not fully developed until around age 25 and yet we are expecting children to make these life changing decisions? Instead of pushing this ideology and following up with life altering "treatment" let's help our children to understand their identity. Let's provide clear, science based mental health treatment before we destroy our next generation.

I am also aghast at the money trail: Insurance companies paired with drug companies! Just WHO is making money at the expense of our nest generation!!!

I strongly urge that these so-called affirming cars rules be dumped immediately and more beneficial mental health processes be considered, for the sake of our nest generation and generations to come. This is an ideology that must be STOPPED! Our state should be th3 bastion of HEALTH for all people. I think we are quickly finding out that we need to take a new look, a healthy look and a look that promotes a healthy lifestyle.

Thank you for your consideration…
Sincerely,
Terri Fair

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Heather Fercho
Sent: Monday, November 25, 2024 1:43 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Heather Fercho and I am an Oregon health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Heather Fercho
Portland, OR 97218-1733

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-Affirming Treatment Rule
Date: Monday, November 18, 2024 6:08:38 PM

> You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules go way beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists. Ascovered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme CourtWPATH-8 is heavily influenced by a radical political agenda.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services,the proposed rules are completely silent on this issue. Further, no detransitioners were included in the advisory group that helped write the rules.

Children in Oregon deserve the best medical care possible, and they won't be getting it from this non-evidence-based standard of care.

I appreciate your consideration of this matter.

Sincerely,

Claire Fischer

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
10/30/2024 11:50 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2025 Gender-Affirming Treatment Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/19/2024
TIME: 11:00 AM - 12:00 PM
OFFICER: Brooke Hall

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm A, Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 599636230
SPECIAL INSTRUCTIONS:
Meeting ID: 267 195 468 800
Passcode: j3NgqJ

NEED FOR THE RULE(S)

House Bill 2002 (2023) prohibits a carrier offering a health benefit plan from denying or limiting coverage for medically necessary gender-affirming treatment that is prescribed in accordance with accepted standards of care. The bill also prohibits health benefit plans from applying cosmetic or blanket exclusions to medically necessary gender affirming treatment and establishes requirements for notices of adverse benefit determinations and network adequacy.

HB 2002 (2023) requires the Department of Consumer and Business Services (DCBS) to adopt rules to implement these provisions. DCBS convened a Rulemaking Advisory Committee (RAC) which met on Dec. 12, 2023, Jan. 25, Mar. 21, Apr.

25, Jun. 11, Jul. 18, and Aug. 7, 2024. The RAC included insurers, health care providers, consumer and patient advocates. Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

House Bill 2002 (2023)
ORS 743A.325 (4)(b)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

A Rulemaking Advisory Committee was consulted regarding this equity statement. This rule implements HB 2002, which increases access to gender affirming care. This rule is not anticipated to have any disparate negative impact on any particular demographic of Oregon consumers.

This rule is expected to have a positive impact on equity in the state by increasing access to healthcare services for underserved individuals, particularly for transgender and non-binary individuals, resulting in reduced barriers to necessary medical treatments, enhanced affordability, and improvements in behavioral health and overall well-being for those receiving gender-affirming care.

FISCAL AND ECONOMIC IMPACT:

The rule primarily affects health insurance carriers issuing health benefit plans. The rule mandates that health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.

This training comes with a cost. Based on the information available to the department, the training sessions facilitated by WPATH are priced based on contractual arrangements that depend on factors including the number of participants. DCBS does not have specific information about the number of insurance company employees that will take the training as a result of this rule, so it is not possible to estimate the total cost to affected industry entities. However, since the training can be made available to an insurer's existing reviewers, the training requirement is likely less financially burdensome than alternative approaches that could require hiring or contracting with different or additional reviewers.

The rule will have indirect positive effects on health care providers, including small businesses, to the extent that it requires health insurance carriers to reimburse for services that may not previously have been covered, but the extent of this impact is impossible to estimate from the information available to DCBS.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not (or does not have) a fiscal or

economic impact on state agencies, local government units, nor the public.

(2)(a) Based on financial filings made to the Division of Financial Regulation (DFR), no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule will have indirect effects on health care providers, including small businesses, but DCBS does not have access to information to determine the number of small provider organizations that would be affected.

(2)(b) The rule primarily affects health insurance carriers. It does not require additional reporting or recordkeeping activities. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

(2)(c) The rule primarily affects health insurance carriers. Based on the information available to the department, it does not require additional professional services, equipment or supplies. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rule primarily applies to health insurance carriers. Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule has indirect impacts on health care providers, some of whom are small businesses.

Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers. The department also received written and oral public comment during the RAC process from small business health care provider representatives.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-053-0441

RULE SUMMARY: A carrier offering a health benefit plan may not deny or limit coverage under the plan, including, but not limited to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and
(b) Prescribed in accordance with accepted standards of care.

CHANGES TO RULE:

836-053-0441
Gender-Affirming Treatment
(1) For purposes of this rule:¶
(a) "Gender-affirming treatment" has the meaning given to that term under ORS 743A.325; and¶
(b) "Accepted standards of care" includes, at a minimum, the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (WPATH-8). ¶
(2) A carrier offering a health benefit plan may not deny or limit coverage under the plan including, but not limited

to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost-sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:¶
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and¶
(b) Prescribed in accordance with accepted standards of care.¶
(3) Carriers may use utilization review practices to verify adherence to the accepted standards of care described in subsection (2)(b), provided that such practices are consistent with the requirements of this rule, OAR 836-053-1200, and all other applicable provisions of Oregon law. Utilization review practices shall be implemented in a manner that does not unreasonably limit or delay access to care.¶
(4) A carrier offering a health benefit plan may not:¶
(a) Apply a categorical cosmetic or blanket exclusion to medically necessary gender-affirming treatment; or¶
(b) Exclude, as a cosmetic service, a medically necessary procedure prescribed by a physical or behavioral health care provider as gender-affirming treatment, including but not limited to: ¶
(A) Tracheal shave;¶
(B) Hair electrolysis; ¶
(C) Facial feminization surgery or other facial gender-affirming treatment; ¶
(D) Revisions to prior forms of gender-affirming treatment; or¶
(E) Any combination of gender-affirming treatment procedures.¶
(5) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must ensure that the adverse benefit determination is reviewed and approved in accordance with the following requirements: ¶
(a) The adverse benefit determination is reviewed by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.¶
(b) To demonstrate experience the reviewing provider must:¶
(A) Meet the criteria for external medical review found in OAR 836-053-1325(6)(b)(A-C);¶
(B) Have experience utilizing the WPATH-8; and¶
(C) Have completed the WPATH SOC-8 Health Plan Providers training program or an equivalent training program.¶
(c) This subsection (5) does not apply to an adverse benefit determination that only involves the application of cost-sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment. ¶
(6) In the event of an adverse benefit determination that denies or limits coverage for gender-affirming treatment, the carrier must meet all the requirements in:¶
(a) ORS 743B.250, and if requested under ORS 743B.250(2)(h)(B), disclosure of the identity of the physical or behavioral health care provider who reviewed the determination, which at a minimum includes information to demonstrate experience prescribing or delivering gender-affirming treatment:¶
(A) The provider's job title and specific role in the review process; and¶
(B) The provider's specialty, board certification status, and any other relevant qualifications that affirm their experience in gender-affirming treatment.¶
(b) OAR 836-053-1030; and¶
(c) OAR 836-053-1100. ¶
(7) Carriers offering health benefit plans shall:¶
(a) Satisfy any network adequacy standards under ORS 743B.505 related to gender-affirming treatment providers; and¶
(b)(A) Contract with a network of gender-affirming treatment providers that is sufficient in numbers and geographic locations to ensure that gender-affirming treatment services are accessible to all enrollees without unreasonable delay; or¶
(B) Ensure that all enrollees have geographical access without unreasonable delay to out-of-network gender-affirming treatment services with cost-sharing or other out-of-pocket costs for the services no greater than the cost-sharing or other out-of-pocket costs for the services when furnished by an in-network provider, and meet all the requirements in:¶
(i) OAR 836-053-1030;¶
(ii) OAR 836-053-1035; and¶
(iii) OAR 836-053-1408.
Statutory/Other Authority: ORS 731.244, ORS 743A.325
Statutes/Other Implemented: ORS 743A.325

2023 Regular Session

HB 2002 Enrolled
(/liz/2023R1/Downloads/MeasureDocument/HB2002)

Overview

At the request of:

Chief Sponsors:	Representative Valderrama, (https://www.oregonlegislature.gov/valderrama) Nelson, (https://www.oregonlegislature.gov/nelson) Senator Lieber, (https://www.oregonlegislature.gc Steiner
Regular Sponsors:	Representative Andersen, (https://www.oregonlegislature.gov/andersen) Bowman, (https://www.oregonlegislature.gov/bowman) Bynum, (https://www.oregonlegislature.gov/byr Fahey, (https://www.oregonlegislature.gov/fahey) Gamba, (https://www.oregonlegislature.gov Gomberg, (https://www.oregonlegislature.gov/gomberg) Grayber, (https://www.oregonlegislature.gov/grayber) Hartman, (https://www.oregonlegislature.gov/ha (https://www.oregonlegislature.gov/helm) Holvey, (https://www.oregonlegislature.gov/holvey) (https://www.oregonlegislature.gov/hudson) Kropf, (https://www.oregonlegislature.gov/kropf) (https://www.oregonlegislature.gov/marsh) McLain, (https://www.oregonlegislature.gov/mclai (https://www.oregonlegislature.gov/nguyend) Nguyen H, (https://www.oregonlegislature.gov/ (https://www.oregonlegislature.gov/nosse) Pham H, (https://www.oregonlegislature.gov/phan (https://www.oregonlegislature.gov/pham) Reynolds, (https://www.oregonlegislature.gov/reyr (https://www.oregonlegislature.gov/ruiz) Sosa, (https://www.oregonlegislature.gov/sosa) Tran (https://www.oregonlegislature.gov/tran) Walters, (https://www.oregonlegislature.gov/walters Campos, (https://www.oregonlegislature.gov/campos) Dembrow, (https://www.oregonlegislature.gov/dembrow) Frederick, (https://www.oregonlegislature.gov/ Gelser Blouin, (https://www.oregonlegislature.gov/gelser) Golden, (https://www.oregonlegislature.gov/golden) Gorsek, (https://www.oregonlegislature.gov/gorse (https://www.oregonlegislature.gov/jama) Manning Jr, (https://www.oregonlegislature.gov/Ma (https://www.oregonlegislature.gov/meek) Patterson, (https://www.oregonlegislature.gov/patt Prozanski, (https://www.oregonlegislature.gov/prozanski) Sollman, (https://www.oregonlegislature.gov/sollman) Taylor, (https://www.oregonlegislature.gov/taylor (https://www.oregonlegislature.gov/wagner) Woods (https://www.oregonlegislature.gov/wood
Bill Title:	Relating to health; and declaring an emergency.
Catchline/Summary:	Modifies provisions relating to reproductive health rights.
Chapter Number:	Chapter 228
Fiscal Impact:	Fiscal Impact Issued
Revenue Impact:	No Revenue Impact
Measure Analysis:	Staff Measure Summary / Impact Statements (/liz/2023R1/Measures/Analysis/HB2002)
Current Location:	Chapter Number Assigned

Current Committee: ()

Current Subcommittee:

Subsequent Referral(s):

Potential Conflicts of Interest/Vote Explanations: Potential Conflicts of Interest/Vote Explanation Documents (https://www.oregonlegislature.gov/pcive/Forms/Display.aspx?View={F16B1F7B-33C4-4EA7-9D3022EE155C}&FilterField1=Session&FilterValue1=2023R1&FilterField2=Measure&Filter\

Measure History ❯

Scheduled Events ❯

Standards of Care Version 8

VIEW THE SOC8 HERE (OPEN ACCESS)

SOC8

SOC8 publication is complete. Please follow the link below to view the document.

As new translations become available, we will add to this page. Currently listed are: Bosnian, Czech, Croatian, French, Georgian, Italian, Korean, Mandarin, Montenegrin, Norwegian, Portuguese, Spanish, Thai, and Ukrainian.

VIEW SOC8 CHAPTERS

VIEW SOC8 TRANSLATION PAGE

History and Purpose

The field of transgender healthcare is a rapidly evolving interdisciplinary field. The last few years have seen a globally unprecedented increase and visibility of transgender and gender diverse people seeking support . . .

LEARN MORE

CHAIRS & LEAD EVIDENCE TEAM

Establishing the SOC8 Revision Committee

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select

LEARN MORE

Methodology for the Development of SOC8

Following the publication of the SOC8, in the future, unless there is a major need to adapt the entire document, small adaptations/addendums can take place, if/when new data is available that will affect specific recommendations . . .

LEARN MORE

Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show

Newly released emails from an influential group issuing transgender medical guidelines indicate that U.S. health officials lobbied to remove age minimums for surgery in minors because of concerns over political fallout.

Listen to this article · 8:53 min Learn more

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for care of transgender minors, according to newly unsealed court documents.

Age minimums, officials feared, could fuel growing political opposition to such treatments.

Email excerpts from members of the World Professional Association for Transgender Health recount how staff for Adm. Rachel Levine, assistant secretary for health at the Department of Health and Human Services and herself a transgender woman, urged them to drop the proposed limits from the group's guidelines and apparently succeeded.

If and when teenagers should be allowed to undergo transgender treatments and surgeries has become a raging debate within the political world. Opponents say teenagers are too young to make such decisions, but supporters including an array of medical experts posit that young people with gender dysphoria face depression and worsening distress if their issues go unaddressed.

United States | The WPATH files

Leaked discussions reveal uncertainty about transgender care

The files shed light on a controversial area of medicine that has largely retreated into the shadows

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Mar 5th 2024 | WASHINGTON, DC

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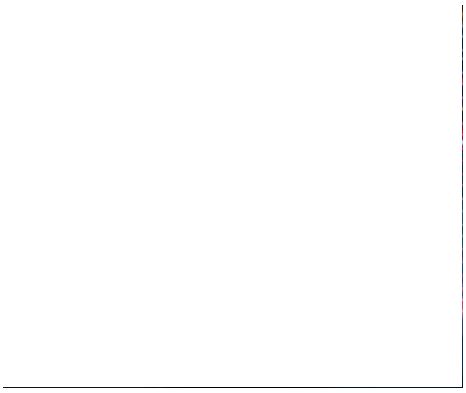

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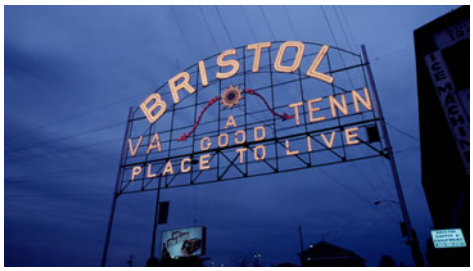

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Feature BMJ Investigation

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

BMJ 2024; 387 doi: https://doi.org/10.1136/bmj.q2227 (Published 30 October 2024) Cite this as: BMJ 2024;387:q2227

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Jennifer Block, freelance journalist
writingblock@protonmail.com

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1,2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2,3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4,5,6,7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in

January, but it provided no details or references regarding the “evidence synthesis” that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO’s statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. “While we welcome the commitment to upholding human rights,” she tells *The BMJ*, “liberalised access to healthcare interventions that might in fact have harmful effects is not actually in support of anyone’s human rights.”

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that “proper evidence reviews have been commissioned to address key questions.” After the June revelations regarding WPATH’s executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the “strong overlap” between the WHO guideline group and WPATH “will have direct negative implications for the credibility of WHO’s own process.” WHO didn’t respond directly to either group.

Reviews “completed and submitted” but not approved

WPATH’s updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having “followed the most rigorous protocol in the world . . . a long and painstaking scientific review process.”[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an “approval process” over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team “completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters,” said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn’t go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13][14] “We had hoped to publish more of those reviews but for a few reasons have not done so,” wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting “reports of reviews (dozens!)” to WPATH, but she added that “we have been having issues with this sponsor trying to restrict our ability to publish.”

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*’s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new “policy and procedures,” which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH’s board. Only then would the Johns Hopkins researchers be given a “green light to be published.”

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, “It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.”

The approval process was to be overseen by the organisation’s president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO’s guideline development group for transgender health and remain members. Neither responded to *The BMJ*’s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its “consensus based” methodology, offering instead to downgrade those recommendations into weaker “suggestions.” But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn’t made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the “evidence based standard of care for the evaluation and treatment of trans individuals.” The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO’s guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. “If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area,” she says, “it may harm WHO’s reputation in other areas of medicine, where its clinical guidance is sorely needed.”

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was “aware of allegations and media reports regarding WPATH” but “does not comment on legal issues involving external organisations.” WHO conducts “careful reviews on conflicts of interest,” it said, and “GDG [guideline development group] members act in their own expert capacity.” Regarding evidence reviews for hormonal treatments, WHO said only that “members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence.”

In late August it provided more detail, telling *The BMJ* that “systematic reviews have been commissioned” to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn’t been made explicit, particularly given all the calls for more transparency. “Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence,” says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn’t locate a public link for the final commission, titled “Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people.”**1819202122232425** The registration details indicate that reviews were started as early as January 2023 and that some commenced months earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, “They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don’t specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition.” Abbruzzese adds, “There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications.”

Ryan also expresses concern that the systematic reviews “fail to examine the impacts” of legal recognition of self-identified gender—which WHO has defined as a health measure—“on any group other than trans and gender diverse people.” Abbruzzese concurs, saying that “research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women’s safety and values and preferences must be a key part of the research.”

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it’s likely to be submitted for inclusion on WHO’s essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO’s Expert Committee that evaluates essential medicine applications, and it’s “likely” to be approved. “Once it goes on the essential medicines list, that obliges governments to supply the drug,” he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn’t bothered by this. “I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them,” he says. While there may be only low quality evidence of benefit, adds Guyatt, “it seems to me a very value and preference sensitive decision.”

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as “the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events.”

“An untenable position”

Robinson of Johns Hopkins pushed back on WPATH’s demands, apparently many times. She wrote to WPATH, “We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018.”

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH’s SOC8 publication process and is now legal evidence, a chapter author wrote, “Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits.” Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as “insufficient evidence” or “limited data”—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that “we found little to no evidence about children and adolescents.” WHO came to a similar conclusion this year, calling the evidence “limited and variable.”**3** Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, “We were told by WPATH leadership that Johns Hopkins couldn’t do a review for the child or

adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

- Provenance: Commissioned; externally peer reviewed.

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Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

* * *

Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

Steve Marshall
Attorney General
Edmund G. LaCour Jr.
Solicitor General
Counsel of Record
A. Barrett Bowdre
Principal Deputy Solicitor General
STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL
501 Washington Avenue
P.O. Box 300152
Montgomery, AL 36130-0152
(334) 242-7300
Edmund.LaCour@AlabamaAG.gov

Counsel for Amicus Curiae

OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: HB2002 written comment
Date: Wednesday, November 20, 2024 3:00:19 PM
Attachments: Julien HB2002 comment.docx.pdf

> You don't often get email from [redacted]. Learn why this is important

Hi there,

My coworker Luca let me know that you would be the appropriate person to send my written comment regarding HB2002. Let me know if I am incorrect! Otherwise, see the attached document and let me know if you need anything else.

Thanks,

Julien

Julien Fitzpatrick, BSN, RN (they/them)
Registered Triage Nurse
[redacted] | Portland, OR 97205 | 503-535-3860 | outsidein.org

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Julien Fitzpatrick, RN - Outside In, downtown clinic**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Julien Fitzpatrick and I am a registered nurse in Oregon. I am also a member of the local trans community in Portland, OR. I work at the Outside In primary care clinic downtown, where nearly 40% of our patients identify as transgender or gender diverse. Our clinic has remained a well-regarded and trusted healthcare source for the local trans community for decades.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, WPATH Standards of Care version 8. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage; Oregon is now a leader in providing care that is crucial for many transgender people, including electrolysis (hair removal) necessary for certain surgeries and patient safety, and facial affirmation surgeries that have been historically commonly denied. The HB2002 rulemaking process intent is not to debate the validity of gender affirming treatment as some may submit letters about in this public hearing who seek to dismantle gender affirming care access, it was to establish a clear definition for HB2002 that was passed by the legislature so that insurers understand expectations to be in compliance.

I have sat with patients as they sobbed in fear of their gender-affirming healthcare being taken away. I have held their hands as they cried in frustration and fear that they might never get the facial feminization surgery or tracheal shave that would not only allow

them to finally feel at home in their body, but also help to keep them safe in an increasingly transphobic world. I have assessed our folks for suicide risk and provided crisis resources in response to their despair when denied access to gender-affirming care more times than I can count.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002

- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

- Transparency for the patient if requested related to adverse benefit determinations

- Alignment with network adequacy standards

- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Establishing this rule will help me do my best possible job to take care of our patients because I will be able to say, yes, this procedure that you require is in fact covered by your insurance. So many of our patients are low-income and struggle to meet basic needs as it is, so they rely heavily on their health insurance to provide their medical needs. If a procedure or treatment isn't covered by insurance, they can't access it. Full stop.

We hear the phrase "gender-affirming care is life-saving care" a lot in my line of work. Most people assume that when we say this, we are referring to the risk of suicide in the trans population - the main concern is that if folks aren't able to access this care, their lives are at risk for this reason. What I've observed in my work is that it's much more than that - folks who are able to access the care they need to be at home living in their bodies are also much more likely to engage in other health care and take better care of themselves generally. Once their gender is in alignment, they start taking care of their other often long-neglected health needs - hypertension, diabetes, getting up-to-date on vaccinations. We may never know many trans folks we have lost to these and other

treatable or preventable health conditions. It’s not just about suicide risk - gender-affirming care is life-saving care for all these reasons as well.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Julien Fitzpatrick, BSN, RN

Registered Triage Nurse, Outside In Clinic

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Hayley Fitzsimmons [redacted]>
Sent: Tuesday, November 26, 2024 12:52 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Hayley Fitzsimmons
Portland, OR 97216-1442

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lexx Fluder [redacted] >
Sent: Saturday, November 23, 2024 7:07 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Lexx Fluder and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have trans friends who have greatly benefited from gender affirming care. They're able to live lives more true to themselves and it has benefitted their mental well-being greatly.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lexx Fluder
Portland, OR 97202-1927

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Caito Foster <[redacted]>
Sent: Tuesday, November 26, 2024 9:10 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Caito Foster
Portland, OR 97214-5934

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-Affirming Treatment Rules
Date: Sunday, November 24, 2024 10:09:47 AM

> You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment and firmly stand in opposition.

As a healthcare professional and mother, I believe in the upmost importance of informed consent and evidence based care.

I believe most Oregonians share these sentiments.

Adopting any guidelines from WPATH "Standards of Care" fails to meet these criteria. Gender-distressed children and adults deserve safe and effective healthcare.

Adopting them would prevent ethical medical practitioners from providing the best support to their patients by forcing them to adhere to unscientific and harmful ideological guidelines.

- WPATH-8 removed recommended age limits from their final publication at the last minute for fear of lawsuits
-WPATH-8 references the Eunich archives, and has members who are involved with this website that promotes engaging in pedophilic fantasies
- WPATH is a self appointed "expert" and allies silence any dissent from their ideological agenda and suppress studies that do not support their beliefs

Do you want to be held personally accountable for supporting the permanent sterilization of the autistic? For encouraging teens and young adults to mutilate their bodies because no therapist sat down and simply asked them compassionately "why?"

Other states are waking up to this.
Other counties have reversed course.

It is not too late to do what is right.

Karen Fowler, D.V.M.

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Quinn Francis [redacted] >
Sent: Saturday, November 23, 2024 11:57 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Quinn Francis and I am an Oregon resident and mental health counselor.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

As a mental health counselor, I support transgender Oregonians with their mental health concerns and know first hand how important gender affirming care is for psychological well-being. Every Oregonian deserves access to life-saving medical care, including gender-affirming care. Protecting access to these services is of utmost importance for public health and particularly to prevent increases in mental health concerns for transgender residents.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,

Quinn Francis
Portland, OR 97215-1983

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Erin Frazier-Maskiell [redacted] >
Sent: Monday, November 25, 2024 10:02 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Erin Frazier-Maskiell
Eugene, OR 97401-2721

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Robin Friedman [redacted]>
Sent: Monday, November 25, 2024 7:54 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Robin Friedman I am mental health therapiat/ LCSW.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

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- Transparency for the patient if requested related to adverse benefit determinations
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- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

I have many non-binary and transgender clients who need access to ongoing gender affirming care such as hormones, surgery, counseling, and mental health therapy.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Robin Friedman
Portland, OR 97202-2020

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Janet Frisella [redacted] >
Sent: Monday, November 25, 2024 1:39 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Janet Frisella and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

This language and including the world professional standards of trans health will especially help historically underserved communities within the transgender population, it is important to me that humans are treated with respect and dignity aligned with these world professional standards of trans health.
By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Janet Frisella
Williams, OR 97544-9507

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Chloe Frisella Kunst [redacted] >
Sent: Monday, November 25, 2024 1:51 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Chloe Frisella Kunst and I am an Oregon community member and health provider. I am trans myself and I also write letters for gender affirming care for many of my clients.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

When my clients have not been able to access gender affirming care it has greatly impacted their mental health sometimes resulting in suicidal ideation.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Chloe Frisella Kunst
Portland, OR 97218-3448

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Aimee Fritsch [redacted] >
Sent: Monday, November 25, 2024 9:36 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

Hello Lisa, Brooke, Karen, and the members of the committee, [UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Aimee Fritsch and I am a queer Oregonian.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I've had the gift of seeing the miracle of my trans friends finally having access to gender affirming healthcare, and it's an amazing thing. This rule will extend this life-saving healthcare to so many more people. The language in this rule will ensure that this care isn't left up to chance for others who will come after us.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
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- Transparency for the patient if requested related to adverse benefit determinations
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Growing up in Ontario, then living in Eugene and now Salem, I've seen how different parts of our state respond to queer and especially trans folks quite differently. I'm grateful for the clarity and lack of wiggle room that this wording creates. Unfortunately, some folks are looking for those loopholes, and this language is both firm and clear. And, as researcher Brene Brown frequently says "clear is kind". It's kind to providers who want to do the right thing and fear push back, and it's kind to transgender Oregonians who can count on their right to healthcare.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story, and all queer Oregonians when you finalize this draft into rule.

Thank you.

Sincerely,
Aimee Fritsch
Salem, OR 97301-4504

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Jarid Fryer [redacted] >
Sent: Tuesday, November 26, 2024 9:10 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

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WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Jarid Fryer
Portland, OR 97214-5943

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Shawn Furst [redacted]>
Sent: Monday, November 25, 2024 8:27 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Shawn Furst and I am a disabled Oregon resident and member of the LGBTQ+ community.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Healthcare coverage is life-saving to so many in my communities. Lack of educated, covered care has made many loved ones with complex needs home bound, preventing them from working and isolating them from their communities. Quick and easy treatment options will provide dignity and relief to so many people, allowing them to more fully participate in social, economic and civic life.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
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- Transparency for the patient if requested related to adverse benefit determinations
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Shawn Furst
Portland, OR 97212-4583

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule
Date: Wednesday, November 20, 2024 6:24:17 AM

You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules go way beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists. Ascovered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme CourtWPATH-8 is heavily influenced by a radical political agenda.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services,the proposed rules are completely silent on this issue. Further, no detransitioners were included in the advisory group that helped write the rules.

I appreciate your consideration of this matter.

Sincerely,

Sent from a Human Being.

Keith C. Fuselier

512.293.2506

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
10/30/2024 11:50 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2025 Gender-Affirming Treatment Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/19/2024
TIME: 11:00 AM - 12:00 PM
OFFICER: Brooke Hall

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm A, Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 599636230
SPECIAL INSTRUCTIONS:
Meeting ID: 267 195 468 800
Passcode: j3NgqJ

NEED FOR THE RULE(S)

House Bill 2002 (2023) prohibits a carrier offering a health benefit plan from denying or limiting coverage for medically necessary gender-affirming treatment that is prescribed in accordance with accepted standards of care. The bill also prohibits health benefit plans from applying cosmetic or blanket exclusions to medically necessary gender affirming treatment and establishes requirements for notices of adverse benefit determinations and network adequacy.

HB 2002 (2023) requires the Department of Consumer and Business Services (DCBS) to adopt rules to implement these provisions. DCBS convened a Rulemaking Advisory Committee (RAC) which met on Dec. 12, 2023, Jan. 25, Mar. 21, Apr.

25, Jun. 11, Jul. 18, and Aug. 7, 2024. The RAC included insurers, health care providers, consumer and patient advocates. Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

House Bill 2002 (2023)
ORS 743A.325 (4)(b)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

A Rulemaking Advisory Committee was consulted regarding this equity statement. This rule implements HB 2002, which increases access to gender affirming care. This rule is not anticipated to have any disparate negative impact on any particular demographic of Oregon consumers.

This rule is expected to have a positive impact on equity in the state by increasing access to healthcare services for underserved individuals, particularly for transgender and non-binary individuals, resulting in reduced barriers to necessary medical treatments, enhanced affordability, and improvements in behavioral health and overall well-being for those receiving gender-affirming care.

FISCAL AND ECONOMIC IMPACT:

The rule primarily affects health insurance carriers issuing health benefit plans. The rule mandates that health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.

This training comes with a cost. Based on the information available to the department, the training sessions facilitated by WPATH are priced based on contractual arrangements that depend on factors including the number of participants. DCBS does not have specific information about the number of insurance company employees that will take the training as a result of this rule, so it is not possible to estimate the total cost to affected industry entities. However, since the training can be made available to an insurer's existing reviewers, the training requirement is likely less financially burdensome than alternative approaches that could require hiring or contracting with different or additional reviewers.

The rule will have indirect positive effects on health care providers, including small businesses, to the extent that it requires health insurance carriers to reimburse for services that may not previously have been covered, but the extent of this impact is impossible to estimate from the information available to DCBS.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not (or does not have) a fiscal or

economic impact on state agencies, local government units, nor the public.

(2)(a) Based on financial filings made to the Division of Financial Regulation (DFR), no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule will have indirect effects on health care providers, including small businesses, but DCBS does not have access to information to determine the number of small provider organizations that would be affected.

(2)(b) The rule primarily affects health insurance carriers. It does not require additional reporting or recordkeeping activities. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

(2)(c) The rule primarily affects health insurance carriers. Based on the information available to the department, it does not require additional professional services, equipment or supplies. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rule primarily applies to health insurance carriers. Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule has indirect impacts on health care providers, some of whom are small businesses.

Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers. The department also received written and oral public comment during the RAC process from small business health care provider representatives.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-053-0441

RULE SUMMARY: A carrier offering a health benefit plan may not deny or limit coverage under the plan, including, but not limited to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and
(b) Prescribed in accordance with accepted standards of care.

CHANGES TO RULE:

836-053-0441
Gender-Affirming Treatment
(1) For purposes of this rule:¶
(a) "Gender-affirming treatment" has the meaning given to that term under ORS 743A.325; and¶
(b) "Accepted standards of care" includes, at a minimum, the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (WPATH-8). ¶
(2) A carrier offering a health benefit plan may not deny or limit coverage under the plan including, but not limited

to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost-sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:¶
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and¶
(b) Prescribed in accordance with accepted standards of care.¶
(3) Carriers may use utilization review practices to verify adherence to the accepted standards of care described in subsection (2)(b), provided that such practices are consistent with the requirements of this rule, OAR 836-053-1200, and all other applicable provisions of Oregon law. Utilization review practices shall be implemented in a manner that does not unreasonably limit or delay access to care.¶
(4) A carrier offering a health benefit plan may not:¶
(a) Apply a categorical cosmetic or blanket exclusion to medically necessary gender-affirming treatment; or¶
(b) Exclude, as a cosmetic service, a medically necessary procedure prescribed by a physical or behavioral health care provider as gender-affirming treatment, including but not limited to: ¶
(A) Tracheal shave;¶
(B) Hair electrolysis; ¶
(C) Facial feminization surgery or other facial gender-affirming treatment; ¶
(D) Revisions to prior forms of gender-affirming treatment; or¶
(E) Any combination of gender-affirming treatment procedures.¶
(5) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must ensure that the adverse benefit determination is reviewed and approved in accordance with the following requirements: ¶
(a) The adverse benefit determination is reviewed by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.¶
(b) To demonstrate experience the reviewing provider must:¶
(A) Meet the criteria for external medical review found in OAR 836-053-1325(6)(b)(A-C);¶
(B) Have experience utilizing the WPATH-8; and¶
(C) Have completed the WPATH SOC-8 Health Plan Providers training program or an equivalent training program.¶
(c) This subsection (5) does not apply to an adverse benefit determination that only involves the application of cost-sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment. ¶
(6) In the event of an adverse benefit determination that denies or limits coverage for gender-affirming treatment, the carrier must meet all the requirements in:¶
(a) ORS 743B.250, and if requested under ORS 743B.250(2)(h)(B), disclosure of the identity of the physical or behavioral health care provider who reviewed the determination, which at a minimum includes information to demonstrate experience prescribing or delivering gender-affirming treatment:¶
(A) The provider's job title and specific role in the review process; and¶
(B) The provider's specialty, board certification status, and any other relevant qualifications that affirm their experience in gender-affirming treatment.¶
(b) OAR 836-053-1030; and¶
(c) OAR 836-053-1100. ¶
(7) Carriers offering health benefit plans shall:¶
(a) Satisfy any network adequacy standards under ORS 743B.505 related to gender-affirming treatment providers; and¶
(b)(A) Contract with a network of gender-affirming treatment providers that is sufficient in numbers and geographic locations to ensure that gender-affirming treatment services are accessible to all enrollees without unreasonable delay; or¶
(B) Ensure that all enrollees have geographical access without unreasonable delay to out-of-network gender-affirming treatment services with cost-sharing or other out-of-pocket costs for the services no greater than the cost-sharing or other out-of-pocket costs for the services when furnished by an in-network provider, and meet all the requirements in:¶
(i) OAR 836-053-1030;¶
(ii) OAR 836-053-1035; and¶
(iii) OAR 836-053-1408.
Statutory/Other Authority: ORS 731.244, ORS 743A.325
Statutes/Other Implemented: ORS 743A.325

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Bill Title:	Relating to health; and declaring an emergency.
Catchline/Summary:	Modifies provisions relating to reproductive health rights.
Chapter Number:	Chapter 228
Fiscal Impact:	Fiscal Impact Issued
Revenue Impact:	No Revenue Impact
Measure Analysis:	Staff Measure Summary / Impact Statements (/liz/2023R1/Measures/Analysis/HB2002)
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Standards of Care Version 8

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SOC8

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Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for care of transgender minors, according to newly unsealed court documents.

Age minimums, officials feared, could fuel growing political opposition to such treatments.

Email excerpts from members of the World Professional Association for Transgender Health recount how staff for Adm. Rachel Levine, assistant secretary for health at the Department of Health and Human Services and herself a transgender woman, urged them to drop the proposed limits from the group's guidelines and apparently succeeded.

If and when teenagers should be allowed to undergo transgender treatments and surgeries has become a raging debate within the political world. Opponents say teenagers are too young to make such decisions, but supporters including an array of medical experts posit that young people with gender dysphoria face depression and worsening distress if their issues go unaddressed.

United States | The WPATH files

Leaked discussions reveal uncertainty about transgender care

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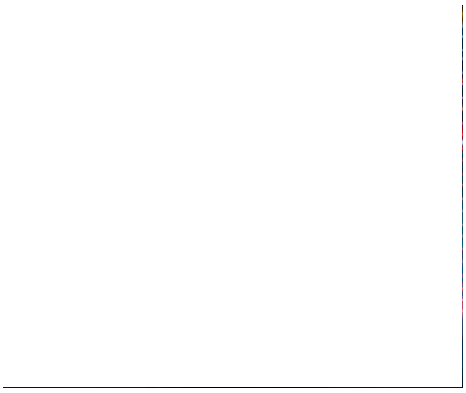

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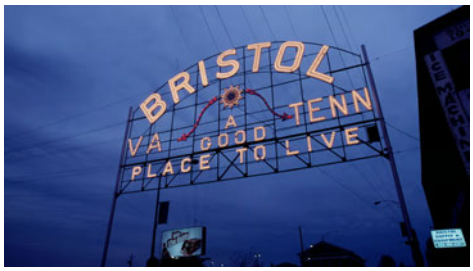

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Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

BMJ 2024; 387 doi: https://doi.org/10.1136/bmj.q2227 (Published 30 October 2024) Cite this as: BMJ 2024;387:q2227

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Jennifer Block, freelance journalist
writingblock@protonmail.com

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1,2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2,3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4,5,6,7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in

January, but it provided no details or references regarding the “evidence synthesis” that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO’s statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. “While we welcome the commitment to upholding human rights,” she tells *The BMJ*, “liberalised access to healthcare interventions that might in fact have harmful effects is not actually in support of anyone’s human rights.”

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that “proper evidence reviews have been commissioned to address key questions.” After the June revelations regarding WPATH’s executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the “strong overlap” between the WHO guideline group and WPATH “will have direct negative implications for the credibility of WHO’s own process.” WHO didn’t respond directly to either group.

Reviews “completed and submitted” but not approved

WPATH’s updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having “followed the most rigorous protocol in the world . . . a long and painstaking scientific review process.”[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an “approval process” over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team “completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters,” said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn’t go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13][14] “We had hoped to publish more of those reviews but for a few reasons have not done so,” wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting “reports of reviews (dozens!)” to WPATH, but she added that “we have been having issues with this sponsor trying to restrict our ability to publish.”

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*’s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new “policy and procedures,” which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH’s board. Only then would the Johns Hopkins researchers be given a “green light to be published.”

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, “It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.”

The approval process was to be overseen by the organisation’s president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO’s guideline development group for transgender health and remain members. Neither responded to *The BMJ*’s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its “consensus based” methodology, offering instead to downgrade those recommendations into weaker “suggestions.” But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn’t made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the “evidence based standard of care for the evaluation and treatment of trans individuals.” The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO’s guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. “If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area,” she says, “it may harm WHO’s reputation in other areas of medicine, where its clinical guidance is sorely needed.”

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was “aware of allegations and media reports regarding WPATH” but “does not comment on legal issues involving external organisations.” WHO conducts “careful reviews on conflicts of interest,” it said, and “GDG [guideline development group] members act in their own expert capacity.” Regarding evidence reviews for hormonal treatments, WHO said only that “members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence.”

In late August it provided more detail, telling *The BMJ* that “systematic reviews have been commissioned” to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn’t been made explicit, particularly given all the calls for more transparency. “Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence,” says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn’t locate a public link for the final commission, titled “Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people.”**1819202122232425** The registration details indicate that reviews were started as early as January 2023 and that some commenced months earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, “They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don’t specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition.” Abbruzzese adds, “There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications.”

Ryan also expresses concern that the systematic reviews “fail to examine the impacts” of legal recognition of self-identified gender—which WHO has defined as a health measure—“on any group other than trans and gender diverse people.” Abbruzzese concurs, saying that “research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women’s safety and values and preferences must be a key part of the research.”

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it’s likely to be submitted for inclusion on WHO’s essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO’s Expert Committee that evaluates essential medicine applications, and it’s “likely” to be approved. “Once it goes on the essential medicines list, that obliges governments to supply the drug,” he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn’t bothered by this. “I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them,” he says. While there may be only low quality evidence of benefit, adds Guyatt, “it seems to me a very value and preference sensitive decision.”

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as “the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events.”

“An untenable position”

Robinson of Johns Hopkins pushed back on WPATH’s demands, apparently many times. She wrote to WPATH, “We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018.”

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH’s SOC8 publication process and is now legal evidence, a chapter author wrote, “Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits.” Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as “insufficient evidence” or “limited data”—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that “we found little to no evidence about children and adolescents.” WHO came to a similar conclusion this year, calling the evidence “limited and variable.”**3** Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, “We were told by WPATH leadership that Johns Hopkins couldn’t do a review for the child or

adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

- Provenance: Commissioned; externally peer reviewed.

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In the Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

JONATHAN SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, *et al.*,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

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Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Laurel Fuson-Lang [redacted] >
Sent: Tuesday, November 26, 2024 10:22 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Laurel Fuson-Lang and I am an Oregon licensed psychologist. I currently practice at Portland Mental Health & Wellness, where we serve transgender and nonbinary individuals at a much higher rate than the general population (constituting half of my caseload at present). We provide therapy and do assessment for gender affirming surgeries.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

As a psychologist working at a practice where we regularly provide services to transgender and nonbinary individuals, I have observed firsthand the impact of barrier to accessing gender affirming care. I have had a patient forgo needed treatment due to limitations placed by insurers and the psychological impact of this is devastating and long-lasting.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Given the current increase in restrictions on gender affirming care in other areas of the United States at present, I believe that it is critical to clarify and uphold the proposed rule to the full extent possible. This will ensure that the work I and my colleagues are doing is not to place a bandaid on the distress caused by inadequate care, but to support individuals to

truly find wellbeing by having access to the services they need. Gender affirming care is life-saving care. Recently, a trans patient of mine expressed fears about losing access to needed hormone replacement treatment and stated "I would die" if they were unable to access this care. History has shown this to be the case, as the suicide rates amongst trans individuals are notably higher than the general population. Please do what you can to ensure that we are able to be effective in our work.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Laurel Fuson-Lang
Oregon City, OR 97045-1773

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Hayden Gabriel <[redacted]
Sent: Tuesday, November 26, 2024 10:47 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name Hayden Jay Gabriel and I am an Oregon community member working for a mental health nonprofit. Many of our staff members and participants alike are trans and gender non-comforming. Access to Gender Affirming Care keeps us healthy, mentally and physically well. Inconsistencies and interruptions in medical care or medications can cause significant trauma and harm to the community.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:
- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Hayden Gabriel

Portland, OR 97221-1923

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Rorynn Gaillard <[redacted]>
Sent: Tuesday, November 26, 2024 1:09 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Rorynn and I am an Oregon community member and advocate for gender affirming care.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have personally known multiple people, many of whom are cisgender, who have been denied medical benefits for their necessary gender affirming care. This greatly impacts their health and well-being, as well as makes it more difficult for them to participate in our workplaces and economies.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

With increasing attacks on healthcare for all genders, but particularly for our transgender siblings, it is vitally imp that Oregon and other states step up to protect our loved ones, and especially to protect those most likely to face violence without proper care, such as our Black Trans sisters.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Rorynn Gaillard
Portland, OR 97211-7202

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Ada Gallagher <[redacted]>
Sent: Monday, November 25, 2024 3:51 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is ada Gallagher and I am an Oregon advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Ada Gallagher
Portland, OR 97266-1561

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Carolyn Gallagher <[redacted]>
Sent: Monday, November 25, 2024 3:00 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Carolyn Gallagher and I am an Oregon community member and mother of a Trans Woman

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My trans daughter won the 400m state championship last year and received so much hate from adults world wide. We were fixed and lived in fear for months. She fell in love with track immediately and just wants to run as her true self. She deserves, all trans people, deserve to live as their true selves.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Over 700 people took their lives after the 2024 election. Taking away trans, gender affirming care will cause so many more deaths. Trans people have zero effect on the people around them. They simply want to live.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Carolyn Gallagher
Portland, OR 97266-1561

From: [redacted]
To: WINKEL Karen J * DCBS; EMERSON Lisa * DCBS; HALL Brooke M * DCBS
Subject: Testimony Re. HB 2002 Rule Making
Date: Tuesday, November 26, 2024 3:50:40 PM
Attachments: image001.gif
image002.jpg
image003.png
ACLU_OR_Testimony HB 2002 Rule Making Novemebr 26, 2024.pdf

> Some people who received this message don't often get email from [redacted]. Learn why this is important

Hello,

I hope you are doing well. I have attached ACLU of OR's testimony in support of the proposed Rule Making from the November 19th, 2024 meeting. Please let us know if you have any questions.

Warmly,

Mariana Garcia Medina
Pronouns: she, her/ ella
Senior Policy Associate
American Civil Liberties Union of Oregon
[redacted] Portland, OR 97240
Cell: 503:523.9613 | [redacted]
aclu-or.org

The ACLU of Oregon is ready to resist the anti-democratic and anti-freedom attacks of a second Trump presidency. Explore opportunities to get involved and renew your membership today.

November 25, 2024

Gender Affirming Treatment Rules Advisory Committee
Department of Consumer and Business Services
900 Court St. NE
Salem, OR 97301

RE: Testimony in Support of Proposed Rulemaking

Dear Gender Affirming Treatment Rules Advisory Committee,

Thank you for the opportunity to provide testimony on behalf of the American Civil Liberties Union of Oregon (ACLU of Oregon). The ACLU of Oregon is a nonpartisan, nonprofit organization dedicated to preserving and enhancing civil liberties and civil rights, with more than 37,000 supporters statewide. **We strongly support the proposed rulemaking for HB 2002, presented on November 19th, 2024, for the Department of Consumer and Business Services Health Benefit Plans on Gender Affirming Care, that clarifies what is expected of insurance carriers to be in compliance with the HB 2002.**

Reproductive and gender-affirming care are essential healthcare services that all Oregonians deserve access to as part of our constitutional liberties. In order to protect our community's access to healthcare and autonomy to make decisions about their bodies, it is important we remove barriers to trans healthcare and ensure that trans people have meaningful, comprehensive access to transition-related care without burdensome or unnecessary preconditions and limitations. This is why the ACLU of Oregon proudly supported HB 2002.

The Gender Affirming Treatment Rules Advisory Committee has worked for over a year to craft the current rulemaking that clarifies what is expected of insurance carriers to be in compliance with HB 2002. The proposed rulemaking defines the standard of care that insurers must follow to determine coverage and provide necessary health care to our trans community in Oregon. The standard of care aligns with the best health care practices from the World Professional Association for Transgender Health: the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, (WPATH-8).

We thank you for your time and dedication to the rulemaking process and urge you to pass the current proposed rules on the Department of Consumer and Business Services Health Benefit Plans on Gender Affirming Care.

Respectfully,

Mariana Garcia Medina, Senior Policy Associate

Email: [redacted]

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender Treatment Rule
Date: Monday, November 18, 2024 8:43:56 PM

> You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment which go well beyond what the legislature authorized last year in HB2002 and do not explicitly include coverage for the specialized care needed by those who revert to identifying as their sex; often referred to as detransitioners.

While HB2002 requires insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go far beyond the legislative mandate. The Commissioner proposes defining the only "accepted standard of care" as adherence to WPATH-8, a controversial document which ignored & silenced systemic reviews ordered by its own drafters when those evidence-based reviews did not produce the desired results.

Also interesting in HB2002 is the provision that "reproductive healthcare" does not include the voluntary sterilization of a female under the age of 15, yet what is not acknowledged in later passages related to gender affirming care is the likelihood of sterility with these treatments. WPATH-8 removes all age restrictions, meaning that a female who identifies as male, subjected to puberty blockers at Tanner stage 2 (usually under the age of 15) followed by cross-sex hormones, is most likely rendered sterile.

As covered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court WPATH-8 is NOT a standard of care, merely "guidelines" heavily influenced by a radical agenda.

According to the new rules, WPATH is both the arbiter of the treatments offered, with no alternatives to gender distress other than transition, as well as the required training body. This offers no alternative treatment views to physicians or the ability to exercise their clinical expertise. There are no areas in medicine where alternative, less invasive and less expensive treatments are not offered as care, especially in areas where the diagnosis is so indeterminant of outcome.

Neither the Insurance Commissioner nor his staff possess medical expertise or licensure. Their agency is charged with regulating insurance companies, financial institutions not healthcare entities. No licensed health care professionals or detransitioners were included on the advisory committee that helped draft these rules – rules that now define a clinical standard of care for the practice of medicine regarding individuals experiencing gender distress. The insurance commission should not set a legally binding precedent for care in such a fast moving, controversial, low evidence-based area of healthcare.

I appreciate your consideration of this matter.

Sincerely,

Dorothy Garland

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
10/30/2024 11:50 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2025 Gender-Affirming Treatment Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/19/2024
TIME: 11:00 AM - 12:00 PM
OFFICER: Brooke Hall

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm A, Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 599636230
SPECIAL INSTRUCTIONS:
Meeting ID: 267 195 468 800
Passcode: j3NgqJ

NEED FOR THE RULE(S)

House Bill 2002 (2023) prohibits a carrier offering a health benefit plan from denying or limiting coverage for medically necessary gender-affirming treatment that is prescribed in accordance with accepted standards of care. The bill also prohibits health benefit plans from applying cosmetic or blanket exclusions to medically necessary gender affirming treatment and establishes requirements for notices of adverse benefit determinations and network adequacy.

HB 2002 (2023) requires the Department of Consumer and Business Services (DCBS) to adopt rules to implement these provisions. DCBS convened a Rulemaking Advisory Committee (RAC) which met on Dec. 12, 2023, Jan. 25, Mar. 21, Apr.

25, Jun. 11, Jul. 18, and Aug. 7, 2024. The RAC included insurers, health care providers, consumer and patient advocates. Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

House Bill 2002 (2023)
ORS 743A.325 (4)(b)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

A Rulemaking Advisory Committee was consulted regarding this equity statement. This rule implements HB 2002, which increases access to gender affirming care. This rule is not anticipated to have any disparate negative impact on any particular demographic of Oregon consumers.

This rule is expected to have a positive impact on equity in the state by increasing access to healthcare services for underserved individuals, particularly for transgender and non-binary individuals, resulting in reduced barriers to necessary medical treatments, enhanced affordability, and improvements in behavioral health and overall well-being for those receiving gender-affirming care.

FISCAL AND ECONOMIC IMPACT:

The rule primarily affects health insurance carriers issuing health benefit plans. The rule mandates that health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.

This training comes with a cost. Based on the information available to the department, the training sessions facilitated by WPATH are priced based on contractual arrangements that depend on factors including the number of participants. DCBS does not have specific information about the number of insurance company employees that will take the training as a result of this rule, so it is not possible to estimate the total cost to affected industry entities. However, since the training can be made available to an insurer's existing reviewers, the training requirement is likely less financially burdensome than alternative approaches that could require hiring or contracting with different or additional reviewers.

The rule will have indirect positive effects on health care providers, including small businesses, to the extent that it requires health insurance carriers to reimburse for services that may not previously have been covered, but the extent of this impact is impossible to estimate from the information available to DCBS.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not (or does not have) a fiscal or

economic impact on state agencies, local government units, nor the public.

(2)(a) Based on financial filings made to the Division of Financial Regulation (DFR), no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule will have indirect effects on health care providers, including small businesses, but DCBS does not have access to information to determine the number of small provider organizations that would be affected.

(2)(b) The rule primarily affects health insurance carriers. It does not require additional reporting or recordkeeping activities. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

(2)(c) The rule primarily affects health insurance carriers. Based on the information available to the department, it does not require additional professional services, equipment or supplies. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rule primarily applies to health insurance carriers. Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule has indirect impacts on health care providers, some of whom are small businesses.

Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers. The department also received written and oral public comment during the RAC process from small business health care provider representatives.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-053-0441

RULE SUMMARY: A carrier offering a health benefit plan may not deny or limit coverage under the plan, including, but not limited to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and
(b) Prescribed in accordance with accepted standards of care.

CHANGES TO RULE:

836-053-0441
Gender-Affirming Treatment
(1) For purposes of this rule:¶
(a) "Gender-affirming treatment" has the meaning given to that term under ORS 743A.325; and¶
(b) "Accepted standards of care" includes, at a minimum, the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (WPATH-8). ¶
(2) A carrier offering a health benefit plan may not deny or limit coverage under the plan including, but not limited

to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost-sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:¶
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and¶
(b) Prescribed in accordance with accepted standards of care.¶
(3) Carriers may use utilization review practices to verify adherence to the accepted standards of care described in subsection (2)(b), provided that such practices are consistent with the requirements of this rule, OAR 836-053-1200, and all other applicable provisions of Oregon law. Utilization review practices shall be implemented in a manner that does not unreasonably limit or delay access to care.¶
(4) A carrier offering a health benefit plan may not:¶
(a) Apply a categorical cosmetic or blanket exclusion to medically necessary gender-affirming treatment; or¶
(b) Exclude, as a cosmetic service, a medically necessary procedure prescribed by a physical or behavioral health care provider as gender-affirming treatment, including but not limited to: ¶
(A) Tracheal shave;¶
(B) Hair electrolysis; ¶
(C) Facial feminization surgery or other facial gender-affirming treatment; ¶
(D) Revisions to prior forms of gender-affirming treatment; or¶
(E) Any combination of gender-affirming treatment procedures.¶
(5) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must ensure that the adverse benefit determination is reviewed and approved in accordance with the following requirements: ¶
(a) The adverse benefit determination is reviewed by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.¶
(b) To demonstrate experience the reviewing provider must:¶
(A) Meet the criteria for external medical review found in OAR 836-053-1325(6)(b)(A-C);¶
(B) Have experience utilizing the WPATH-8; and¶
(C) Have completed the WPATH SOC-8 Health Plan Providers training program or an equivalent training program.¶
(c) This subsection (5) does not apply to an adverse benefit determination that only involves the application of cost-sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment. ¶
(6) In the event of an adverse benefit determination that denies or limits coverage for gender-affirming treatment, the carrier must meet all the requirements in:¶
(a) ORS 743B.250, and if requested under ORS 743B.250(2)(h)(B), disclosure of the identity of the physical or behavioral health care provider who reviewed the determination, which at a minimum includes information to demonstrate experience prescribing or delivering gender-affirming treatment:¶
(A) The provider's job title and specific role in the review process; and¶
(B) The provider's specialty, board certification status, and any other relevant qualifications that affirm their experience in gender-affirming treatment.¶
(b) OAR 836-053-1030; and¶
(c) OAR 836-053-1100. ¶
(7) Carriers offering health benefit plans shall:¶
(a) Satisfy any network adequacy standards under ORS 743B.505 related to gender-affirming treatment providers; and¶
(b)(A) Contract with a network of gender-affirming treatment providers that is sufficient in numbers and geographic locations to ensure that gender-affirming treatment services are accessible to all enrollees without unreasonable delay; or¶
(B) Ensure that all enrollees have geographical access without unreasonable delay to out-of-network gender-affirming treatment services with cost-sharing or other out-of-pocket costs for the services no greater than the cost-sharing or other out-of-pocket costs for the services when furnished by an in-network provider, and meet all the requirements in:¶
(i) OAR 836-053-1030;¶
(ii) OAR 836-053-1035; and¶
(iii) OAR 836-053-1408.
Statutory/Other Authority: ORS 731.244, ORS 743A.325
Statutes/Other Implemented: ORS 743A.325

2023 Regular Session

HB 2002 Enrolled
(/liz/2023R1/Downloads/MeasureDocument/HB2002)

Overview

At the request of:

Chief Sponsors:	Representative Valderrama, (https://www.oregonlegislature.gov/valderrama) Nelson, (https://www.oregonlegislature.gov/nelson) Senator Lieber, (https://www.oregonlegislature.gc Steiner
Regular Sponsors:	Representative Andersen, (https://www.oregonlegislature.gov/andersen) Bowman, (https://www.oregonlegislature.gov/bowman) Bynum, (https://www.oregonlegislature.gov/byr Fahey, (https://www.oregonlegislature.gov/fahey) Gamba, (https://www.oregonlegislature.gov Gomberg, (https://www.oregonlegislature.gov/gomberg) Grayber, (https://www.oregonlegislature.gov/grayber) Hartman, (https://www.oregonlegislature.gov/ha (https://www.oregonlegislature.gov/helm) Holvey, (https://www.oregonlegislature.gov/holvey) (https://www.oregonlegislature.gov/hudson) Kropf, (https://www.oregonlegislature.gov/kropf) (https://www.oregonlegislature.gov/marsh) McLain, (https://www.oregonlegislature.gov/mclai (https://www.oregonlegislature.gov/nguyend) Nguyen H, (https://www.oregonlegislature.gov/ (https://www.oregonlegislature.gov/nosse) Pham H, (https://www.oregonlegislature.gov/phan (https://www.oregonlegislature.gov/pham) Reynolds, (https://www.oregonlegislature.gov/reyr (https://www.oregonlegislature.gov/ruiz) Sosa, (https://www.oregonlegislature.gov/sosa) Tran (https://www.oregonlegislature.gov/tran) Walters, (https://www.oregonlegislature.gov/walters Campos, (https://www.oregonlegislature.gov/campos) Dembrow, (https://www.oregonlegislature.gov/dembrow) Frederick, (https://www.oregonlegislature.gov/ Gelser Blouin, (https://www.oregonlegislature.gov/gelser) Golden, (https://www.oregonlegislature.gov/golden) Gorsek, (https://www.oregonlegislature.gov/gorse (https://www.oregonlegislature.gov/jama) Manning Jr, (https://www.oregonlegislature.gov/Ma (https://www.oregonlegislature.gov/meek) Patterson, (https://www.oregonlegislature.gov/patt Prozanski, (https://www.oregonlegislature.gov/prozanski) Sollman, (https://www.oregonlegislature.gov/sollman) Taylor, (https://www.oregonlegislature.gov/taylor (https://www.oregonlegislature.gov/wagner) Woods (https://www.oregonlegislature.gov/wood
Bill Title:	Relating to health; and declaring an emergency.
Catchline/Summary:	Modifies provisions relating to reproductive health rights.
Chapter Number:	Chapter 228
Fiscal Impact:	Fiscal Impact Issued
Revenue Impact:	No Revenue Impact
Measure Analysis:	Staff Measure Summary / Impact Statements (/liz/2023R1/Measures/Analysis/HB2002)
Current Location:	Chapter Number Assigned

Current Committee: ()

Current Subcommittee:

Subsequent Referral(s):

Potential Conflicts of Interest/Vote Explanations: Potential Conflicts of Interest/Vote Explanation Documents (https://www.oregonlegislature.gov/pcive/Forms/Display.aspx?View={F16B1F7B-33C4-4EA7-9D3022EE155C}&FilterField1=Session&FilterValue1=2023R1&FilterField2=Measure&Filter\

Measure History ❯

Scheduled Events ❯

Standards of Care Version 8

VIEW THE SOC8 HERE (OPEN ACCESS)

SOC8

SOC8 publication is complete. Please follow the link below to view the document.

As new translations become available, we will add to this page. Currently listed are: Bosnian, Czech, Croatian, French, Georgian, Italian, Korean, Mandarin, Montenegrin, Norwegian, Portuguese, Spanish, Thai, and Ukrainian.

VIEW SOC8 CHAPTERS

VIEW SOC8 TRANSLATION PAGE

History and Purpose

The field of transgender healthcare is a rapidly evolving interdisciplinary field. The last few years have seen a globally unprecedented increase and visibility of transgender and gender diverse people seeking support . . .

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CHAIRS & LEAD EVIDENCE TEAM

Establishing the SOC8 Revision Committee

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select

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Methodology for the Development of SOC8

Following the publication of the SOC8, in the future, unless there is a major need to adapt the entire document, small adaptations/addendums can take place, if/when new data is available that will affect specific recommendations . . .

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Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show

Newly released emails from an influential group issuing transgender medical guidelines indicate that U.S. health officials lobbied to remove age minimums for surgery in minors because of concerns over political fallout.

Listen to this article · 8:53 min Learn more

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for care of transgender minors, according to newly unsealed court documents.

Age minimums, officials feared, could fuel growing political opposition to such treatments.

Email excerpts from members of the World Professional Association for Transgender Health recount how staff for Adm. Rachel Levine, assistant secretary for health at the Department of Health and Human Services and herself a transgender woman, urged them to drop the proposed limits from the group's guidelines and apparently succeeded.

If and when teenagers should be allowed to undergo transgender treatments and surgeries has become a raging debate within the political world. Opponents say teenagers are too young to make such decisions, but supporters including an array of medical experts posit that young people with gender dysphoria face depression and worsening distress if their issues go unaddressed.

United States | The WPATH files

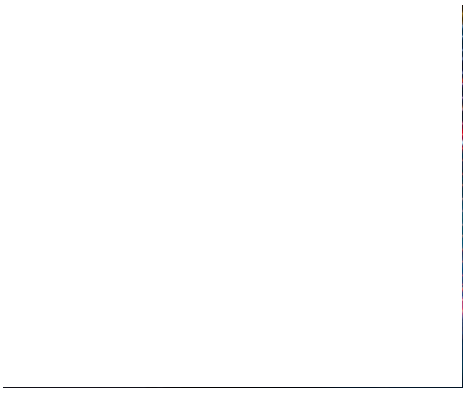
Leaked discussions reveal uncertainty about transgender care

The files shed light on a controversial area of medicine that has largely retreated into the shadows

ILLUSTRATION: NATHALIE LEES

Mar 5th 2024 | WASHINGTON, DC

FEW AREAS of medicine arouse as strong emotions in America as transgender care. The publication this



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Health care | United States

United States
March 9th 2024

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→ A private company will send your ashes to the moon

→ **Leaked discussions reveal uncertainty about transgender care**

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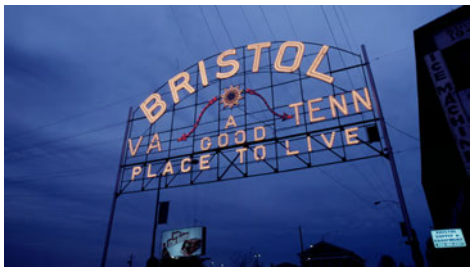

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Published since September 1843 to take part in *"a severe contest between intelligence, which presses forward, and an unworthy, timid ignorance*

obstructing our progress."

Intended for healthcare professionals

Feature BMJ Investigation

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

BMJ 2024; 387 doi: https://doi.org/10.1136/bmj.q2227 (Published 30 October 2024) Cite this as: BMJ 2024;387:q2227

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Jennifer Block, freelance journalist
writingblock@protonmail.com

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1,2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2,3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4,5,6,7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in

January, but it provided no details or references regarding the “evidence synthesis” that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO’s statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. “While we welcome the commitment to upholding human rights,” she tells *The BMJ*, “liberalised access to healthcare interventions that might in fact have harmful effects is not actually in support of anyone’s human rights.”

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that “proper evidence reviews have been commissioned to address key questions.” After the June revelations regarding WPATH’s executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the “strong overlap” between the WHO guideline group and WPATH “will have direct negative implications for the credibility of WHO’s own process.” WHO didn’t respond directly to either group.

Reviews “completed and submitted” but not approved

WPATH’s updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having “followed the most rigorous protocol in the world . . . a long and painstaking scientific review process.”[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an “approval process” over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team “completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters,” said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn’t go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13][14] “We had hoped to publish more of those reviews but for a few reasons have not done so,” wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting “reports of reviews (dozens!)” to WPATH, but she added that “we have been having issues with this sponsor trying to restrict our ability to publish.”

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*’s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new “policy and procedures,” which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH’s board. Only then would the Johns Hopkins researchers be given a “green light to be published.”

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, “It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.”

The approval process was to be overseen by the organisation’s president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO’s guideline development group for transgender health and remain members. Neither responded to *The BMJ*’s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its “consensus based” methodology, offering instead to downgrade those recommendations into weaker “suggestions.” But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn’t made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the “evidence based standard of care for the evaluation and treatment of trans individuals.” The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO’s guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. “If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area,” she says, “it may harm WHO’s reputation in other areas of medicine, where its clinical guidance is sorely needed.”

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was “aware of allegations and media reports regarding WPATH” but “does not comment on legal issues involving external organisations.” WHO conducts “careful reviews on conflicts of interest,” it said, and “GDG [guideline development group] members act in their own expert capacity.” Regarding evidence reviews for hormonal treatments, WHO said only that “members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence.”

In late August it provided more detail, telling *The BMJ* that “systematic reviews have been commissioned” to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn’t been made explicit, particularly given all the calls for more transparency. “Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence,” says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn’t locate a public link for the final commission, titled “Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people.”**1819202122232425** The registration details indicate that reviews were started as early as January 2023 and that some commenced months earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, “They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don’t specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition.” Abbruzzese adds, “There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications.”

Ryan also expresses concern that the systematic reviews “fail to examine the impacts” of legal recognition of self-identified gender—which WHO has defined as a health measure—“on any group other than trans and gender diverse people.” Abbruzzese concurs, saying that “research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women’s safety and values and preferences must be a key part of the research.”

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it’s likely to be submitted for inclusion on WHO’s essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO’s Expert Committee that evaluates essential medicine applications, and it’s “likely” to be approved. “Once it goes on the essential medicines list, that obliges governments to supply the drug,” he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn’t bothered by this. “I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them,” he says. While there may be only low quality evidence of benefit, adds Guyatt, “it seems to me a very value and preference sensitive decision.”

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as “the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events.”

“An untenable position”

Robinson of Johns Hopkins pushed back on WPATH’s demands, apparently many times. She wrote to WPATH, “We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018.”

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH’s SOC8 publication process and is now legal evidence, a chapter author wrote, “Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits.” Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as “insufficient evidence” or “limited data”—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that “we found little to no evidence about children and adolescents.” WHO came to a similar conclusion this year, calling the evidence “limited and variable.”**3** Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, “We were told by WPATH leadership that Johns Hopkins couldn’t do a review for the child or

adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

- Provenance: Commissioned; externally peer reviewed.

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Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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Exhibit 180 to Defendants' Motion for Summary Judgment (redacted), *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 700-9, https://www.alabamaag.gov/boe-v-marshall/ 13, 15, 42

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Exhibit 182 to Defendants' Motion for Summary Judgment (redacted), *Boe v. Marshall*, 2:22-cv-184, Doc. 700-11, https://www.alabamaag.gov/boe-v-marshall/ 7, 12, 29, 30, 35

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INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

* * *

Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

Steve Marshall
Attorney General
Edmund G. LaCour Jr.
Solicitor General
Counsel of Record
A. Barrett Bowdre
Principal Deputy Solicitor General
STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL
501 Washington Avenue
P.O. Box 300152
Montgomery, AL 36130-0152
(334) 242-7300
Edmund.LaCour@AlabamaAG.gov

Counsel for Amicus Curiae

OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Thaeus Geier [redacted]>
Sent: Tuesday, November 26, 2024 1:14 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Thaeus Geier and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I and many people in my life would lose hope for control of our lives without the ability to have the bodies that reflect ourselves. Being trapped in a form or state that causes stress over an uninvolved individual's personal belief is dehumanising and cruel.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,

Thaeus Geier
Portland, OR 97229-3503

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender Treatment Rule
Date: Monday, November 25, 2024 1:07:53 PM
Attachments: Public Statement - 2025 Gender Treatment Rules Oregon.docx

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Dear Karen Winkel,
This letter is my public comment regarding the Oregon Insurance Commissioner's proposed rules on gender-affirming treatment.
These proposed rules define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists, not medical professionals.
WPATH-8 should not define the official standard of care in Oregon - it is written based on ideology, not medical care. The WPATH organization has engaged in highly questionable conduct. More transparency is needed along with concrete data and evidence before enshrining WPATH-8 into state law.
The following articles and briefs show that WPATH-8 is heavily influenced by a radical political agenda. See New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court.
In addition, by using WPATH-8 as the official standard of care under Oregon law, patients who are harmed from the transgender treatments may be unable to sue providers for malpractice.
Physicians should decide what is medically necessary and what standards of care should be. Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare.
Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.
Also, no detransitioners were included in the advisory group that helped write the rules.
I appreciate your consideration of this matter.
Sincerely,

[redacted].,

Email: Karen.J.Winkel@dcbs.oregon.gov
Subject: Public Comment on 2025 Gender-Affirming Treatment Rule

Dear Karen Winkel,

This letter is my public comment regarding the Oregon Insurance Commissioner's proposed rules on gender-affirming treatment.

These proposed rules define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists, not medical professionals.

WPATH-8 should not define the official standard of care in Oregon - it is written based on ideology, not medical care. The WPATH organization has engaged in highly questionable conduct. More transparency is needed along with concrete data and evidence before enshrining WPATH-8 into state law.

The following articles and briefs show that WPATH-8 is heavily influenced by a radical political agenda. See New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court.

In addition, by using WPATH-8 as the official standard of care under Oregon law, patients who are harmed from the transgender treatments may be unable to sue providers for malpractice.

Physicians should decide what is medically necessary and what standards of care should be. Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare.

Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

Also, no detransitioners were included in the advisory group that helped write the rules.
I appreciate your consideration of this matter.

Sincerely,
Sandra George
[redacted]., Molalla, OR 97038

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of lauren gerich <[redacted]>
Sent: Monday, November 25, 2024 10:52 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.

THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
lauren gerich
Portland, OR 97211-6329

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Annahita Ghaboussi <[redacted]>
Sent: Friday, November 22, 2024 6:25 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Annahita Ghaboussi and I am an Oregon Mental Health Counselor.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have been supporting Trans clients in receiving gender affirming care for the last 8 years and have seen what a positive impact it always has on their mental health and quality of life.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Annahita Ghaboussi
Portland, OR 97202-4775

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Nooshafareen Ghasedi <[redacted]>
Sent: Monday, November 25, 2024 11:00 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

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- Alignment with network adequacy standards
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.

THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Nooshafareen Ghasedi
Springfield, OR 97478-6806

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Christien Gholson [redacted]>
Sent: Monday, November 25, 2024 11:53 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Christien Gholson and I am an Oregon mental health counselor at Whitebird and Alive counseling in Eugene.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community, including coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

I encourage the expansion of professional standards for trans health care. In my experience, many are underserved or are severely discriminated against through lack of protections, and far too many people fall through the cracks.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians.

Thank you.

Sincerely,
Christien Gholson
Eugene, OR 97401-5069

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lisa Glasser [redacted] >
Sent: Monday, November 25, 2024 11:06 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

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Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

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- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

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[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lisa Glasser
Eugene, OR 97402-4523

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Elaine Go <[redacted]
Sent: Tuesday, November 26, 2024 2:53 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Elaine Go and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My friends and family are transgender and require access to gender affirming care that is already readily offered to cisgender people. Providing these basic needs allows for self-actualization that civilized society strive toward.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Elaine Go
Portland, OR 97232-3625

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Submitting comment: 2025 Gender-Affirming Treatment Rule
Date: Tuesday, November 19, 2024 2:54:57 PM

You don't often get email from [redacted]. Learn why this is important

Hi Ms. Winkel,

I spoke during today's public comment hearing on the proposed rulemaking with regard to the 2025 Gender-Affirming Treatment Rule.

I wanted to also submit a written record of my comment. I'm not 100% positive that I understood correctly, but I think I was supposed to submit my comment to your email address?

Please let me know if there's a better way to submit it.

My comment is as follows:

My name is Katherine Goforth. I'm a resident of Portland, OR. I'm an opera singer and artist trained at the Juilliard School and Oper Köln in Cologne, Germany, and I've been both nationally and internationally recognized for my work in classical music. I'm an adjunct professor at Clark College in Vancouver and a former adjunct professor at Reed College. I'm also a transgender woman receiving Gender Affirming healthcare in Oregon. I'm asking you to support this proposed rule and establish the accepted standard of care for this field as WPATH Standards of Care Version 8.

The World Professional Association for Transgender Health has its roots in the Magnus Hirschfeld Institute for Sexual Science in Berlin during the Weimar Germany period over 100 years ago. The Hirschfeld Institute was one of the first clinics internationally to conduct research that supported the normalization of Lesbian, Gay, and Transgender people, before being destroyed by the Nazi Party in 1933. Many of us who are gender and sexual minorities grow up believing that we are better off dead. I certainly did. Those teachings have had a life-long impact on me. The original aim of the scientific work that WPATH continues was to let Lesbian, Gay, Bisexual, Transgender, Intersex, and other Queer people know that who we are by nature is okay and normal, and we deserve to live our lives and be happy.

I understand that insurance companies are concerned about how much this care might cost and whether they are ill-prepared to provide it. However, while I would love to pay for my healthcare out-of-pocket, the reality is that transitioning has made it harder for me to find work and harder to make money. Discrimination against transgender people means that, without insurance coverage, I will probably never be able to access the care I need to live a full life.

When I hear insurance companies talk about how long they need to implement new programs, those periods of time aren't abstract to me. They represent years of my life. It took me decades to come to terms with the self-hatred that my society taught me, before I learned that there was something I could do about it. Yet, although I started my medical transition in 2018, I'm still

waiting for my first surgeries. The care is available, but only if you have the money, so I'm still waiting. The reality is that for those of us who want to live the same kind of lives as cisgender people, who want to participate equally in society, who want the same treatment and same opportunities, we need care that is aligned with WPATH version 8. Really, we need more care than WPATH version 8 covers, but it's still a good start.

I don't know whether the personal suffering of transgender individuals is important to this committee or not. But waiting and waiting and waiting is agony. Like any other person who requires medical care to heal, I just want my care. The more I have to wait, the more our society has to wait for all the things I have to contribute. Please don't put any more barriers in the way of that. I just want to live my life, and so does every transgender person.

Sincerely,
Katherine

--
Katherine Goforth (she / her)
Performing and Creative Artist
Instructor of Voice, Clark College
katherinegoforth.com
@g0furtherr
TNBGD Opera & Classical Voice Artists Directory

"A culture of domination always wants us to think of power as something outside ourselves... power over something, and not, what is my power within." -bell hooks

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Jenna Goldin [redacted] >
Sent: Monday, November 25, 2024 8:36 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Jenna Goldin and I am an Oregon community member, business owner and informal advocate for unhoused community members. In my experience at work as well as within the community, I feel strongly that everyone's identity belongs to them and that as a society it is our job to support folks in getting the necessary resources to get the medical care they need, that includes gender-affirming care.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Jenna Goldin
Portland, OR 97220-3149

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of abby goodman [redacted]>
Sent: Monday, November 25, 2024 12:03 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is abby and I am an Oregon resident.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
abby goodman
Eugene, OR 97402-3730

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Colette Gordon <[redacted]>
Sent: Monday, November 25, 2024 10:27 PM
To: WINKEL Karen J * DCBS
Subject: RE: HB2002

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

My name is Colette Gordon, LPC and I am a licensed mental health counselor in Portland, Oregon. My work is in large part focused on serving trans and nonbinary clients.

I am asking you to support this proposed rule as written.The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

The mental health care I and many of my colleagues provide is valuable but it can not suffice when so much of a client's psychological distress is driven by a need for a surgery that I can not provide and they cannot afford. With HB2002 I am seeing clients with new hope for their transitions and futures. Please do right by them.

Thank you.

Sincerely,
Colette Gordon
Portland, OR 97266-4712

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Kay Gordon [redacted] >
Sent: Monday, November 25, 2024 11:45 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Kay Gordon and I am an Oregon community worker.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I know from over a decade of work with the LGBTQ+ community that gender dysphoria can be life-threatening. Gender-affirming care is not optional or a luxury - it is vital. Access to the correct hormones has made the people I serve feel at home in their bodies. Access to gender confirmation surgeries has convinced people in despair that their lives are worth living.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
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- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers to finally address coverage gaps in life-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation have the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Medical specialists in transgender healthcare trust the WPATH standards because they are well-researched and thoroughly reviewed. No matter their income or background, everyone deserves access to the evidence-based healthcare they need.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Kay Gordon
Portland, OR 97217-1867

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment
Date: Tuesday, November 26, 2024 3:36:24 PM

You don't often get email from [redacted] Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules go way beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists.

As covered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court WPATH-8 is heavily influenced by a radical political agenda.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services, the proposed rules are completely silent on this issue. Further, no de-transitioners were included in the advisory group that helped write the rules.

Keep practicing righteousness,

J

Sent from Proton Mail for iOS

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: HB2002, Medical Necessity, and WPATH guidelines
Date: Sunday, November 17, 2024 11:02:31 AM

You don't often get email from [redacted] Learn why this is important

Dear Ms. Winkel,

I am an academic philosopher and bioethicist conducting research and publishing on ethics and pediatric gender medicine. I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on medical treatment for gender dysphoria.

While HB2002 required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists. As covered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court WPATH-8 is heavily influenced by a political agenda.

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In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services, the proposed rules are completely silent on this issue. Further, no detransitioners were included in the advisory group that helped write the rules.

WPATH's guidelines are just that—one set of guidelines among others (and which have been shown to be untrustworthy in a recent peer-reviewed systematic review commissioned by the UK's National Health Service). They are not the "standard of care," which is a medico-legal concept meant to set a standard for clinical practice based on the best available scientific evidence and professional consensus. There currently is no medical consensus with respect to the best treatment for youth diagnosed with gender dsyphora/incongruence. For example, the UK recently banned the use of puberty blockers for gender dysphoric minors, and Sweden and Finland—with two of the best healthcare delivery systems in the world—restrict hormonal interventions to "exceptional circumstances" and research contexts.

WPATH's clinical guidelines do not define the standard of care in this field of medicine and should not set the standard for care in the State of Oregon or anywhere else.

Sincerely,

Moti Gorin, PhD, MBE

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Heather Goshea <[redacted]>
Sent: Monday, November 25, 2024 8:48 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Heather and I am an Oregon Community Member(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Heather Goshea
Portland, OR 97239

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Joey Grafton <[redacted]>
Sent: Tuesday, November 26, 2024 9:50 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Joey Grafton and I am an Oregon mental health provider, gender-affirming letter writer, and transgender person who has benefited from gender-affirming care.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have seen the wonderful ways in which gender-affirming care has impacted my clients. Gender-affirming care provides an amazing change in the ways that people are able to live their lives with less distress, which allows them to work on themselves in amazing other ways.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,

Joey Grafton
Portland, OR 97214-5067

ROMADKA Jennifer * DCBS

From: Nancy Graybeal <[redacted]
Sent: Wednesday, November 20, 2024 12:48 PM
To: WINKEL Karen J * DCBS
Subject: My comment in Gender Treatment Rule.

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Poor Oregon children and families. The state is imposing and requiring “gender affirming care” on confused children while the rest of the world is backing away from it as not evidence based and without merit (the Cass Report, changes in England, Scotland, France, Finland, Norway etc).

WPATH is not a medical organization, it’s a trans activist organization. Its protocol shouldn’t be anywhere near our children. Children can’t possibly give informed consent to a life of sexual dysfunction, forever drugs, bone disfigurements, cancers. Nor can parents if they aren’t apprised of the lack of medical evidence and the enormous consequences of puberty blockers and mutilating surgeries on the bodies of children.

This “gender affirming care” nonsense. It’s like prescribing ozempic to kids with anorexia. It makes no sense.

Please, this needs to stop. For the children. The state of Oregon, elected officials have all fallen for an ideology that is damaging our children. This isn’t medicine. It’s quackery.

A liberal Democrat,
Nancy Graybeal
[redacted]
Corbett, Or

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Kay Greene
Sent: Monday, November 25, 2024 12:22 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Kay Greene and I am an Oregon Therapist(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

This would prove to be an massive support for my gender non-conforming clients. I've seen first-hand the impacts having access to gender-affirming care can be for folks.

I want to share appreciation for the following that are in the proposed rule:
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,

Kay Greene
Eugene, OR 97403-1891

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Kay Greene [redacted] >
Sent: Monday, November 25, 2024 12:22 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

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By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,

Kay Greene
Eugene, OR 97403-1891

ROMADKA Jennifer * DCBS

From: HERBERT GREY <[redacted]>
Sent: Tuesday, November 26, 2024 2:18 PM
To: WINKEL Karen J * DCBS
Subject: Comment letter re OAR 836-053-0441
Attachments: 2024_11_26 COMMENT LETTER re OAR 836-053-0441.pdf

> You don't often get email from [redacted]. Learn why this is important

Please see attached comment letter. Thank you.

Herbert G. Grey
Attorney at Law

Herbert G. Grey
Attorney at Law

November 26, 2024

Karen J. Winkel, Rules Coordinator
Karen.j.winkel@dcbs.oregon.gov
DEPARTMENT OF CONSUMER &
BUSINESS SERVICES
350 Winter Street NE
Salem, OR 97301

Re: NPRM re proposed OAR 836-053-0441

Dear Ms. Winkel:

I write in opposition to the above administrative rule because it lacks any kind of religious exemption or other First Amendment protections for the free exercise rights of religious employers required by controlling authority from the United States Supreme Court and the Ninth Circuit. Moreover, the rule must be evaluated under a strict scrutiny standard of review it cannot meet. Finally, adoption of the rule is premature in view of pending review of a similar Washington law currently before the Ninth Circuit Court of Appeals in

Over a decade ago, the United States Supreme Court expressly disapproved of imposing abortion regulations and coverage requirements upon religious employers without providing accommodations for their religious beliefs and practices in *Burwell v. Hobby Lobby*, 573 U.S. 682 (2014). More recently, the Ninth Circuit Court of Appeals has before it a Washington law similar to HB2002 and the proposed rule addressing the same issues. *Cedar Park Assembly of God v. Kreidler*, Case Nos. 23-35560 and 23-35585 involves mandates to the abortion and gender-affirming treatment and coverage provisions comparable to HB2002 and the proposed rule. To adopt the proposed rule in the face of the *Hobby Lobby* case and the pending appeal in *Cedar Park* is premature and ill-advised.

Neither the statutory provisions implemented by HB2002 nor Sections (2)-(4) or (5)-(7) of the proposed rule comply with these constitutional requirements. Such mandates must carve out religious exemptions or make other accommodations to make the imposition on fundamental rights as narrowly tailored as possible to meet a strict scrutiny standard of review, which are conspicuously lacking in the proposed rule. Compelling religious organizatoins to procure and pay for insurance coverage that violates their faith requirements for themselves and their employees adds further insult to injury. Even if they do not have to have such insurance, the statutory scheme arguably requires them to make such services available through other means, also in contravention of their religious beliefs and practices, to avoid civil liability.

[redacted] Beaverton, Oregon 97005-8716
Telephone 503.641.4908 | Email: [redacted]
Of Counsel, Tyler Smith & Associates

As if the preceding legal precedents were not persuasive enough, there is a substantial body of authority confirming the unconstitutionality of mandates creating disadvantages for religious organizations that do not similarly impact non-religious organizations in a variety of contexts. *See Fulton v. City of Philadelphia*, 141 S.Ct. 1868 (2021); *Tandon v. Newsom*, 141 S.Ct. 1294 (2021); *Church of the Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520 (1993). All these authorities require application of strict scrutiny to any burden imposed on the free exercise rights of religious organizations, as the Ninth Circuit recently made clear in *Fellowship of Christian Athletes v. San Jose Unified School District*, 82 F.4th 664 (9th Cir. 2023). None of the government mandates or restrictions in these cases met the strict scrutiny standard, and the proposed rule does not either.

Respectfully, HB2002 and this proposed rule implementing it are constitutionally deficient and deprive religious organizations of their fundamental religious rights. They further invite legal challenges to restore those foundational rights and should not be adopted or implemented in their current form.

Very truly yours,

Herbert G. Grey

From: [redacted]
To: WINKEL Karen J * DCBS
Cc: EMERSON Lisa * DCBS; HALL Brooke M * DCBS
Subject: Rulemaking for HB 2002
Date: Tuesday, November 26, 2024 4:37:51 PM
Attachments: Guerriero Public Comment HB2002 rulemaking.docx

> Some people who received this message don't often get email from [redacted]. Learn why this is important

Thank you for your time and attention on this matter!
Happy holidays!

Best,
Jess Guerriero
Pediatric Social Worker

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: **Jess Guerriero, Pediatric Social Worker**

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Jess Guerriero and I am an Oregon healthcare provider and recipient of gender affirming care in Oregon. I work and live in Oregon. I am a pediatric social worker and a board-certified clinical social work associate. I have worked with gender diverse youth and their families since 2011, offering comprehensive psychosocial assessments, individual and family therapy, resource navigation, support for gender identity and transition goal exploration, and participation as a mental health provider on an interdisciplinary clinical team. While I currently serve in a pediatric gender clinic, and my initial training was completed in a lifespan gender program, my work with gender diverse youth and their families has also occurred in residential, crisis response, and intensive community-based treatment environments.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.

My clinical practice has been informed by the guidance offered in the WPATH Standards of Care, versions 6, 7, and 8, and has evolved alongside of the revisions and updated recommendations each version has provided. Remaining up-to-date on the most recent version of the standards of care allows me to ensure that I am working according to the most updated literature and evidence, and that my practice is responsive to the community care needs identified in the present version.

Additionally, in partnership with a clinical psychologist, we developed, and continue to evaluate and improve, the mental health assessment and treatment model for our clinic. This model emphasizes that any treatment decisions are made in collaboration with the patient, their family, outside mental health professionals and experienced medical providers. Because the WPATH standards are our foundation, our clinical model is in alignment with other gender centers statewide, nationally, and internationally.

The WPATH standards of care describe medical and mental healthcare practices that holistically support gender diverse youth. These guidelines are based on robust clinical evidence, highlighting the mental and physical health benefits that gender-affirming treatment can provide.

Version 8 represents the current international best practice guidelines for gender diverse individuals, and utilizes a review of all current literature on safety, risks, benefits, and outcomes for all treatment decisions, including the decision to not pursue medical support for gender affirmation. The development of the current version was undertaken by an international group of medical and mental health professionals of varying backgrounds, representing key stakeholder regions, and including professionals of trans experience. The implementation of the standards first required a period of public comment and then a certification of at least 75% of the membership.

Version 8 also specifically addresses the treatment of adolescents as a separate and unique set of treatment considerations, compared to earlier versions that conflated the treatment needs of adolescents, peripubertal youth, and younger pre-pubertal children.

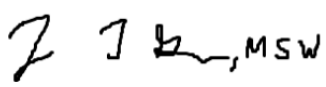
Additionally, version 8 explicitly recognizes that medical treatment for gender dysphoria is only appropriate for some adolescents, as determined by individual goals and identity exploration, parental input and support, mental health evaluation, and medical provider input.

The WPATH guidelines are recognized as authoritative by the major medical and mental health professional organizations in the United States, including the American Academy of Pediatrics, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine and Pediatric Endocrine Societies, the American Academy of Child & Adolescent Psychiatry, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists. Other care models have not been recognized as standard practice and some have elements that have already been shown to do harm and that border on conversion therapy, which Oregon has rightly banned. The RAC has the opportunity to ensure that Oregon's provision of gender affirming care remains consistent with evidence-based practices in other states and countries, and with the backing of major medical and mental health professional organizations.

As we advocate for policies that protect the right to medical care for transgender youth and respect parental rights, we need to rely upon trusted, well-established guidelines during the creation of rules that will impact clinical care. By utilizing version 8 of the WPATH Standards of Care, the RAC can support the safety, well-being, and future of Oregon's transgender and gender diverse youth.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,



Jess Guerriero, MSW, CSWA

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Ben Gulick [redacted]>
Sent: Monday, November 25, 2024 5:08 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Ben Gulick
Portland, OR 97206-3750

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lily Gunn [redacted] >
Sent: Monday, November 25, 2024 10:38 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

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· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lily Gunn
Sandy, OR 97055-9745

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Avantika Gupta [redacted]>
Sent: Tuesday, November 26, 2024 3:26 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Avantika Gupta and I am an Oregon mental health provider (Psy.D. pre-licensed post-doctoral resident). I have worked with several folks of diverse gender identities and personally witnessed the harm that barriers to receiving gender affirming care can have and the benefits that access to gender affirming care provide.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have worked with individuals who have been unable to receive gender affirming care due to insurance barriers and faced immense stress and emotional toll in having to maintain certain jobs/face financial burden to access specialized insurance that covers gender affirming care.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in life-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

Barriers to accessing gender-affirming care create hopelessness and despair that is highly linked with suicidal ideation, attempts, and completion. Even if folks who see barriers to receiving this care finally do obtain it, the emotional impact of years and often decades and lifetimes of battling barriers can have long-lasting effects of mental, emotional, and physical health. Mentally and physically well Oregonians are better able to participate in their personal lives and

professional and societal lives, contributing to society. This bill will allow for reduced barriers to care, leading to wellness on a large scale beyond just access to gender affirming care.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Avantika Gupta
Portland, OR 97239-4571

From: [redacted]
To: WINKEL Karen J * DCBS
Cc: [redacted]
Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule
Date: Tuesday, November 19, 2024 8:17:49 AM

> You don't often get email from [redacted]. Learn why this is important

I'm going to keep this simple. Sex denying medicalization of children is child abuse. Please read the WPATH Files that were leaked. Children can not consent to losing their sexual function. They don't know what it means yet. This is the most dangerous agenda I have ever seen. If you tell a child they can be born in the wrong body, they will believe you. We can't be born in the wrong body. It is a lie. Please do not support the destruction of our children.
I am an old lesbian that can see this agenda destroying young lesbians. Butch lesbians are not boys or men. We are women. I hope that you will look very carefully at this and support healthy children. This agenda is criminal medical fraud, criminal medical malpractice. Children can not consent to being sterilized or having healthy body parts amputated.
Please, protect our children. Feel free to contact me if you would like more information.
Thank you,
Skylar Gwynn

ROMADKA Jennifer * DCBS

From: LaNita Hafer [redacted] >
Sent: Sunday, November 24, 2024 7:11 PM
To: WINKEL Karen J * DCBS
Subject: WPATH

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

I am writing to submit a comment regarding the gender affirming care rule before the insurance commissioner.

An accepted standard of care can only be proposed by a medical professional, licensed by the state of Oregon, not by those advocating, gender affirming surgeries. The commissioner and or his staff do not have any medical licensure in Oregon and do not practice medicine. Assuming the “affirmations”of those in the LGBTQ community goes against best practice.

There is also no consideration of the De-Transition in this proposal. If we want to present an unbiased rule, then both sides of the issue must be considered. I’m sure that the insurance commissioner wants to due diligence and represent all of the constituents of Oregon. Assuming anything less capitulates his responsibility for fair and equal practice and is assumptive in nature.

Respectfully submitted,
L. Hafer.

Sent from my iPhone

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Everett Hagan
Sent: Tuesday, November 26, 2024 5:36 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Everett Hagan
Staunton, VA 24401-5680

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Rebecca Hagerwaite [redacted]>
Sent: Tuesday, November 26, 2024 8:52 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Rebecca Hagerwaite and I am an Oregon Family Nurse Practitioner and parent of an adored transgender child. I am so proud to live in a state that has the wonderful protection of HB2002!

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My child and patients deserve dignity, privacy, safe and affordable access to evidence-based care. I have seen so many patients and my own child go through treatment and absolutely thrive afterwards. I have had numerous patients coming from in and out of state who were finally able to receive treatment after years of waiting— I have only witnessed positive outcomes.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Rebecca Hagerwaite
Eugene, OR 97403-1967

ROMADKA Jennifer * DCBS

From: Nancy Haldeman <[redacted]>
Sent: Monday, November 18, 2024 7:48 PM
To: WINKEL Karen J * DCBS
Subject: Public comment on 2025 Gender Treatment rule

> You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I am writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules go way beyond what the legislature authorized last year in HB 2002.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for detransition services, the proposed rules are completely silent on this issue.

I appreciate your consideration of this matter.

Sincerely,

Nancy Haldeman

From: [redacted]
To: WINKEL Karen J * DCBS; brooke.m.hall@scbs.oregon.gov; EMERSON Lisa * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB 2002
Date: Friday, November 22, 2024 1:28:23 PM

> Some people who received this message don't often get email from [redacted]. Learn why this is important

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Katryn Haley-Little, LCSW and I live and work in Central Oregon. I am a mental health therapist in Bend working with individuals of all ages who are gender expansive and impacted by the current and future decisions around gender affirming care. As you may know, the last few weeks especially have been filled with increased angst and fear for those of us who either are gender expansive or care about those who are.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The evidence Review Team at WPATH conducted internal systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence based approach. Evidenced-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. *Gender-affirming care is lifesaving care.* According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population - but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015 the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender affirming treatment through HB 2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

As a mental health provider, I have and continue to see the negative impact of folks being denied gender-affirming care. There is an increase in reports of suicidality, depression, anxiety, and isolation when their ability to access the care that cisgender people access every day is impaired. Everyone in our community deserves to have access to the care that allows them to feel at home in their body. We cannot be gatekeepers for that.

I want to share appreciation for the following that are in the proposed rule:
*Determining a standard of care in rule for insurers to be in compliance with HB2002.
*Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations.
*Transparency for the patient if requested related to adverse benefit determinations
*Alignent with network adequacy standards
*Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met.

HB2002 has already helped close coverage gaps in life saving gender affirming care access fo transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable healthcare for transgender Oregonians. Please remember this letter when you finalize this draft into rule.

Thank you,
Katryn Haley-Little, LCSW

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Angie Hamilton [redacted] >
Sent: Saturday, November 23, 2024 4:15 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Angie Hamilton and I am an Oregon mental health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Evidence overwhelmingly indicates that trans and nonbinary youth suicide rates are among the highest compared with other demographic groups. Gender affirming care is critical and life saving, and allows people at any stage of life to live a more authentic, happy, fulfilling life. The impact of anti-trans legislation and societal narratives is that a huge portion of the population lives in fear, and in a state of mind where they believe they are “wrong” or “abnormal” which over time causes anyone to develop debilitating symptoms of mental unrest such as clinical anxiety, depression, and suicidality. Please contribute to a the health and safety of Oregonians by supporting the proposed rule as written.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

As a mental health provider, I frequently hear from clients and colleagues how challenging it is to navigate healthcare coverage and how much time and energy goes into advocating for care with insurance companies. It is extremely challenging for people who hold levels of privilege due to their financial resources and their identities. Infinitely more so for people who hold marginalized identities. We need to advocate for consumers to get the healthcare they need and deserve.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Angie Hamilton
Portland, OR 97214-3597

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Steven Hancher <[redacted]>
Sent: Monday, November 25, 2024 5:15 PM
To: WINKEL Karen J * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

My name is Steven Hancher, and I am a resident of Portland Oregon.

I am asking you to support this proposed rule as written. I support and appreciate the effort to define a clear standard of care for insurers to follow in compliance with HB2002. The inclusion of evidence-based standards, like those from WPATH, ensures that transgender Oregonians can access the care they need without unnecessary delays or denials.

Gender-affirming care is life-saving. Without it, transgender individuals face much higher risks of depression, anxiety, and suicide. Ensuring access to this care helps people live authentically and improves their overall well-being. This rule will especially help marginalized groups within the trans community, including trans people of color, trans women, low-income individuals, and immigrants, who often face additional barriers to accessing care.

I support the following aspects of the proposed rule:

-Clear standards of care for insurers
-Improved training for those making coverage decisions -Transparency for patients regarding coverage denials -Ensuring timely access to out-of-network care when needed

By supporting this rule, you will protect the health and dignity of transgender Oregonians and help create a more equitable healthcare system.

Thank you for considering my comment.

Sincerely,
Steven Hancher

Sincerely,
Steven Hancher
Portland, OR 97220-4021

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Gabby Hancher [redacted] >
Sent: Monday, November 25, 2024 5:12 PM
To: WINKEL Karen J * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

My name is Gabby and I am an Oregon mental health provider who supports the queer and trans community.

I am asking you to support this proposed rule as written. I support and appreciate the effort to define a clear standard of care for insurers to follow in compliance with HB2002. The inclusion of evidence-based standards, like those from WPATH, ensures that transgender Oregonians can access the care they need without unnecessary delays or denials.

Gender-affirming care is life-saving. Without it, transgender individuals face much higher risks of depression, anxiety, and suicide. Ensuring access to this care helps people live authentically and improves their overall well-being. This rule will especially help marginalized groups within the trans community, including trans people of color, trans women, low-income individuals, and immigrants, who often face additional barriers to accessing care. As a therapist, I see the impacts of safe and clear access to gender affirming care on the daily.

I support the following aspects of the proposed rule:

Clear standards of care for insurers
Improved training for those making coverage decisions Transparency for patients regarding coverage denials Ensuring timely access to out-of-network care when needed

By supporting this rule, you will protect the health and dignity of transgender Oregonians and help create a more equitable healthcare system. Thank you for considering my comment.

Gabby Hancher, Registered Associate through the Oregon Board of Licensed Professional Counselors and Therapists

Sincerely,
Gabby Hancher
Portland, OR 97220-4021

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Madison HancockVarughese [redacted] >
Sent: Monday, November 25, 2024 6:53 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Madi Hancock-Varughese and I am an Oregon resident.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have worked with various trans youth in Oregon and have seen firsthand the need for trans affirming healthcare being offered and affordable for all.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Madison HancockVarughese
Portland, OR 97202-6598

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Catie Hannigan [redacted]>
Sent: Tuesday, November 26, 2024 7:59 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Catie Hannigan and I am an Oregon queer community member, educator, and current therapy student / future therapist.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

As someone in the queer community, literally all of my closest friends, including my spouse of 8 years, has received or in the process of attempting to obtain gender affirming surgery/care. It has saved their lives, created immense joy and belonging. At the same time, I have seen the despair that denial of this life saving care has created.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

As a future therapist, it is my intention to work with the queer community and provide therapeutic guidance in the process of receiving gender affirming care.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Catie Hannigan
Portland, OR 97217-1730

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: transgender
Date: Tuesday, November 26, 2024 9:46:16 AM

> You don't often get email from [redacted]. Learn why this is important

I want to share my concerns on the topic of transgender surgeries and treatment. I would like to see a slow down on these medical procedures. I truly believe the end result has not been fully investigated. I come at this from a religious point of view and also a former staff member of Hillsboro School District.
I have to state I believe this a mental condition as God made us man and woman.
I also have witnessed the confused students at Liberty High School in Hillsboro Oregon and pandering to this confusion did not make for happy students.
The chemical and surgical changes that are being made to healthy bodies and not reversible. In some cases patients are having serious health issues as the result of these drastic measures.
Please for the sake of our future generations take a pause on this and really do what is truly best for the kids.
Respectfully
Pam Hardwick

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender Treatment Rule
Date: Monday, November 18, 2024 1:52:29 PM

You don't often get email from [redacted] Learn why this is important

Dear Ms. Winkel,

I am hoping to submit a public comment (see below) to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. I didn't see anywhere on the Oregon website where I could submit this myself. Can you help? Also, can members of the public attend this session?

Thank you!
Holly Harrington

Oregon Insurance Commissioner
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97301

Dear Commissioner Stolfi,

I am writing to submit a public comment regarding the proposed rules on gender-affirming treatment under HB2002. While I fully support the intent of HB2002 to ensure access to "medically necessary" care as prescribed by licensed medical and behavioral providers, I have significant concerns regarding the scope and content of the proposed rules, particularly in their adoption of WPATH's Standards of Care (SOC) 8 as the "accepted standard."

HB2002 was carefully designed to defer clinical decision-making to the medical community, allowing for flexibility and a focus on individual patient needs. However, the proposed rules go far beyond this intent by codifying a specific and highly controversial model of care. SOC 8, developed by a small group of transgender rights activists, is problematic for several reasons. As documented by reputable sources such as *The New York Times*, *The Economist*, *The BMJ*, and an amicus brief from the Alabama Attorney General to the U.S. Supreme Court, SOC 8 is heavily influenced by political agendas rather than solid evidence. Key concerns include:

1. **Lack of Transparency and Evidence**: SOC 8 does not provide a clear, evidence-based framework for clinical decision-making. For instance, it fails to adequately define gender identity, pathologizes gender-atypical behavior, and assigns undue clinical importance to sex-based stereotypes. Furthermore, it disregards the

implications of comorbidities such as autism, ADHD, OCD, and eating disorders, which complicate gender-related care and demand careful, individualized treatment.

2. **Radical Shifts in Treatment Approaches**: The inclusion of new categories, such as eunuch identities, without sufficient scientific basis raises serious concerns. Removing the ethics chapter from SOC 8 and other controversial revisions further undermine its credibility as a reliable medical guideline.

Given the concerns surrounding SOC 8, it is troubling that the proposed rules would elevate it to the "accepted standard of care." We are also aware that the recent Cass Review in the UK, which assessed the long-term efficacy of gender-affirming treatments, has led to a shift in treatment guidelines, with a focus on behavioral interventions and restrictions on medical and surgical treatments for minors. The Cass Review's conclusions call for a more cautious, evidence-based approach that prioritizes patient well-being over unproven, activist-driven agendas. With this in mind, I question whether it is wise for Oregon to adopt a model of care based on the controversial and unsupported principles found in SOC 8.

Moreover, the issue of detransition is conspicuously absent from the proposed rules. The Insurance Commissioner had promised Oregon legislators that insurers would cover "detransition" services, yet no mention is made of this in the proposed rules. Were individuals who have detransitioned included in the advisory group that informed these rules? If not, why were they excluded from the discussion? Will insurers be required to cover care for individuals harmed by gender-affirming treatments, or will this be left to the discretion of individual insurance companies?

As a parent of a young adult who, like many of her peers, became trans-identified during the COVID lockdowns, I am deeply invested in ensuring that healthcare decisions are based on the best available scientific evidence, not political ideology. My child and others like her deserve care that is informed by rigorous research, clinical expertise, and the fundamental principle of "do no harm."

In light of the concerns I have outlined, I urge the Insurance Commissioner to reconsider the proposed rules and ensure that Oregon's policies are grounded in solid scientific evidence and ethical clinical practices, rather than activist-driven agendas. Healthcare decisions must be based on what is best for each patient, not on the latest political trends.

Thank you for your attention to this important issue. I look forward to your response and to seeing the rules revised in a manner that best serves the health and well-being of all Oregonians.

Sincerely,
Holly Harrington
Salem, Oregon

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Jessica Harrison <[redacted]>
Sent: Monday, November 25, 2024 11:09 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Jessica and I am an Oregon native. I believe in the progress Oregon has made in regards to affirming health care and treatment and ensuring the right to equal access to healthcare FOR ALL.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My best friend of 20 years is transgender; access to gender-affirming care has provided him a path for a safe life.

I want to share appreciation for the following that are in the proposed rule:
- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Jessica Harrison
Portland, OR 97233-4138

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Jordan Hartman Haight [redacted]>
Sent: Tuesday, November 26, 2024 9:49 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

My name is Jordan Hartman Haight, and I am an Oregon community member, as well as a mental health care provider. I am asking you to support this proposed rule as written. I support and appreciate the effort to define a clear standard of care for insurers to follow in compliance with HB2002.

The inclusion of evidence-based standards, like those from WPATH, ensures that transgender Oregonians can access the care they need without unnecessary delays or denials. Gender-affirming care is life-saving. Without it, transgender individuals face much higher risks of depression, anxiety, and suicide. Ensuring access to this care helps people live authentically and improves their overall well-being. This rule will especially help marginalized groups within the trans community, including trans people of color, trans women, low-income individuals, and immigrants, who often face additional barriers to accessing care.

I support the following aspects of the proposed rule:
- Clear standards of care for insurers
- Improved training for those making coverage decisions
- Transparency for patients regarding coverage denials
- Ensuring timely access to out-of-network care when needed

By supporting this rule, you will protect the health and dignity of transgender Oregonians and help create a more equitable healthcare system.

Thank you for considering my comment.
Jordan Hartman Haight

Sincerely,
Jordan Hartman Haight
Portland, OR 97239-2957

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule
Date: Tuesday, November 26, 2024 7:29:24 AM
Attachments: Letter to Karen Winkel.pdf

> You don't often get email from [redacted]. Learn why this is important

Please include the attached letter in the public comments

Mike and Linda Hartwig

--

Email: Karen.J.Winkel@dcbs.oregon.gov

Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule

Dear Karen Winkel

We are writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. Quite frankly, we are horrified to think of the children who have been permanently damaged due to the treatment that they received due to gender confusion. It is a travesty to fast-track them into a irreversible course of medical intervention, sometimes without their parent's knowledge.

The science is not settled and those in other countries, including United Kingdom, are pulling back from pushing this kind of treatment for children. Research has shown that the children who received the supposed "gender-affirming care" are not happier, or less depressed than before undergoing treatment.

WPATH is a controversial document that was developed by trans-activists. For years activists have cited the document in order to claim that the science on "gender-affirming care" is "settled," and that social, chemical, and surgical "transition" interventions are safe, reversible, and lifesaving. However, early in 2024, internal files leaked from the World Professional Association of Transgender Health (WPATH), the self-anointed medical association that has pushed for the chemical and surgical "gender transition" of minors, were made public.

In a leaked video, a leading WPATH doctor admitted that a minor could not fully understand the implications of "treatment," especially for his or her future fertility. Yet, this was being pushed on minors who were unable to grant consent. Far from being settled science, these "treatments" were known to be experimental and known to lead to painful complications, including life-threatening conditions like cancers.

A few weeks later, the U.K.'s National Health Service released an almost 400-page report on the state of "gender identity services for children and young people." The Cass Review affirmed that "gender-affirming care" is built on "shaky foundations" and that evidence supporting the use of puberty blockers, cross-sex hormones, and sex-change surgeries is "remarkably weak." According to the report, most of the studies cited in support of social, chemical, or surgical "transition" lacked the quality required to safely guide clinicians and families in caring for gender dysphoric young people.

In addition, in 2024 much was learned about the co-morbidities that accompany gender confusion. For example, research out of the U.K. showed that adults who identified as transgender were six to seven times more likely to have ADHD, four times more likely to suffer from depression, five times more likely to have bipolar disorder, more than five times as likely to have obsessive compulsive disorder and over 28 times more likely to have a diagnosis of schizophrenia.

Another study found that youth who experience gender dysphoria are far more likely to have experienced emotional abuse and physical and emotional neglect. In addition, a survey of millions of patients over the course of two decades suggested that those who undergo "gender transition" surgery are 12 times more likely to attempt suicide than the general population.

We as Oregonians should consider our children to be worth protecting at all costs. Instead of continuing down this road, we should put the brakes on, and reverse directions by truly protecting children so they can flourish. Please carefully read the research and reconsider the direction our state is heading for our children's sake. We don't want to be on the wrong side of history.

Sincerely,

Mike and Linda Hartwig

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Sarah Haskew <[redacted]>
Sent: Tuesday, November 26, 2024 11:54 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Sarah and I am a community member and advocate for unrestricted unambiguous access to healthcare.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Sarah Haskew
Hudson, NY 12534-3018

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule
Date: Monday, November 18, 2024 1:46:17 PM

> You don't often get email from [redacted] Learn why this is important

Dear Ms. Winkel,

I am writing to express my concerns about the Insurance Commissioner's proposed rules on gender-affirming treatment, which seem to go beyond the scope of HB2002 enacted last year. Specifically:

- **Influence by Controversial Standards:** The rules appear influenced by standards from an organization (WPATH) that was recently criticized for hiding evidence about the lack of effectiveness and safety of its medical recommendations.
- **Absence of Medical Expertise:** Neither the Insurance Commissioner nor his staff have medical licensure, and no licensed healthcare professionals were involved in drafting these rules.
- **Detransition Services Omitted:** Despite previous assurances, the rules fail to address detransition services.

I urge you to ensure these rules align with: legislative intent, the Insurance Commissioner's commitment to including detransition services, and accepted medical standards.

Sincerely,

C Haverson

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Protect our children
Date: Tuesday, November 26, 2024 3:34:04 PM

> You don't often get email from [redacted]. Learn why this is important

About four years ago, my grandson re-enrolled in the Bend School district for sixth grade after they reopened following the covid shutdown. Everything was going great for the first two or three months until he came home upset at what had taken place that day. When questioned, he explained they had pulled him out of his favorite class, science, and put him in another one where the kids sat around in a circle and were told to tell each other what their pronouns were.

My son went down to the principal's office the next day, demanding to know what precipitated this action. The assistant principal explained that my grandson had been given a questionnaire at the beginning of the term. One of the questions was "Is there anything you're afraid to tell your parents"? and your son answered "yes" so we assume he's transgendered. The staff went on to explain that they didn't have to answer any more questions and were under no obligation to notify his parents.

My son was both enraged at how the school district could just make this decision with no parental input and fearful at what they could do to his boy. So, he did the only thing he could.....move out of state.

The family moved to a town outside of Reno, Nevada and have settled in nicely. My grandson gets good grades, runs track, plays clarinet in the marching band, and finished 6th out of 135 boys on the Paradise Ski Team at Squaw Valley.

On the negative side, Oregon no longer gets the $25,000 income tax my son paid each year, the school district misses out on the $32,000 (2 kids) subsidy from the state, and I have to drive nine hours instead of three, to see my grandchildren.

Oh yeah, what was he afraid to tell his parents? As he explained to me, "I was only 11, and getting my first pimple. I was too embarrassed to ask my mom and dad what I should do.

Thank you Oregon. If I could move my vineyard to Nevada, I would leave as well.

Jeff Havlin
Perrydale

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Maggie Hawthorne [redacted] >
Sent: Tuesday, November 26, 2024 7:26 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Maggie Hawthorne and I am an Oregon community member and public health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
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HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.

· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Maggie Hawthorne
Portland, OR 97212-3543

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: PUBLIC COMMENT on 2025 Gender-Affirming Treatment Rule
Date: Monday, November 18, 2024 8:32:33 PM

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatments. These rules go way beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists. As reported in the New York Times, The Economist , The BMJ, and a briefing filed by the Alabama Attorney General with the Supreme Court, WPATH-8 is heavily influenced by a radical political agenda.
Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress. In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services, the proposed rules are completely silent on this issue. Further, no detransitioners were included in the advisory group that helped write the rules.

WPATH-8 should NOT be the guide in such profound physical interventions since the Cass Review and all of the European guidelines have now moved away from using it as a sound source. WPATH-8 would trap doctors and not allow their recommendations to evolve as evidence and understanding grows and changes. It is this same rigidity of thought and treatment plans that created so much pain for detransitioners. Perhaps it's time to let in more flexibility for doctors when they're attempting to "Do No Harm" and not lock them in to a treatment plan devised by a commission with no medical training.

I appreciate your consideration of this matter.

Sincerely,
Linda Hayden

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Laura Haywood-Cory [redacted] >
Sent: Tuesday, November 26, 2024 9:50 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment

My name is Laura Haywood-Cory and I am an Oregon LGBTQ-affirming mental health provider.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
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- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the standards of care.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Laura Haywood-Cory
Portland, OR 97202-3802

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-AffirmingTreatment Rule
Date: Thursday, November 21, 2024 2:09:18 AM

> You don't often get email from [redacted]. Learn why this is important

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules go way beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules go MUCH further. They define "accepted standard of care" as adherence to WPATH-8, a controversial document developed by transgender rights activists. Ascovered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court WPATH-8 is heavily influenced by a radical political agenda.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services,the proposed rules are completely silent on this issue. Further, no detransitioners were

included in the advisory group that helped write the rules.

Consider adding more from the “Key Points” page here or include your own personal story.

I appreciate your consideration of this matter.

Sincerely,

Michelle and Donald Hazeltine

Sent from my iPhone

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
10/30/2024 11:50 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2025 Gender-Affirming Treatment Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/19/2024
TIME: 11:00 AM - 12:00 PM
OFFICER: Brooke Hall

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm A, Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

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MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 599636230
SPECIAL INSTRUCTIONS:
Meeting ID: 267 195 468 800
Passcode: j3NgqJ

NEED FOR THE RULE(S)

House Bill 2002 (2023) prohibits a carrier offering a health benefit plan from denying or limiting coverage for medically necessary gender-affirming treatment that is prescribed in accordance with accepted standards of care. The bill also prohibits health benefit plans from applying cosmetic or blanket exclusions to medically necessary gender affirming treatment and establishes requirements for notices of adverse benefit determinations and network adequacy.

HB 2002 (2023) requires the Department of Consumer and Business Services (DCBS) to adopt rules to implement these provisions. DCBS convened a Rulemaking Advisory Committee (RAC) which met on Dec. 12, 2023, Jan. 25, Mar. 21, Apr.

25, Jun. 11, Jul. 18, and Aug. 7, 2024. The RAC included insurers, health care providers, consumer and patient advocates. Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

House Bill 2002 (2023)
ORS 743A.325 (4)(b)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

A Rulemaking Advisory Committee was consulted regarding this equity statement. This rule implements HB 2002, which increases access to gender affirming care. This rule is not anticipated to have any disparate negative impact on any particular demographic of Oregon consumers.

This rule is expected to have a positive impact on equity in the state by increasing access to healthcare services for underserved individuals, particularly for transgender and non-binary individuals, resulting in reduced barriers to necessary medical treatments, enhanced affordability, and improvements in behavioral health and overall well-being for those receiving gender-affirming care.

FISCAL AND ECONOMIC IMPACT:

The rule primarily affects health insurance carriers issuing health benefit plans. The rule mandates that health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.

This training comes with a cost. Based on the information available to the department, the training sessions facilitated by WPATH are priced based on contractual arrangements that depend on factors including the number of participants. DCBS does not have specific information about the number of insurance company employees that will take the training as a result of this rule, so it is not possible to estimate the total cost to affected industry entities. However, since the training can be made available to an insurer's existing reviewers, the training requirement is likely less financially burdensome than alternative approaches that could require hiring or contracting with different or additional reviewers.

The rule will have indirect positive effects on health care providers, including small businesses, to the extent that it requires health insurance carriers to reimburse for services that may not previously have been covered, but the extent of this impact is impossible to estimate from the information available to DCBS.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not (or does not have) a fiscal or

economic impact on state agencies, local government units, nor the public.

(2)(a) Based on financial filings made to the Division of Financial Regulation (DFR), no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule will have indirect effects on health care providers, including small businesses, but DCBS does not have access to information to determine the number of small provider organizations that would be affected.

(2)(b) The rule primarily affects health insurance carriers. It does not require additional reporting or recordkeeping activities. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

(2)(c) The rule primarily affects health insurance carriers. Based on the information available to the department, it does not require additional professional services, equipment or supplies. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rule primarily applies to health insurance carriers. Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule has indirect impacts on health care providers, some of whom are small businesses.

Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers. The department also received written and oral public comment during the RAC process from small business health care provider representatives.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-053-0441

RULE SUMMARY: A carrier offering a health benefit plan may not deny or limit coverage under the plan, including, but not limited to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and
(b) Prescribed in accordance with accepted standards of care.

CHANGES TO RULE:

836-053-0441
Gender-Affirming Treatment
(1) For purposes of this rule:¶
(a) "Gender-affirming treatment" has the meaning given to that term under ORS 743A.325; and¶
(b) "Accepted standards of care" includes, at a minimum, the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (WPATH-8). ¶
(2) A carrier offering a health benefit plan may not deny or limit coverage under the plan including, but not limited

to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost-sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:¶
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and¶
(b) Prescribed in accordance with accepted standards of care.¶
(3) Carriers may use utilization review practices to verify adherence to the accepted standards of care described in subsection (2)(b), provided that such practices are consistent with the requirements of this rule, OAR 836-053-1200, and all other applicable provisions of Oregon law. Utilization review practices shall be implemented in a manner that does not unreasonably limit or delay access to care.¶
(4) A carrier offering a health benefit plan may not:¶
(a) Apply a categorical cosmetic or blanket exclusion to medically necessary gender-affirming treatment; or¶
(b) Exclude, as a cosmetic service, a medically necessary procedure prescribed by a physical or behavioral health care provider as gender-affirming treatment, including but not limited to: ¶
(A) Tracheal shave;¶
(B) Hair electrolysis; ¶
(C) Facial feminization surgery or other facial gender-affirming treatment; ¶
(D) Revisions to prior forms of gender-affirming treatment; or¶
(E) Any combination of gender-affirming treatment procedures.¶
(5) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must ensure that the adverse benefit determination is reviewed and approved in accordance with the following requirements: ¶
(a) The adverse benefit determination is reviewed by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.¶
(b) To demonstrate experience the reviewing provider must:¶
(A) Meet the criteria for external medical review found in OAR 836-053-1325(6)(b)(A-C);¶
(B) Have experience utilizing the WPATH-8; and¶
(C) Have completed the WPATH SOC-8 Health Plan Providers training program or an equivalent training program.¶
(c) This subsection (5) does not apply to an adverse benefit determination that only involves the application of cost-sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment. ¶
(6) In the event of an adverse benefit determination that denies or limits coverage for gender-affirming treatment, the carrier must meet all the requirements in:¶
(a) ORS 743B.250, and if requested under ORS 743B.250(2)(h)(B), disclosure of the identity of the physical or behavioral health care provider who reviewed the determination, which at a minimum includes information to demonstrate experience prescribing or delivering gender-affirming treatment:¶
(A) The provider's job title and specific role in the review process; and¶
(B) The provider's specialty, board certification status, and any other relevant qualifications that affirm their experience in gender-affirming treatment.¶
(b) OAR 836-053-1030; and¶
(c) OAR 836-053-1100. ¶
(7) Carriers offering health benefit plans shall:¶
(a) Satisfy any network adequacy standards under ORS 743B.505 related to gender-affirming treatment providers; and¶
(b)(A) Contract with a network of gender-affirming treatment providers that is sufficient in numbers and geographic locations to ensure that gender-affirming treatment services are accessible to all enrollees without unreasonable delay; or¶
(B) Ensure that all enrollees have geographical access without unreasonable delay to out-of-network gender-affirming treatment services with cost-sharing or other out-of-pocket costs for the services no greater than the cost-sharing or other out-of-pocket costs for the services when furnished by an in-network provider, and meet all the requirements in:¶
(i) OAR 836-053-1030;¶
(ii) OAR 836-053-1035; and¶
(iii) OAR 836-053-1408.
Statutory/Other Authority: ORS 731.244, ORS 743A.325
Statutes/Other Implemented: ORS 743A.325

2023 Regular Session

HB 2002 Enrolled
(/liz/2023R1/Downloads/MeasureDocument/HB2002)

Overview

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Bill Title:	Relating to health; and declaring an emergency.
Catchline/Summary:	Modifies provisions relating to reproductive health rights.
Chapter Number:	Chapter 228
Fiscal Impact:	Fiscal Impact Issued
Revenue Impact:	No Revenue Impact
Measure Analysis:	Staff Measure Summary / Impact Statements (/liz/2023R1/Measures/Analysis/HB2002)
Current Location:	Chapter Number Assigned

Current Committee: ()

Current Subcommittee:

Subsequent Referral(s):

Potential Conflicts of Interest/Vote Explanations: Potential Conflicts of Interest/Vote Explanation Documents (https://www.oregonlegislature.gov/pcive/Forms/Display.aspx?View={F16B1F7B-33C4-4EA7-9D3022EE155C}&FilterField1=Session&FilterValue1=2023R1&FilterField2=Measure&Filter\

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Standards of Care Version 8

VIEW THE SOC8 HERE (OPEN ACCESS)

SOC8

SOC8 publication is complete. Please follow the link below to view the document.

As new translations become available, we will add to this page. Currently listed are: Bosnian, Czech, Croatian, French, Georgian, Italian, Korean, Mandarin, Montenegrin, Norwegian, Portuguese, Spanish, Thai, and Ukrainian.

VIEW SOC8 CHAPTERS

VIEW SOC8 TRANSLATION PAGE

History and Purpose

The field of transgender healthcare is a rapidly evolving interdisciplinary field. The last few years have seen a globally unprecedented increase and visibility of transgender and gender diverse people seeking support . . .

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CHAIRS & LEAD EVIDENCE TEAM

Establishing the SOC8 Revision Committee

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select

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Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show

Newly released emails from an influential group issuing transgender medical guidelines indicate that U.S. health officials lobbied to remove age minimums for surgery in minors because of concerns over political fallout.

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By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for care of transgender minors, according to newly unsealed court documents.

Age minimums, officials feared, could fuel growing political opposition to such treatments.

Email excerpts from members of the World Professional Association for Transgender Health recount how staff for Adm. Rachel Levine, assistant secretary for health at the Department of Health and Human Services and herself a transgender woman, urged them to drop the proposed limits from the group's guidelines and apparently succeeded.

If and when teenagers should be allowed to undergo transgender treatments and surgeries has become a raging debate within the political world. Opponents say teenagers are too young to make such decisions, but supporters including an array of medical experts posit that young people with gender dysphoria face depression and worsening distress if their issues go unaddressed.

United States | The WPATH files

Leaked discussions reveal uncertainty about transgender care

The files shed light on a controversial area of medicine that has largely retreated into the shadows

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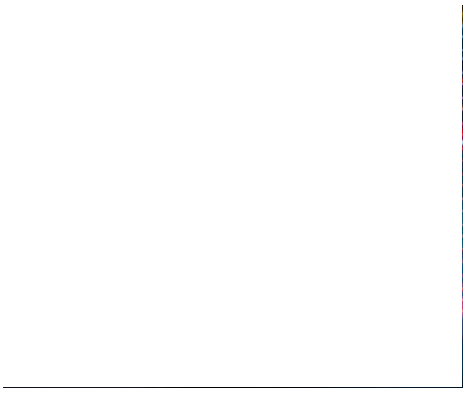
Mar 5th 2024 | WASHINGTON, DC

FEW AREAS of medicine arouse as strong emotions in America as transgender care. The publication this



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Health care | United States

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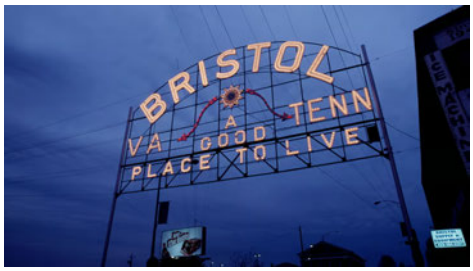

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Intended for healthcare professionals

Feature BMJ Investigation

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

BMJ 2024; 387 doi: https://doi.org/10.1136/bmj.q2227 (Published 30 October 2024) Cite this as: BMJ 2024;387:q2227

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Jennifer Block, freelance journalist
writingblock@protonmail.com

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1,2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2,3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4,5,6,7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in

January, but it provided no details or references regarding the “evidence synthesis” that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO’s statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. “While we welcome the commitment to upholding human rights,” she tells *The BMJ*, “liberalised access to healthcare interventions that might in fact have harmful effects is not actually in support of anyone’s human rights.”

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that “proper evidence reviews have been commissioned to address key questions.” After the June revelations regarding WPATH’s executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the “strong overlap” between the WHO guideline group and WPATH “will have direct negative implications for the credibility of WHO’s own process.” WHO didn’t respond directly to either group.

Reviews “completed and submitted” but not approved

WPATH’s updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having “followed the most rigorous protocol in the world . . . a long and painstaking scientific review process.”[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an “approval process” over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team “completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters,” said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn’t go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13][14] “We had hoped to publish more of those reviews but for a few reasons have not done so,” wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting “reports of reviews (dozens!)” to WPATH, but she added that “we have been having issues with this sponsor trying to restrict our ability to publish.”

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*’s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new “policy and procedures,” which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH’s board. Only then would the Johns Hopkins researchers be given a “green light to be published.”

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, “It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.”

The approval process was to be overseen by the organisation’s president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO’s guideline development group for transgender health and remain members. Neither responded to *The BMJ*’s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its “consensus based” methodology, offering instead to downgrade those recommendations into weaker “suggestions.” But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn’t made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the “evidence based standard of care for the evaluation and treatment of trans individuals.” The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO’s guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. “If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area,” she says, “it may harm WHO’s reputation in other areas of medicine, where its clinical guidance is sorely needed.”

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was “aware of allegations and media reports regarding WPATH” but “does not comment on legal issues involving external organisations.” WHO conducts “careful reviews on conflicts of interest,” it said, and “GDG [guideline development group] members act in their own expert capacity.” Regarding evidence reviews for hormonal treatments, WHO said only that “members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence.”

In late August it provided more detail, telling *The BMJ* that “systematic reviews have been commissioned” to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn’t been made explicit, particularly given all the calls for more transparency. “Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence,” says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn’t locate a public link for the final commission, titled “Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people.”**1819202122232425** The registration details indicate that reviews were started as early as January 2023 and that some commenced months earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, “They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don’t specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition.” Abbruzzese adds, “There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications.”

Ryan also expresses concern that the systematic reviews “fail to examine the impacts” of legal recognition of self-identified gender—which WHO has defined as a health measure—“on any group other than trans and gender diverse people.” Abbruzzese concurs, saying that “research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women’s safety and values and preferences must be a key part of the research.”

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it’s likely to be submitted for inclusion on WHO’s essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO’s Expert Committee that evaluates essential medicine applications, and it’s “likely” to be approved. “Once it goes on the essential medicines list, that obliges governments to supply the drug,” he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn’t bothered by this. “I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them,” he says. While there may be only low quality evidence of benefit, adds Guyatt, “it seems to me a very value and preference sensitive decision.”

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as “the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events.”

“An untenable position”

Robinson of Johns Hopkins pushed back on WPATH’s demands, apparently many times. She wrote to WPATH, “We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018.”

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH’s SOC8 publication process and is now legal evidence, a chapter author wrote, “Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits.” Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as “insufficient evidence” or “limited data”—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that “we found little to no evidence about children and adolescents.” WHO came to a similar conclusion this year, calling the evidence “limited and variable.”**3** Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, “We were told by WPATH leadership that Johns Hopkins couldn’t do a review for the child or

adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

- Provenance: Commissioned; externally peer reviewed.

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v.

JONATHAN SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, *et al.*,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

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Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Cynthia Healey [redacted] >
Sent: Monday, November 25, 2024 12:07 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____cynthia Healey _____ and I am an Oregon _____health care provider_____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Cynthia Healey
Eugene, OR 97405-1636

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Public Comment on 2025 Gender-Affirming Treatment Rule
Date: Tuesday, November 19, 2024 6:28:59 PM

Dear Karen Winkel,

I'm writing to submit a public comment to Oregon's Insurance Commissioner about his proposed rules on gender-affirming treatment. These rules should not be enacted because they go far beyond what the legislature authorized last year in HB2002.

While HB2002 simply required insurers to cover "medically necessary" care prescribed by a licensed provider deferring clinical questions to the medical community, the Insurance Commissioner's proposed rules define "accepted standard of care" as adherence to WPATH-8. WPATH-8 a controversial document developed primarily by transgender rights activists not by impartial scientists or medical professionals. As covered in the New York Times, Economist, The BMJ, and a briefing filed by the Alabama Attorney General with the US Supreme Court, WPATH-8 is heavily influenced by a radical political agenda.

Neither the Insurance Commissioner nor his staff possess any medical expertise or licensure. Their agency regulates financial institutions not healthcare. Furthermore, no licensed health care professionals were included on the advisory committee that helped draft these rules – rules that now define a legally binding clinical standard of care for the practice of medicine regarding individuals experiencing gender distress.

In addition, while the Insurance Commissioner promised the legislature that he would use this new law to require insurers to pay for "detransition" services, the proposed rules are completely silent on this issue. Further, no detransitioners were included in the advisory group that helped write the rules.

I have a transgender student who goes to college at Oregon State University, and thus will be directly impacted by this ruling. I want my adult child to be treated according to best practices, not according to WPATH profiteers who have made their own self-serving rules.

I appreciate your consideration of this matter.

Sincerely,

Fran Hegel

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
10/30/2024 11:50 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2025 Gender-Affirming Treatment Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/19/2024
TIME: 11:00 AM - 12:00 PM
OFFICER: Brooke Hall

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm A, Salem, OR 97301
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 599636230
SPECIAL INSTRUCTIONS:
Meeting ID: 267 195 468 800
Passcode: j3NgqJ

NEED FOR THE RULE(S)

House Bill 2002 (2023) prohibits a carrier offering a health benefit plan from denying or limiting coverage for medically necessary gender-affirming treatment that is prescribed in accordance with accepted standards of care. The bill also prohibits health benefit plans from applying cosmetic or blanket exclusions to medically necessary gender affirming treatment and establishes requirements for notices of adverse benefit determinations and network adequacy.

HB 2002 (2023) requires the Department of Consumer and Business Services (DCBS) to adopt rules to implement these provisions. DCBS convened a Rulemaking Advisory Committee (RAC) which met on Dec. 12, 2023, Jan. 25, Mar. 21, Apr.

25, Jun. 11, Jul. 18, and Aug. 7, 2024. The RAC included insurers, health care providers, consumer and patient advocates. Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

House Bill 2002 (2023)
ORS 743A.325 (4)(b)

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

A Rulemaking Advisory Committee was consulted regarding this equity statement. This rule implements HB 2002, which increases access to gender affirming care. This rule is not anticipated to have any disparate negative impact on any particular demographic of Oregon consumers.

This rule is expected to have a positive impact on equity in the state by increasing access to healthcare services for underserved individuals, particularly for transgender and non-binary individuals, resulting in reduced barriers to necessary medical treatments, enhanced affordability, and improvements in behavioral health and overall well-being for those receiving gender-affirming care.

FISCAL AND ECONOMIC IMPACT:

The rule primarily affects health insurance carriers issuing health benefit plans. The rule mandates that health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.

This training comes with a cost. Based on the information available to the department, the training sessions facilitated by WPATH are priced based on contractual arrangements that depend on factors including the number of participants. DCBS does not have specific information about the number of insurance company employees that will take the training as a result of this rule, so it is not possible to estimate the total cost to affected industry entities. However, since the training can be made available to an insurer's existing reviewers, the training requirement is likely less financially burdensome than alternative approaches that could require hiring or contracting with different or additional reviewers.

The rule will have indirect positive effects on health care providers, including small businesses, to the extent that it requires health insurance carriers to reimburse for services that may not previously have been covered, but the extent of this impact is impossible to estimate from the information available to DCBS.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Based on information currently available to DCBS, the proposed rule would not (or does not have) a fiscal or

economic impact on state agencies, local government units, nor the public.

(2)(a) Based on financial filings made to the Division of Financial Regulation (DFR), no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule will have indirect effects on health care providers, including small businesses, but DCBS does not have access to information to determine the number of small provider organizations that would be affected.

(2)(b) The rule primarily affects health insurance carriers. It does not require additional reporting or recordkeeping activities. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

(2)(c) The rule primarily affects health insurance carriers. Based on the information available to the department, it does not require additional professional services, equipment or supplies. In accordance with the statute, the rule requires carriers to meet certain standards for providers reviewing adverse benefit determinations, which will impose additional administrative costs on carriers. As noted above, the specific cost will depend on the number of employees that take the required training, which cannot be estimated based on information currently available to the department.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rule primarily applies to health insurance carriers. Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. As noted above, the rule has indirect impacts on health care providers, some of whom are small businesses.

Basic Rights Oregon and the Oregon Medical Association were both members of the RAC, serving as advocacy organizations that represent affected small businesses, including independent healthcare providers. The department also received written and oral public comment during the RAC process from small business health care provider representatives.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

ADOPT: 836-053-0441

RULE SUMMARY: A carrier offering a health benefit plan may not deny or limit coverage under the plan, including, but not limited to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and
(b) Prescribed in accordance with accepted standards of care.

CHANGES TO RULE:

836-053-0441
Gender-Affirming Treatment
(1) For purposes of this rule:¶
(a) "Gender-affirming treatment" has the meaning given to that term under ORS 743A.325; and¶
(b) "Accepted standards of care" includes, at a minimum, the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (WPATH-8). ¶
(2) A carrier offering a health benefit plan may not deny or limit coverage under the plan including, but not limited

to denying or limiting coverage of a claim, issuing automatic denials of coverage or imposing additional cost-sharing or other limitations or restrictions on coverage for gender-affirming treatment that is:¶
(a) Medically necessary, as determined by the physical or behavioral health care provider who prescribes the treatment; and¶
(b) Prescribed in accordance with accepted standards of care.¶
(3) Carriers may use utilization review practices to verify adherence to the accepted standards of care described in subsection (2)(b), provided that such practices are consistent with the requirements of this rule, OAR 836-053-1200, and all other applicable provisions of Oregon law. Utilization review practices shall be implemented in a manner that does not unreasonably limit or delay access to care.¶
(4) A carrier offering a health benefit plan may not:¶
(a) Apply a categorical cosmetic or blanket exclusion to medically necessary gender-affirming treatment; or¶
(b) Exclude, as a cosmetic service, a medically necessary procedure prescribed by a physical or behavioral health care provider as gender-affirming treatment, including but not limited to: ¶
(A) Tracheal shave;¶
(B) Hair electrolysis; ¶
(C) Facial feminization surgery or other facial gender-affirming treatment; ¶
(D) Revisions to prior forms of gender-affirming treatment; or¶
(E) Any combination of gender-affirming treatment procedures.¶
(5) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must ensure that the adverse benefit determination is reviewed and approved in accordance with the following requirements: ¶
(a) The adverse benefit determination is reviewed by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.¶
(b) To demonstrate experience the reviewing provider must:¶
(A) Meet the criteria for external medical review found in OAR 836-053-1325(6)(b)(A-C);¶
(B) Have experience utilizing the WPATH-8; and¶
(C) Have completed the WPATH SOC-8 Health Plan Providers training program or an equivalent training program.¶
(c) This subsection (5) does not apply to an adverse benefit determination that only involves the application of cost-sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment. ¶
(6) In the event of an adverse benefit determination that denies or limits coverage for gender-affirming treatment, the carrier must meet all the requirements in:¶
(a) ORS 743B.250, and if requested under ORS 743B.250(2)(h)(B), disclosure of the identity of the physical or behavioral health care provider who reviewed the determination, which at a minimum includes information to demonstrate experience prescribing or delivering gender-affirming treatment:¶
(A) The provider's job title and specific role in the review process; and¶
(B) The provider's specialty, board certification status, and any other relevant qualifications that affirm their experience in gender-affirming treatment.¶
(b) OAR 836-053-1030; and¶
(c) OAR 836-053-1100. ¶
(7) Carriers offering health benefit plans shall:¶
(a) Satisfy any network adequacy standards under ORS 743B.505 related to gender-affirming treatment providers; and¶
(b)(A) Contract with a network of gender-affirming treatment providers that is sufficient in numbers and geographic locations to ensure that gender-affirming treatment services are accessible to all enrollees without unreasonable delay; or¶
(B) Ensure that all enrollees have geographical access without unreasonable delay to out-of-network gender-affirming treatment services with cost-sharing or other out-of-pocket costs for the services no greater than the cost-sharing or other out-of-pocket costs for the services when furnished by an in-network provider, and meet all the requirements in:¶
(i) OAR 836-053-1030;¶
(ii) OAR 836-053-1035; and¶
(iii) OAR 836-053-1408.
Statutory/Other Authority: ORS 731.244, ORS 743A.325
Statutes/Other Implemented: ORS 743A.325

2023 Regular Session

HB 2002 Enrolled
(/liz/2023R1/Downloads/MeasureDocument/HB2002)

Overview

At the request of:

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Bill Title:	Relating to health; and declaring an emergency.
Catchline/Summary:	Modifies provisions relating to reproductive health rights.
Chapter Number:	Chapter 228
Fiscal Impact:	Fiscal Impact Issued
Revenue Impact:	No Revenue Impact
Measure Analysis:	Staff Measure Summary / Impact Statements (/liz/2023R1/Measures/Analysis/HB2002)
Current Location:	Chapter Number Assigned

Current Committee: ()

Current Subcommittee:

Subsequent Referral(s):

Potential Conflicts of Interest/Vote Explanations: Potential Conflicts of Interest/Vote Explanation Documents (https://www.oregonlegislature.gov/pcive/Forms/Display.aspx?View={F16B1F7B-33C4-4EA7-9D3022EE155C}&FilterField1=Session&FilterValue1=2023R1&FilterField2=Measure&Filter\

Measure History ❯

Scheduled Events ❯

Standards of Care Version 8

VIEW THE SOC8 HERE (OPEN ACCESS)

SOC8

SOC8 publication is complete. Please follow the link below to view the document.

As new translations become available, we will add to this page. Currently listed are: Bosnian, Czech, Croatian, French, Georgian, Italian, Korean, Mandarin, Montenegrin, Norwegian, Portuguese, Spanish, Thai, and Ukrainian.

VIEW SOC8 CHAPTERS

VIEW SOC8 TRANSLATION PAGE

History and Purpose

The field of transgender healthcare is a rapidly evolving interdisciplinary field. The last few years have seen a globally unprecedented increase and visibility of transgender and gender diverse people seeking support . . .

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CHAIRS & LEAD EVIDENCE TEAM

Establishing the SOC8 Revision Committee

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select

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Methodology for the Development of SOC8

Following the publication of the SOC8, in the future, unless there is a major need to adapt the entire document, small adaptations/addendums can take place, if/when new data is available that will affect specific recommendations . . .

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Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show

Newly released emails from an influential group issuing transgender medical guidelines indicate that U.S. health officials lobbied to remove age minimums for surgery in minors because of concerns over political fallout.

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By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for

By Azeen Ghorayshi

June 25, 2024

Health officials in the Biden administration pressed an international group of medical experts to remove age limits for adolescent surgeries from guidelines for care of transgender minors, according to newly unsealed court documents.

Age minimums, officials feared, could fuel growing political opposition to such treatments.

Email excerpts from members of the World Professional Association for Transgender Health recount how staff for Adm. Rachel Levine, assistant secretary for health at the Department of Health and Human Services and herself a transgender woman, urged them to drop the proposed limits from the group's guidelines and apparently succeeded.

If and when teenagers should be allowed to undergo transgender treatments and surgeries has become a raging debate within the political world. Opponents say teenagers are too young to make such decisions, but supporters including an array of medical experts posit that young people with gender dysphoria face depression and worsening distress if their issues go unaddressed.

United States | The WPATH files

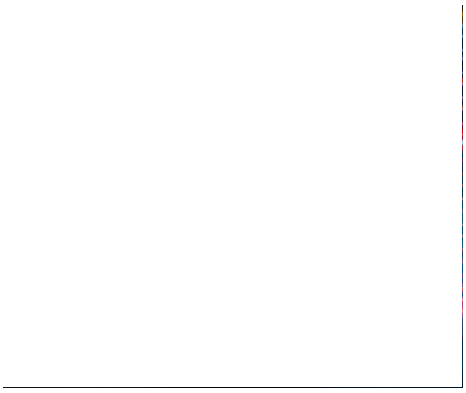
Leaked discussions reveal uncertainty about transgender care

The files shed light on a controversial area of medicine that has largely retreated into the shadows

ILLUSTRATION: NATHALIE LEES

Mar 5th 2024 | WASHINGTON, DC

FEW AREAS of medicine arouse as strong emotions in America as transgender care. The publication this



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Health care | United States

United States
March 9th 2024

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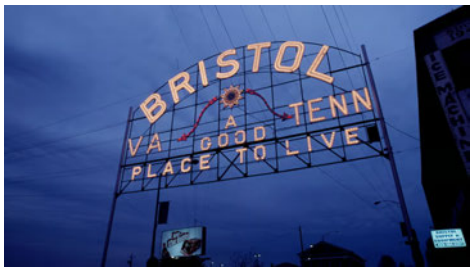

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Intended for healthcare professionals

Feature BMJ Investigation

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

BMJ 2024; 387 doi: https://doi.org/10.1136/bmj.q2227 (Published 30 October 2024) Cite this as: BMJ 2024;387:q2227

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Jennifer Block, freelance journalist
writingblock@protonmail.com

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1,2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2,3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4,5,6,7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in

January, but it provided no details or references regarding the “evidence synthesis” that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO’s statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. “While we welcome the commitment to upholding human rights,” she tells *The BMJ*, “liberalised access to healthcare interventions that might in fact have harmful effects is not actually in support of anyone’s human rights.”

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that “proper evidence reviews have been commissioned to address key questions.” After the June revelations regarding WPATH’s executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the “strong overlap” between the WHO guideline group and WPATH “will have direct negative implications for the credibility of WHO’s own process.” WHO didn’t respond directly to either group.

Reviews “completed and submitted” but not approved

WPATH’s updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having “followed the most rigorous protocol in the world . . . a long and painstaking scientific review process.”[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an “approval process” over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team “completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters,” said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn’t go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13][14] “We had hoped to publish more of those reviews but for a few reasons have not done so,” wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting “reports of reviews (dozens!)” to WPATH, but she added that “we have been having issues with this sponsor trying to restrict our ability to publish.”

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*’s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new “policy and procedures,” which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH’s board. Only then would the Johns Hopkins researchers be given a “green light to be published.”

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, “It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.”

The approval process was to be overseen by the organisation’s president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO’s guideline development group for transgender health and remain members. Neither responded to *The BMJ*’s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its “consensus based” methodology, offering instead to downgrade those recommendations into weaker “suggestions.” But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn’t made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the “evidence based standard of care for the evaluation and treatment of trans individuals.” The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO’s guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. “If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area,” she says, “it may harm WHO’s reputation in other areas of medicine, where its clinical guidance is sorely needed.”

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was “aware of allegations and media reports regarding WPATH” but “does not comment on legal issues involving external organisations.” WHO conducts “careful reviews on conflicts of interest,” it said, and “GDG [guideline development group] members act in their own expert capacity.” Regarding evidence reviews for hormonal treatments, WHO said only that “members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence.”

In late August it provided more detail, telling *The BMJ* that “systematic reviews have been commissioned” to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn’t been made explicit, particularly given all the calls for more transparency. “Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence,” says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn’t locate a public link for the final commission, titled “Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people.”**1819202122232425** The registration details indicate that reviews were started as early as January 2023 and that some commenced months earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, “They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don’t specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition.” Abbruzzese adds, “There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications.”

Ryan also expresses concern that the systematic reviews “fail to examine the impacts” of legal recognition of self-identified gender—which WHO has defined as a health measure—“on any group other than trans and gender diverse people.” Abbruzzese concurs, saying that “research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women’s safety and values and preferences must be a key part of the research.”

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it’s likely to be submitted for inclusion on WHO’s essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO’s Expert Committee that evaluates essential medicine applications, and it’s “likely” to be approved. “Once it goes on the essential medicines list, that obliges governments to supply the drug,” he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn’t bothered by this. “I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them,” he says. While there may be only low quality evidence of benefit, adds Guyatt, “it seems to me a very value and preference sensitive decision.”

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as “the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events.”

“An untenable position”

Robinson of Johns Hopkins pushed back on WPATH’s demands, apparently many times. She wrote to WPATH, “We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018.”

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH’s SOC8 publication process and is now legal evidence, a chapter author wrote, “Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits.” Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as “insufficient evidence” or “limited data”—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that “we found little to no evidence about children and adolescents.” WHO came to a similar conclusion this year, calling the evidence “limited and variable.”**3** Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, “We were told by WPATH leadership that Johns Hopkins couldn’t do a review for the child or

adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

- Provenance: Commissioned; externally peer reviewed.

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JONATHAN SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, *et al.*,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

BRIEF OF ALABAMA AS *AMICUS CURIAE* SUPPORTING STATE RESPONDENTS

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WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.....39

WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.....29

WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K 10

Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.....32

INTEREST OF *AMICUS CURIAE*

Like Tennessee and half the other States,[1] Alabama determined that sex-change procedures should not be made available to kids. That legislative determination should not be controversial. Until a few years ago, the notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized.

How did we get here? Alabama has at least part of the answer. Through years of litigation defending its own age limits against challenges by private plaintiffs and the United States, Alabama has exposed a medical, legal, and political scandal that will be studied for decades to come. The federal government, "social justice lawyers" from prominent activist organizations, and self-appointed experts at the World Professional Association for Transgender Health (WPATH) conspired to abolish age limits for sterilizing chemical treatments and surgeries. Central to their strategy was the WPATH Standards of Care 8 (SOC-8)[2]—a purportedly evidence-based set of recommendations that would be used by their lawyers to convince courts to enshrine in law the previously unimaginable.

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[1] Equality Map (Oct. 10, 2024), https://perma.cc/L46X-NSUR.

[2] Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022).

Their job wasn't easy. When WPATH hired Johns Hopkins to review the evidence behind permanently altering children's bodies to address gender confusion, the team "found little to no evidence about children and adolescents," a fact shared with (and privately acknowledged by) the federal government.[3] Perhaps for that reason, WPATH suppressed publication of most of those reviews. Some SOC-8 authors opted to conduct no systematic evidence reviews precisely because doing so would "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[4] And after finalizing SOC-8, WPATH shared a copy with Admiral Rachel Levine, the Assistant Secretary for Health at the U.S. Department of Health and Human Services. Levine demanded that WPATH remove from the guideline *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged.

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[3] *See* Defs' Ex. 173 at 22, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.), Doc. 560-23.

Throughout this brief, Alabama will reference evidence and briefing it submitted to the district court. Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186(Doc.700-15):32.

The strategy for "winning lawsuits" was initially a success. Like Tennessee, Alabama had its law preliminarily enjoined.[6] And like Tennessee, Alabama had its legislative determination overruled by the United States' appeal to the imprimatur of WPATH. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the Alabama court dismissed the Legislature's concerns with two words: "Nevertheless, WPATH."[7] "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments," and interest groups like the American Medical Association and the American Academy of Pediatrics "endorse" the WPATH "guidelines as evidence-based methods for treating gender dysphoria in minors."[8] Because Alabama did not defer to those guidelines, the court held, its law to the contrary had to be enjoined.[9]

Alabama later obtained discovery from WPATH and HHS to test the court's deference.[10] Since Alabama's case was about a year ahead of Tennessee's, discovery in Alabama was winding down when the

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[6] *See Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

[7] *Eknes-Tucker*, 603 F. Supp. 3d at 1139.

[8] *Id.*

[9] *Id.* at 1145, 1148.

[10] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery), Doc.261 (ordering HHS to produce discovery).

Sixth Circuit ruled in *Skrmetti*. As Alabama noted at the time, the United States was a party in both cases and knew from its overlapping attorneys that Alabama's case would soon be headed to trial on a fully developed record.[11] Yet the Department of Justice seemed to strategically choose to seek certiorari in a case with only a preliminary record and no discovery—and then tried to shut down discovery in Alabama on the basis that it had merely filed a cert petition here.[12] Fortunately, the court in Alabama denied the United States' motion and allowed discovery to conclude. Alabama then moved for summary judgment (proceedings are now stayed pending the Court's decision here), and the court unsealed portions of the evidentiary exhibits.

The new evidence suggests clear reasons for why the United States acted as it did—and why it continues to oppose unsealing other evidence Alabama received. Discovery uncovered that not only does the WPATH emperor have no clothes but that senior HHS officials and "social justice lawyers" acted as the organization's tailor. Alabama submits this brief to discuss just some of that evidence showing why the Court should not constitutionalize the WPATH standards.

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[11] *See* Brief of Alabama as *Amicus Curiae* at 1-2, No. 23-477, *United States v. Skrmetti* (U.S. Feb. 2, 2024).

[12] *See* United States' Mot. to Stay All District Court Proceedings, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 4, 2023), Doc. 387.

SUMMARY OF ARGUMENT

As part of her independent review for England's National Health Service, Dr. Hilary Cass commissioned a team of researchers to assess the various guidelines for treating gender dysphoria in minors. They found that all the guidelines that recommended sex-change procedures for minors flunked the "bedrock" criterion of developmental rigor.[13] The researchers also found that those guidelines were really WPATH's all the way down: WPATH authored the initial guideline, which other groups used as the basis for their recommendations, which WPATH then cited as "evidence" for the next edition of its guideline.[14] "The circularity of this approach," Dr. Cass concluded, "may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[15]

There is another "circularity" at work. While the United States points to WPATH's "evidence-based guidelines" to support its disagreement with Tennessee's law, U.S.Br.3, it fails to disclose its own role in the creation of those guidelines—and that its interference caused WPATH authors to complain of "making changes based on current US politics."[16]

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[13] *Cass Review* 126-30 (Apr. 2024), https://perma.cc/3QVZ-9Y52.

[14] *Id.*; *see* Taylor, *Clinical Guidelines for Children and Adolescents*, ARCH. DIS. CHILD 6 (2024), https://perma.cc/2NWP-XKBJ.

[15] *Cass Review*, *supra* note 13, at 130.

[16] Ex.186(Doc.700-15):32.

The United States also ignores its recent and unexplained about-face regarding sex-change surgeries on children. Two years ago, the United States sought to enjoin Alabama's age limits on sex-change surgeries, alleging that for some children "surgery is essential and medically necessary to alleviate gender dysphoria."[17] But then on June 25, 2024, reporting showed that Biden Administration officials had pressured WPATH to remove age limits from its guideline.[18] A few days later, the United States declared that it now also "oppose[s] gender-affirming surgery for minors."[19] Having read the political winds (and reasonably concluded that it didn't wish to bring a surgery case to this Court), the United States glides over its significant departure from SOC-8, which continues to recommend transitioning surgeries like orchiectomy (removal of testicles) and vaginoplasty (inversion of penis to create faux vagina) for minors.[20] Likewise, the United States never explains why age limits for sterilizing surgeries are okay, while age limits for sterilizing chemical treatments are not.

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[17] U.S. Am. Compl., *Boe*, 2:22-cv-184 (M.D. Ala. May 4, 2022), Doc.92 ¶39.

[18] Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery*, N.Y. TIMES (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[19] Rabin, *Biden Administration Opposes Surgery for Transgender Minors*, N.Y. TIMES (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

[20] *See* SOC-8, *supra* note 2, at S48.

The United States is also mum about other influences on SOC-8. As it learned in discovery (if not before), some WPATH authors, acting on the advice of "social justice lawyers we spoke with," intentionally chose *not* to seek a systematic review of the evidence before making treatment recommendations.[21] The reason? Because "evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[22] Other contributors drew on their experiences as expert witnesses in cases like this one to suggest removing "language such as 'insufficient evidence,' 'limited data,' etc." that could "empower" groups "trying to claim that gender-affirming interventions are experimental."[23] The WPATH Board also had litigation in mind, commissioning one of the plaintiff's lawyers in Alabama's case to conduct a legal review of SOC-8.[24] As a former president of WPATH explained, such review was "necessary" "because we will have to argue it in court at some point."[25] So they have. *See* Amicus Br. of AAP, WPATH et al. 8 (asking Court to defer to WPATH guideline).

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[21] Ex.174(Doc.560-24):1-2.

[22] *Id.*

[23] Ex.184(Doc.700-13):55.

[24] *See* SOC-8, *supra* note 2, at S177 (thanking Jennifer Levi for offering "Legal Perspectives"); Jennifer Levi, *GLAD, Legal Advocates & Defenders*, https://www.glad.org/staff/jennifer-levi/.

[25] Ex.182(Doc.700-11):152.

Then there is the lack of evidence underlying the United States' preferred guideline. The federal government promises that SOC-8 is "evidence-based." U.S.Br.3. But well before the United States made that representation, officials at HHS received word from the SOC-8 evidence review team that it "found little to no evidence about children and adolescents"—and that WPATH was "trying to restrict [its] ability to publish" the findings.[26] The United States wrote back to confirm: "Knowing that there is little/no evidence about children and adolescents is helpful."[27] Yet when seeking certiorari, the United States said the exact opposite, assuring this Court that giving gender dysphoric kids "puberty blockers and hormones" was supported by "overwhelming evidence." U.S.Pet.7.

The WPATH scandal confirms the wisdom of leaving policy disagreements to political branches. When courts transfer political power from legislatures to self-appointed experts, they don't end political disputes; they just move them from democratically accountable bodies to opaque institutions. And by conferring such power on these "expert" groups, courts incentivize turning those institutions into sites and then "weapons of political warfare" for those seeking "victories" in court "that elude[] them in the political arena."[28] Power is still exercised, but it's less clear who is pulling the levers, how, or why. That lack of accountability here led to serious abuses, helping

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[26] Ex.173(Doc.560-23):22-23.

[27] *Id.* at 22.

[28] *Alexander v. S.C. State Conf. of the NAACP*, 144 S. Ct. 1221, 1236 (2024).

create what Dr. Cass described as the only "area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[29]

Yet the United States and WPATH press on, pretending the science is settled, the debate over. They assure anxious parents that sex-change procedures are the only way to help their 13-year-old daughter feeling uncomfortable in her body, and they pose impossible questions to kids who must decide whether to alter their bodies and risk their future fertility by treating their psychological ailments with hormones and surgeries—all before they are old enough to vote. Thankfully, the Tennessee Legislature acted. Kids suffering from gender dysphoria deserve better. In areas like this, "legislative options must be especially broad and courts should be cautious not to rewrite legislation."[30] The Constitution does not mandate that States bow to the dictates of radical interest groups like WPATH. The Court should affirm.

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[29] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024).

[30] *Marshall v. United States*, 414 U.S. 417, 427 (1974).

ARGUMENT

The United States tells the Court that WPATH is "the leading association of medical professionals treating transgender individuals" and that its SOC-8 is "the accepted standard of care for treating gender dysphoria." U.S.Br.3. But the United States has long known there is much more to the story. It could tell how the United States and "social justice lawyers" influenced the SOC-8 for political ends. How WPATH failed to follow the principles of evidence-based medicine it told the world it obeyed. How WPATH has long prioritized advocacy over scientific inquiry. But the United States stays silent because episodes like these reveal just how empty is its argument that the Constitution empowers groups like WPATH, rather than the open political process, to regulate medicine.

I. WPATH, Joined By The United States And "Social Justice Lawyers," Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 in September 2022. Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[31] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon

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[31] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; SOC-8, *supra* note 2, at S248-49.

in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[32] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[33] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[34] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[35] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been

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[32] SOC-8, *supra* note 2, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[33] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

[34] Ex.21(Doc.700-3):158:17-25.

[35] Ex.184(Doc.700-13):24.

critical to our successes, and I hope the same will hold for Version 8."[36]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[37]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[38] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[39] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health the following week.[40] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[41]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[42]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's

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[36] Ex.184(Doc.700-13):15.

[37] Ex.182(Doc.700-11):152.

[38] Ex.4(Doc.557-4):vi.

[39] Ex.182(Doc.700-11):151.

[40] *Id.* at 150-51.

[41] Ex.184(Doc.700-13):14.

[42] SOC-8, *supra* note 2, at S177; *see supra* note 24.

embodiment goals,"[43] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[44] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[45] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[46]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[47] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and

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[43] Ex.180(Doc.700-9):11.

[44] *Id.* at 64.

[45] Ex.181(Doc.700-10):43.

[46] *Id.* at 75.

[47] *Id.* at 66; *see also id.* at 1 (Another author commented: "In essence, the [medical necessity statement] should apply to any trans and gender diverse person, independent of age [and independent of diagnosis]. The problem is—of course—as we all know—that medical practice is based on a diagnosis … so—being a pragmatic person, if anyone can think of a way of avoiding the use of diagnostic criteria please come with suggestions ….").

body contouring"; and "puberty blocking medication and gender-affirming hormones."[48]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[49]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[50] but WPATH never pauses to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position

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[48] SOC-8, *supra* note 2, at S18.

[49] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[50] SOC-8, *supra* note 2, at S45-46.

in terms of affecting policy or winning lawsuits."[51] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[52] all while authors and WPATH leaders raised such concerns internally.[53]

B. The United States Used SOC-8 to Advance Political and Legal Goals.

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[54] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[55]

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[51] Ex.174(Doc.560-24):1-2.

[52] Ex.184(Doc.700-13):55.

[53] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[54] Ex.184(Doc.700-13):54. Evidence indicates that Levine met or communicated with WPATH leaders about SOC-8 on August 12, August 26, and November 22, 2021; and May 2, May 31, June 10, July 1 (at least Levine's chief of staff), July 26, August 5, August 8, and September 3, 2022. *See Boe.*Reply (Doc.700-1) at 61 n.145 (collecting sources).

[55] Ex.184(Doc.700-13):54.

Another member reported: "I am meeting with Rachel Levine and her team," "as the US Department of Health is very keen to bring the trans health agenda forward."[56]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[57]), WPATH sent Admiral Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[58] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[59] (That guidance was not generally followed by American surgeons affiliated with WPATH—including Dr. Bowers—but that was the guidance.[60]) The draft SOC-

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[56] Ex.185(Doc.700-14):1.

[57] *See* Ex.187(Doc.700-16):4-5.

[58] Ex.170(Doc.700-4):61-64.

[59] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[60] According to a 2017 paper published by Dr. Karasic, over half of the WPATH-affiliated surgeons surveyed said they "[p]erformed vaginoplasty on [a] transgender minor" in the United States, despite SOC-7 requiring surgeons to "defer orchiectomy and/or vaginoplasty until 18 years of age." Milrod & Karasic, *Age is Just a Number*, 14 J. SEXUAL MED. 624, 625-26 (2017). Dr. Bowers admitted to first performing a "trans-feminine vaginoplasty" "on a patient younger than 18" in "the late 2000s." Ex.18(Doc.564-8):34:19-24. Bowers performed the surgery before knowing of *any* medical literature discussing clinical outcomes of transitioning surgeries for minors. *Id.* at 34:19–36:25. Bowers

8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[61] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age: "unless there are significant, compelling reasons to take an individualized approach when considering the factors unique to the adolescent treatment time frame."[62]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[63] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[64] WPATH leaders met with Levine and HHS officials to discuss

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said it was a "chicken and the egg question" about whether "evidence from adult populations" applied to minors, so someone would have to perform the surgery on a minor to find out if it is a good idea to perform the surgery on a minor. *Id.* Yet Bowers did not conduct the surgery as part of a formal research protocol and never published any findings about how the patient fared. *Id.*; *Boe*.Reply(Doc.700-1):18 n.31.

[61] Ex.170(Doc.700-4):143.

[62] *Id.*

[63] Ex.186(Doc.700-15):28.

[64] *Id.* at 29.

the age recommendations.[65] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[66] Levine's solution was simple: "She asked us to remove them."[67]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[68]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[69]
- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[70]
- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political

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[65] *See* Ex.186(Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[66] Ex.186(Doc.700-15):11.

[67] *Id.*

[68] *Id.* at 32.

[69] *Id.*

[70] *Id.*

> issues are even a thing and are impacting our own discussions and strategies."[71]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[72] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[73]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[74] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[75]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[76] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same,"[77]

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[71] *Id.* at 33.

[72] *Id.* at 17.

[73] *Id.* at 57.

[74] *Id.* at 17.

[75] *See* Ex.18(Doc.564-8):226:8–229:18; *Boe.*MSJ(Doc.619):20; Ex.186(Doc.700-15):73, 88-91; *supra* note 54.

[76] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").

[77] *Id.* at 100.

while Dr. Bouman "struggle[d] to find any sound evidence-based argument(s)" in AAP's comments and was "surprised that a 'reputable' association as the AAP is so thin on scientific evidence."[78] But then the political reality set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[79] WPATH thus caved and "agreed to remove the ages."[80]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. "Given the complexity of" that procedure, SOC-8 states, "it is not recommended this surgery be considered in youth under 18 at this time."[81] WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[82]

That is concerning enough. But perhaps even more worrisome is what the episode revealed. *First*, it showed that both the United States and AAP sought, and WPATH agreed, to make changes in a clinical

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[78] *Id.* at 107.

[79] *Id.* at 191.

[80] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[81] SOC-8, *supra* note 2, at S66.

[82] *See* SOC-8, *supra* note 2, at S66.

guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums "without being presented any new science of which the committee was previously unaware."[83] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing authors] in three rounds),"[84] WPATH did not send the last-minute change through Delphi.[85] Instead, it treated its decision as "highly, highly confidential."[86]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[87] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[88] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[89]

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[83] Ex.21(Doc.700-3):293:25–295:16.

[84] SOC-8, *supra* note 2, at S250 (emphasis added).

[85] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").

[86] Ex.188(Doc.700-17):152.

[87] *Id.* at 120.

[88] Ex.177(Doc.700-6):124.

[89] *Id.* at 119.

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[90] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[91] Apparently, it didn't matter that the explanation itself could be considered "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[92]

Third, when evidence of Levine's tinkering became public,[93] the federal government immediately flipped positions and "opposed gender-affirming surgery for

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[90] Ex.188(Doc.700-17):113.

[91] *Id.*

[92] Ex.177(Doc.700-6):102. At deposition, Bowers performed another "balancing act," proclaiming that WPATH "opted to remove" the age minimums to "fall back to the more conservative SOC-7 language" that expressly prohibited most surgeries for adolescents. *See* Ex.18(Doc.564-8):115:15-16; *Boe*.Reply(Doc.700-1):2. That is an interesting position given that SOC-8 expressly *recommends* surgeries like "orchiectomy, vaginoplasty, hysterectomy, phalloplasty, [and] metoidioplasty" that SOC-7 prohibited. SOC-8, *supra* note 2, at S48.

[93] Ghorayshi, *supra* note 18.

minors."[94] But it has yet to explain either (1) its past support for such surgeries (even to the point of pressuring WPATH (and suing Alabama) to make them available for kids of any age),[95] or (2) its current disagreement with the very guideline it tells this Court is evidence-based and "reflect[s] the accepted standard of care for treating gender dysphoria." U.S.Br.3.

Given that WPATH's hormonal and surgical recommendations for adolescents are in the same chapter and based on much of the same evidence, this is a serious problem for the United States. Either WPATH is reliable when it says that surgeries are "medically necessary" for gender dysphoric adolescents, or it is not. If the United States agrees with the WPATH position, it should say so—and then explain whether it thinks a public hospital's decision to limit "penile-inversion vaginoplasty" surgeries to males would be a sex-based classification warranting heightened scrutiny. And if it disagrees with WPATH's recommendation, it should explain why it has nonetheless suggested the guideline to the Court as the constitutional standard—and why it believes the federal government can take and leave parts of that standard but Tennessee cannot. Either way, the United States owes the Court an explanation.

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[94] Rabin, *supra* note 19.

[95] U.S. Am. Compl., *supra* note 17, ¶39 ("surgery is essential and medically necessary to alleviate gender dysphoria").

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[96] It is this appendix that the "Clinical Practice Guideline Experts" rely on—"exclusively"—to assure the Court that "WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound." *See* Brief of *Amici Curiae* Clinical Practice Guideline Experts at 6, 8 n.17.[97] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[98] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international standards it said it used to manage conflicts of interest: one from the

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[96] *See* SOC-8, *supra* note 2, at S247-51.

[97] *Amici*'s purportedly blind reliance on WPATH's appendix is curious because at least two of the *amici*—Dr. Goodman and Dr. Lightdale—serve as expert witnesses for the plaintiffs in Alabama's case and were confronted months ago with evidence that WPATH did *not* do what it said it did. *See generally* Ex.69(Doc.564-26); Ex.74(Doc.564-32); *Boe* Mot. to Exclude Testimony of Dr. Lightdale (Doc.606-3); *Boe* Mot. to Exclude Testimony of Dr. Goodman (Doc.606-4).

[98] SOC-8, *supra* note 2, at S247-50.

National Academies of Medicine and the other from the World Health Organization.[99] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[100] Dr. Cass is a good example: When appointed to conduct the review for England's National Health Service, she was a well-respected pediatrician, but not one who made a living by providing transitioning treatments to minors.[101]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[102] Accordingly, they suggest ways for committees

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[99] *Id.* at S247.

[100] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[101] Though Dr. Cass is a good example of a disinterested expert used to evaluate an area of medicine she does not make a living by providing, it is important to note that the Cass Review itself is not a clinical guideline and does not pretend to be. *See* Cheung, *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U (responding to critiques of the Cass Review by Dr. Meredithe McNamara and others, *see* Br. for *Amici Curiae* Expert Researchers and Physicians).

[102] Institute of Medicine, *supra* note 100, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as

to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[103]

Yet aside from citing them in its methodology section, it appears that WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[104] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[105] Dr. Bowers agreed it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[106]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably

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relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

[103] *Id.* (emphasis added).

[104] SOC-8, *supra* note 2, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[105] Ex.21(Doc.700-3):228:14-19.

[106] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[107] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" last year from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[108] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[109]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[110] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[111] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing

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[107] Institute of Medicine, *supra* note 100, at 78.

[108] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.

[109] SOC-8, *supra* note 2, at S177.

[110] Ex.21(Doc.700-3):230:17-23.

[111] Ex.174(Doc.560-24):7.

interests."[112] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[113] "Unfortunately," she lamented, "this was not done here."[114] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[115]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[116]

B. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[117] According to WPATH, Dr. Robinson's evidence review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[118]

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[112] Ex.166(Doc.560-16):1.

[113] *Id.* (emphasis added).

[114] *Id.*

[115] SOC-8, *supra* note 2, at S177.

[116] Ex.21(Doc.700-3):232:13-15.

[117] SOC-8, *supra* note 2, at S250.

[118] *Id.* at S249-50.

Chapter authors were then to grade the recommendation statements based on the evidence.[119] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[120] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[121] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[122]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[123] Dr. Karasic, the chair of the mental health chapter, testified that rather than

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[119] *Id.* at S250.

[120] *Id.*

[121] *Id.*

[122] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).

[123] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

relying on systematic reviews, some drafters simply "used authors … we were familiar with."[124]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[125] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[126]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[127]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[128]

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[124] Ex.39(Doc.592-39):66:2–67:5.

[125] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[126] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[127] SOC-8, *supra* note 2, at S48.

[128] *Id.* at S46-47. In fact, as the United States' expert Dr. Antommaria testified, "a systematic review is always possible." Ex.43(Doc.557-43):134:25–135:3. But WPATH may have had

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[129]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the evidence available.[130] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based

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other incentives for its statement: One of the literature reviews that Johns Hopkins was able to publish—discussed more below, *supra* II.C—found that "[a]mong adolescents" there was "no difference in [quality of life] scores after a year of endocrine interventions" and determined that the "strength of evidence" in this area was "low." Baker, *Hormone Therapy, Mental Health, and Qualify of Life*, 5 J. ENDOCRINE SOC'Y 1, 8 (2021). WPATH strongly recommends the interventions anyway. *See* SOC-8 at S111.

[129] SOC-8, *supra* note 2, at S111.

[130] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5. Given this definition, it is perhaps unsurprising that for all its emphasis (at 20) on GRADE categories having "highly technical meanings," the Brief for *Amici Curiae* Expert Researchers never tells the Court just what "low quality" and "very-low quality" means.

on low-quality evidence.[131] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them,[132] the Johns Hopkins evidence review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[133] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[134] She reported: "[W]e found little to no evidence about children and adolescents."[135] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[136]

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[131] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[132] As of May 2024, Dr. Bowers—the current president of WPATH who regularly publicly advocates for transitioning treatments (and surgeries) for kids—*still* had not seen any evidence reviews conducted for SOC-8. Ex.18(Doc.564-8):185:4-6, 292:12–293:10; *Boe*.Reply(Doc.700-1):58.

[133] Ex.173(Doc.560-23):22-25.

[134] *Id.* at 24.

[135] *Id.* at 22.

[136] *Id.*

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[137] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[138] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[139] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[140] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[141]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the

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[137] *Id.*

[138] Ex.167(Doc.560-17):86-88.

[139] *Id.* at 75-81.

[140] *Id.* at 37 (emphasis added).

[141] *Id.* at 38.

broadest sense" (again, as WPATH defined it).[142] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[143]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[144]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[145]

D. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[146] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[147]

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[142] *Id.* at 91.

[143] *Id.* at 38.

[144] *Cf.* Ex.167(Doc.560-17):91 ("We were caught on the wrong foot when the Johns Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data….").

[145] Baker, *supra* note 128, at 3; *see* Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. OF TRANSGENDER HEALTH 391, 392 (2020).

[146] SOC-8, *supra* note 2, at S88.

[147] *Id.* at S88-89.

That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[148]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[149] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[150] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[151] No matter: The guideline the United States says States must adopt officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[152] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[153] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary

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[148] Ex.21(Doc.700-3):172:19–173:25.

[149] *Id.*

[150] Ex.182(Doc.700-11):96.

[151] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[152] SOC-8, *supra* note 2, at S88.

[153] *Id.*

eunuch-identified people."[154] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[155] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[156]

Despite all this, the medical interest groups supporting Petitioner still claim that the WPATH guideline "follow[ed] the same types of processes … as other guidelines promulgated by *amici* and other medical organizations." Br. of AAP et al. 15. Let's hope not.

III. WPATH Acts Like An Advocacy Organization, Not A Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[157]) That was evident after SOC-8 was published, when Dr. Coleman circulated an

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[154] *Id.*

[155] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[156] *Id.*

[157] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

internal "12-point strategic plan to advance gender affirming care."[158] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[159]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[160] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[161] He suspected that organizations had only "referenced" the guideline, but "never formally endorsed" it.[162]

Dr. Coleman and other WPATH leaders thus made a concerted effort to obtain formal endorsements from

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[158] Ex.190(Doc.700-18):5 (capitalization altered).

[159] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[160] Ex.190(Doc.700-18):5-6.

[161] *Id.*

[162] *Id.* at 6 (spelling corrected).

other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[163] The AAP, Dr. Coleman said, rejected WPATH's request.[164] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[165] (That didn't stop AMA from filing an amicus brief here based on its purported "specific expertise." *See* Br. of AAP et al. 1-2.) The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[166]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[167] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic

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[163] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[164] Ex.21(Doc.700-3):261:20-23 ("the American Academy of Pediatrics has never endorsed SOC-8"); Ex.188(Doc.700-17):152.

[165] Ex.189(Doc.560-39):15.

[166] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[167] Cheung, *supra* note 101, at 2.

reviews tha[n] the Cass Review."[168] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings; WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public; and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[169] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[170] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender

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[168] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[169] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[170] *See generally* Ex.16(Doc.557-16).

dysphoria have the dysphoria "desist" by adulthood.[171] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[172] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[173] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[174]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[175]

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[171] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[172] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[173] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[174] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[175] Ex.176(Doc.700-5):152.

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Much more could be said about how untrustworthy the United States' favorite medical organization is.[176] But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a presurgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.… It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer.…[177]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer,

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[176] *See* Brief of Alabama, *supra*, at 9-24; *Boe*.Reply(Doc.700-1):20-80.

[177] Ex.176(Doc.700-5):68.

or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[178]

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

Steve Marshall
Attorney General
Edmund G. LaCour Jr.
Solicitor General
Counsel of Record
A. Barrett Bowdre
Principal Deputy Solicitor General
STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL
501 Washington Avenue
P.O. Box 300152
Montgomery, AL 36130-0152
(334) 242-7300
Edmund.LaCour@AlabamaAG.gov

Counsel for Amicus Curiae

OCTOBER 15, 2024

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[178] Ex.180(Doc.700-9):59.

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Salem Heideman [redacted] >
Sent: Monday, November 25, 2024 3:58 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Salem and I am an Oregon community member and volunteer fellow.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

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- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

I am transgender and my life has been changed for the better by accessing trans-related healthcare.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Salem Heideman
Portland, OR 97213-6915

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Jacqueline Henkel
Sent: Monday, November 25, 2024 12:36 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is _____ and I am an Oregon _____(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Jacqueline Henkel
Portland, OR 97220-5346

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Courtney Hermann [redacted] >
Sent: Tuesday, November 26, 2024 10:52 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Courtney Hermann and I am an Oregon State employee.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Courtney Hermann
Portland, OR 97217-5039

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Hunter Hesslink <[redacted]>
Sent: Monday, November 25, 2024 8:12 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Hunter Hesslink (she/they) and I am an Oregon lead paramedic with AMR Washington County.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

My job as a lead paramedic includes working with people of all backgrounds, inviting them into my ambulance, and being sure to provide a space that is safe and inclusive, especially in such urgent or emergency cases. Trans rights are significantly important to me as a health provider, but also as a close friend and family member of several trans people. Socioeconomic factors greatly impact our communities as a whole. Such a rule will no doubt allow people greater opportunity and greater access to such procedures and/or treatments. This will have a positive impact on individual's mental health, physical well-being, and inevitably prevent incidences of ambulance needs. This in turn can keep ambulances available for other calls, whether critical or not, this is important given the uphill battle of staffing and availability of licensed individuals. Not only that but by having these procedures and treatments available and covered by insurance will allow people to access greater financial resources as well which again, greatly impacts mental health and well-being. In such times, these funds can be used for housing, rent, and other goods.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Hunter Hesslink
Tigard, OR 97223-6685

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: My comments regarding gender affirming care
Date: Monday, November 25, 2024 5:12:56 PM

> You don't often get email from [redacted]. Learn why this is important

Dear Ms. Winkel:
I oppose the attempt to further enable abuse of children by the Oregon Insurance Division urging that a Rule become state law that will cover all procedures---tax payer paid---for "gender affirming care" for all ages. An adult, paying for their own procedure on their body can do whatever they choose to do. Life changing surgeries, life long hormone and drug treatments; whatever they choose and pay for themselves. But minor children should not have "gender affirming care".
I read the book WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT, by Ryan T. Anderson. This scholarly book should be read by everyone involved in this proposal.
Please protect children from this overreach and attempt to influence our laws by the radical transgender activists.
I appreciate your consideration in this matter.
Thank you,
Karen Heuberger
[redacted]
Salem, OR 97308

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Christy Hey [redacted] >
Sent: Monday, November 25, 2024 8:28 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Christy Hey and I am an Oregon health provider living in Salem. As a Licensed Professional Counselor and Board-Certified Music Therapist with years of experience providing mental health care to individuals from diverse backgrounds, I have witnessed firsthand the critical importance of gender-affirming healthcare in improving mental well-being and fostering a sense of identity and self-worth. My work often centers on creating safe, affirming spaces for transgender individuals, enabling them to thrive despite systemic challenges.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I have supported clients in their pursuit of gender-affirming surgeries by writing letters of support. Those who have successfully undergone their surgeries and HRT reported profound satisfaction with the outcomes, describing the interventions as pivotal in their mental and emotional well-being. Access to these interventions has allowed them to align their physical and gender identities, reducing distress and dysphoria.

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

The inclusion of clear language and adherence to the World Professional Standards of Trans Health in this rulemaking process is essential to ensuring equitable access to care for all transgender individuals. This clarity will particularly benefit historically underserved communities, including trans individuals of color, low-income individuals, trans women, and immigrants, who often face compounded barriers in navigating healthcare systems. By reducing ambiguity, these

rules will ensure that marginalized populations can access gender-affirming care without undue burden or denial based on insurance policies.

Gender-affirming care is life-saving care. For transgender individuals, it is not elective or cosmetic—it is essential. The ability to access care that aligns one's body with their gender identity profoundly reduces rates of depression, anxiety, self-harm, and suicide, enabling individuals to lead fulfilling lives. Denying or delaying such care only perpetuates harm and exacerbates the systemic inequalities transgender individuals face.

I strongly support the proposed rulemaking and urge its swift implementation to uphold the standard of care and ensure that all transgender Oregonians can access the life-saving healthcare they need.

Sincerely,
Christy Hey
Salem, OR 97302-2528

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Amy Hicks [redacted]>
Sent: Monday, November 25, 2024 10:06 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Amy Hicks and I am a proud Oregonian.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I think we all understand that healthcare decisions should be made by a physician and a patient and when governments put severe restrictions on that their are dire consequences.

I want to share appreciation for the following that are in the proposed rule:

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As a parent to young children I have seen that it is so important to allow families and children to grow in a world that supports their autonomy and allows them to live full healthy lives. Allowing gender affirming care will allow those in our community to not only survive but thrive as their true selves.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Amy Hicks
Portland, OR 97206-3817

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Virginia Hicks [redacted] >
Sent: Monday, November 25, 2024 7:23 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Virginia Hicks and I am an Oregon counseling student (advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Virginia Hicks
Portland, OR 97206-8060

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Justin Himes <[redacted]>
Sent: Tuesday, November 26, 2024 3:14 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Justin Himes and I am an Oregon community member.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Justin Himes
Portland, OR 97206-5511

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Elizabeth Hinze [redacted] >
Sent: Monday, November 25, 2024 7:20 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

My name is Libby Hinze and I am a LCSW in the state of Oregon.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

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Thank you.

Sincerely,
Elizabeth Hinze
Portland, OR 97206-1403

From: [redacted]
To: WINKEL Karen J * DCBS; EMERSON Lisa * DCBS; HALL Brooke M * DCBS
Subject: Gender Affirming Treatment Rulemaking: HB2002
Date: Tuesday, November 19, 2024 4:22:36 PM

Dear Brooke Hall, Lisa Emerson, Karen Winkel, Division and Committee Members,

My name is Olivia Hnilicka(she/her) and I am an Oregon advocate/community member working/living in Portland. Currently I work as a peer support coordinator and patient advocate for transgender patients. I have worked with public health and addiction services in Portland for the last 6 years.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, WPATH Standards of Care version 8. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. According to the 2015 US Trans Survey, transgender people are nine times more likely to attempt suicide compared to the wider US population—but access to gender-affirming care can greatly alleviate this problem.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage; Oregon is now a leader in providing care that is crucial for many transgender people, including electrolysis (hair removal) necessary for certain surgeries and patient safety, and facial affirmation surgeries that have been historically commonly denied. The HB2002 rulemaking process intent is not to debate the validity of gender affirming treatment as some may submit letters about in this public hearing who seek to dismantle gender affirming care access, it was to establish a clear definition for HB2002 that was passed by the legislature so that insurers understand expectations to be in compliance.

As a coordinator of peer support for trans people, I have seen first hand the negative effects that denial, limitations, and long wait times have on trans and gender diverse people. Some of these effects are declining mental health, isolation, harmful use of substances, and in the worst circumstances suicidal ideation and attempts. The

payors who are responsible for the denials, limitations, and long wait times are resistant to the SOC rules, training requirements, and possible out of network service costs. It's my belief they are resistant because it affects their coin purse, which they prioritize over their patients health and wellbeing. My community is currently under attack and your action to uphold this proposed rule would support those who are vulnerable to the political vitriol of this current moment. Upholding the proposed rule is in alignment with the approved goals of HB2002.

In my personal transition, I have experienced years long denials and appeal processes with my insurance for gender affirming surgeries. Some of those long wait times and denials were due to the fact that there were not enough licensed electrologists to prepare me for these surgeries. These denials and appeals were exhausting and unnecessary. The proposed rule would hold payors accountable to their patients and ensure providers would be prepared to meet the needs of their patients.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002

- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

- Transparency for the patient if requested related to adverse benefit determinations

- Alignment with network adequacy standards

- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you,

Olivia Hnilicka

From: [redacted]
To: WINKEL Karen J * DCBS
Subject: Gender Affirming Care
Date: Monday, November 25, 2024 7:36:32 AM

TO: Oregon Division of Financial Regulation

Subject: Gender Affirming Treatment Rulemaking: HB2002

FROM: Shannon Hoell

Dear Committee Members,

I have great concerns about the incoming federal administration's stance on gender affirming care and I would like to see OR strengthen and protect this care for our citizens. I have seen first hand the powerful positive impact that gender affirming care has on individuals. It can be truly life saving for some individuals. This is a decision that should be left to families and their doctors - please continue to protect this important and vital health care option for all Oregonians.

I am asking you to support this proposed rule and keep section 1b establishing the accepted standard of care for this field, the most current version of WPATH Standards of Care. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.Gender-affirming care is lifesaving care. We need to protect trans Oregonians - especially at a time when they are coming under direct attack.

Oregon is already a leader on transgender healthcare access: Since 2015, the Oregon Health Plan and private insurers have covered certain gender-affirming care procedures. The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

Wait times for gender affirming care are already incredibly long. No one is going through with these treatments without taking much time and thought.

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002

· Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations

· Transparency for the patient if requested related to adverse benefit determinations

· Alignment with network adequacy standards

· Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002 has already helped close coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

I cannot tell you enough how incredibly important and truly LIFE SAVING this care can be.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember this as you finalize this draft into rule.

Thank you,

Shannon Hoell

--
Shannon L. Hoell, LMT 8236
Advanced MELT Instructor
ACSM Certified Personal Trainer
www.fullcirclefitnesseugene.com
[redacted]
541-968-2390

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Lauren Hoffman [redacted] >
Sent: Tuesday, November 26, 2024 8:35 AM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Rules Coordinator Karen Winkel,

Subject: Gender Affirming Treatment Rulemaking: HB2002

[UPDATE THE BLANKS BELOW AND ADD 1-2 SENTENCES BRIEFLY DESCRIBING YOUR WORK/EXPERIENCE AND WHY IT IS RELEVANT TO GENDER-AFFIRMING CARE. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]

My name is Lauren Hoffman_ and I am an Oregon _clinical psychologist_(advocate/community member/health provider/).

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

[ADD 1-3 SENTENCES ABOUT EXPERIENCE WITH ANY PERSONAL EXPERIENCE/EXPERIENCE YOU HAVE WITH PATIENTS WHO HAVE BEEN DENIED THESE PROCEDURES, AND HOW THIS IMPACTED THEM. THEN DELETE THIS INSTRUCTION SENTENCE FROM YOUR LETTER]]

I want to share appreciation for the following that are in the proposed rule:

- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

[· PERSONAL ADDITIONS: ADD ANY INSIGHTS YOU HAVE INTO HOW THIS LANGUAGE AND INCLUDING THE WORLD PROFESSIONAL STANDARDS OF TRANS HEALTH WILL ESPECIALLY HELP HISTORICALLY UNDERSERVED COMMUNITIES

WITHIN THE TRANS POPULATION (IE FOLKS OF COLOR, TRANS WOMEN, LOW-INCOME FOLKS, IMMIGRANTS ETC.) · HOW THIS RULE WILL HELP YOU DO THE BEST JOB AS A PROVIDER, if that applies.
· MORE INSIGHT AS A PROVIDER INTO WHY GENDER-AFFIRMING CARE IS LIFE-SAVING CARE.
THEN DELETE THESE INSTRUCTIONS FROM YOUR LETTER]

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians. Please remember my story when you finalize this draft into rule.

Thank you.

Sincerely,
Lauren Hoffman
Portland, OR 97214-4147

ROMADKA Jennifer * DCBS

From: [redacted] on behalf of Tove Holmberg
Sent: Monday, November 25, 2024 1:25 PM
To: WINKEL Karen J * DCBS
Subject: HB2002 Rulemaking Public Comment

Dear Rules Coordinator Karen Winkel,

Subject: Gender-Affirming Treatment Rulemaking: HB2002

My name is Tove and I am a lifelong Oregonian who has been fortunate enough to have my healthcare needs met without interruption, and to have only encountered occasional and slight hiccups in processing insurance claims. It's important to me that my friends, loved ones, and coworkers have the same experience when seeking gender-affirming care.

I am asking you to support this proposed rule as written. I would also like to express appreciation for defining an accepted standard to follow so insurers can be in compliance with HB2002. The Evidence Review Team at WPATH conducted international systematic reviews of the most current data and studies on gender-affirming treatment. This most recent version of the Standards of Care is developed using an evidence-based approach. The legislature passed HB2002 and affirmed that gender-affirming care is lifesaving care and insurance should cover it. It is important that they have a guideline to follow when covering a claim or issuing a denial.

The insurance mandate for gender-affirming treatment through HB2002 addresses many of the gaps in coverage that negatively affected the most marginalized in our community.

I want to share appreciation for the following that are in the proposed rule:
- Determining a standard of care in rule for insurers to be in compliance with HB2002
- Establishing a training requirement and clearer definition of experience in gender-affirming treatment for those who will be issuing adverse benefit determinations
- Transparency for the patient if requested related to adverse benefit determinations
- Alignment with network adequacy standards
- Ensuring access without unreasonable delay to out-of-network gender-affirming treatment services when provider network adequacy is not met

HB2002, with clearer definition in rule, will allow patients and insurance carriers to finally address coverage gaps in live-saving gender-affirming care access for transgender Oregonians. DCBS and the Department of Financial Regulation has the ability to provide clarity for HB2002 for insurance carriers to ensure proper implementation of the law.

By supporting this proposed rule in its current form, you will be protecting access to medically necessary, equitable health care for transgender Oregonians.

Thank you.

Sincerely,
Tove Holmberg
Portland, OR 97227-1535

K&L GATES

November 15, 2024

Brenna K. Legaard
Partner
[redacted]

T +1 503 226 5736

By E-mail and US Mail

Karen Winkel
Rules Coordinator
State of Oregon
350 Winter St. NE
Salem, OR 97301
karen.j.winkel@dcbs.oregon.gov

Re: 2025 Gender-Affirming Treatment Rule

Dear Ms. Winkel:

I am an attorney. I am also the parent of a child with autism and have been engaged in health care advocacy in Oregon as a private citizen for many years, particularly mental healthcare for children.

I have been asked by the nonprofit LGBT Courage Coalition to review the Division's proposed rule implementing HB 2002 ("the Rule"). The Rule establishes WPATH 8 as an "accepted standard of care" for medical treatment of gender diverse individuals, while listing no other guidelines or guidance documents. I have concluded that in adopting the Rule, the Division is acting beyond the scope of its statutory authority, and if the Rule is adopted, it will be invalid.

In HB 2002, the Legislative Assembly expressly reserved to health care providers the determination of whether gender affirming treatment is medically necessary for any given individual:

> A carrier offering a health benefit plan in this state may not: (a) Deny or limit coverage under the plan for gender-affirming treatment that is: (A) Medically necessary as determined by the physical or behavioral health care provider who prescribes the treatment; and (B) Prescribed in accordance with accepted standards of care.

HB 2002, Section 20 (2). The express intent and effect of the law is simply to prevent insurance companies from overriding clinical judgment to deny coverage of services that health care providers reasonably believe are medically necessary for a given patient. The Legislative Assembly left it to providers to determine medical necessity, and to identify standards of care that are accepted by providers. Likewise, HB2002 allows insurance companies to issue adverse

benefit decisions such as a "[d]etermination that a health care item or service is experimental, investigational or not medically necessary, effective or appropriate" so long as the decision is reviewed and approved by "a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment." ORS 743B.001(1)(d))

In adopting WPATH 8 as the sole identified "generally accepted standard of care," the Division is encroaching upon the discretion the Legislative Assembly left to health care providers. For that reason, it is exceeding the scope of its authority.

1. <u>The Rule inappropriately endorses a disputed characterization of the strength of the evidence</u>

The evidence regarding the benefits of gender-affirming care, particularly for adolescents, is sparse, and its interpretation is hotly debated. There is no question that gender-affirming medical interventions pose risks and cause harms: people who undergo mastectomies lose their breasts, adolescents who receive puberty blockers and cross-sex hormones will experience serious impacts on fertility, and long term use of cross sex hormonal treatment causes a number of health risks including osteoporosis and higher risks of cardiovascular disease. These treatments should be offered only where the benefits outweigh the risks and harms.

Some advocates, researchers, and healthcare providers strongly feel that gender-affirming care is life-saving such that notwithstanding its harms it should made be broadly available upon request, including to adolescents. Others believe that given the harms, gender-affirming care should not be as broadly available, particularly to adolescents.

These disagreements among clinicians about care are reflected in disagreements about clinical guidelines. A recent review found twenty-three guidelines/clinical guidance publications regarding treatment of children and adolescents experiencing gender dysphoria or incongruence, and found a general lack of rigor and transparency as well as significant variation in recommendations.[1] For example, regarding gender-affirming surgery for adolescents, of the twenty-three guidelines considered:

> Fourteen guidelines include recommendations about surgery. Six do not recommend surgery for adolescents. Six do not recommend genital surgery but support mastectomy. Only the Swedish guideline includes minimum age criterion for mastectomy if carried out under a research framework. The two remaining guidelines (WPATH and SAHCS), which also support surgery, include no restrictions for adolescents, although WPATH suggests phalloplasty be delayed until adulthood.

[1] Taylor J, Hall R, Heathcote C*, et al* Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1) *Archives of Disease in Childhood* 2024;**109:**s65-s72. Available at: https://adc.bmj.com/content/109/Suppl_2/s65

> Nine guidelines offer no clear recommendations; three describe practice that includes chest surgery for adolescents, three describe surgery as deferred until adulthood, and three contain no discussion.

Id. The authors of this review noted that WPATH 8, like most clinical guidance for managing children/adolescents experiencing gender dysphoria/incongruence, lacks developmental rigor and transparency and recommend that healthcare professionals consider the lack of quality and independence of available guidance when utilizing such guidance for practice. *Id.*

In short, there is significant dispute and no consensus regarding the safety and efficacy of gender-affirming medical interventions, particularly for adolescents.

WPATH 8 does not offer or purport to offer an impartial assessment of the evidence, such as, for example, the Cochrane review. It has a particular point of view and clearly stated policy goals, and it characterizes the evidence in a manner supportive of those policy goals. It asserts that "[t]here is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments," including for adolescents, and that "[g]ender-affirming treatments are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient." WPATH 8 at Statement 2.1. "Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage of any medically necessary procedures or treatments…" *Id.*

In endorsing WPATH 8, and only WPATH 8, the Division endorses WPATH's point of view and policy goals. The act of endorsing that approach is beyond the scope of the authority conveyed by the Legislative Assembly. The Rule tells both the public and carriers that "strong" evidence has established that gender-affirming care is life-saving, with benefits that outweigh the harms, including in adolescents, even though that is not medical consensus.

Here in Oregon, in early 2023 the HERC commissioned a "rapid review" of the evidence by OHSU resulting in a draft report attached hereto. Key questions included:

1. What is the overall impact of receiving gender-affirming medical interventions for adults in this this population?

2. What is the overall impact of receiving gender-affirming medical interventions for adolescents in this population?

The Report found that for adults "there is a trend of improvement in anxiety and quality of life, after gender affirming surgeries overall and in SRs of specific interventions." But for adolescents, reviewers found a "paucity of data" regarding the mental health benefits of gender-affirming medical interventions. This review is not an anomaly. Numerous sources, including the Cass report from the UK, have also found that evidence of benefit of gender-affirming care for adolescents is weak or very weak.

By adopting a Rule that expressly states otherwise, the Division puts its thumb on the scale. It endorses WPATH 8's characterization of the evidence as supporting one philosophy of treatment as "strong" demonstration of benefit, in contrast with the Legislative Assembly, which left the evaluation of evidence and standards to clinicians. The Legislative Assembly did not task the Division with characterizing or even assessing medical evidence. In endorsing one side of the debate about the strength and quality of the evidence along with a particular therapeutic approach, the Division is acting beyond the scope of its authority.

2. <u>The Rule risks eroding access to psychotherapy.</u>

WPATH 8 establishes gender-affirming medical interventions as the preferred treatment for gender-questioning individuals, asserting that gender affirming medical interventions resolve patient distress. WPATH 8 "strongly discourages" psychotherapy that is not aligned with this treatment philosophy. Moreover, having instructed the insurance industry to adopt the belief that gender-affirming care is sufficient to relieve distress in gender-questioning individuals, the Division will make it more difficult for patients to establish that psychotherapy or other treatments are necessary to relieve their distress. Both of these aspects of the Rule can reasonably be expected to limit access to treatments such as psychotherapy. As the intent of the Legislative Assembly was to improve access to medically necessary treatments, in requiring carriers to refuse to cover certain psychotherapy and by endorsing medical intervention over psychotherapeutic interventions, the Division has acted beyond the scope of its authority.

First, WPATH 8 "strongly recommends against" what it calls "reparative" or "conversion therapy." Oregon law prohibits mental health professionals from offering "conversion therapy" for recipients under 18 years of age, and defines "conversion therapy" to mean "providing professional services for the purpose of attempting to change a person's sexual orientation or gender identity, including attempting to change behaviors or expressions of self or to reduce sexual or romantic attractions or feelings towards individuals of the same gender." ORS 675.850. The Oregon law goes on to clarify that "conversion therapy" does not include "counseling that facilitates a client's coping, social support, and identity exploration or development." *Id.*

WPATH 8 defines reparative or conversion therapy more broadly such that the Rule precludes coverage of psychotherapy that could be construed as "promoting" a gender identity that is congruent with sex assigned at birth, such as therapy that challenges a patient to explore alternative root causes of gender distress. *See* WPATH 8 at Statement 6.5. It also "strongly recommends against" what it calls conversion therapy for adults—a prohibition that the Oregon Legislative Assembly considered and rejected in 2023.

Gender-affirming medical interventions carry with them significant costs and risks. Some people may prefer to accept their anatomy rather than endure the costs and consequences of changing it, and they may seek psychotherapy aligned with that goal. This therapy would be expressly permissible under ORS 675.850, particularly for adults. But an insurance carrier processing claims in accordance with WPATH 8 would be required to evaluate therapeutic goals to assess

whether they "promote" sex assigned at birth, and if so, deny coverage. The Rule exceeds the Division's statutory authority.

Second, WPATH 8 states that gender-affirming care, independent of psychotherapy or other mental health interventions, improves mental health and well-being and resolves or prevents gender-related distress. *See* WPATH 8 Statement 5.1.c, d., Statement 5.3.d. There is significant disagreement within the health care community about whether these statements have evidentiary support particularly as applied to adolescents, but the Rule instructs insurance companies to accept them as true and act accordingly. Given that, carriers may deny claims for psychotherapeutic, pharmaceutical, or other mental healthcare as not medically necessary to treat gender incongruence in light of the availability of gender-affirming medical intervention.

In short, in adopting this Rule the Division is instructing carriers to deny coverage for services that providers deem medically necessary and that are prescribed in accordance with standards of care, particularly psychotherapy, and therefore is exceeding the scope of its authority.

3. The Rule treats detransitioners unequally

WPATH 8 acknowledges patients who regret their gender-related surgeries, but questions whether detransition surgeries would be appropriate in such cases. It suggests an "expert multidisciplinary team" should evaluate whether further procedures to "return anatomy to that of the sex assigned at birth may be indicated." Statement 5.7, Statement 13.11. But patients who regret their transitions are patients whose gender identity is incongruent with their anatomy. SB 2002 draws no distinction between pre- and post-surgical incongruity. By adopting a rule which places barriers to care in front of one category of individuals that are not placed in front of the other, the Division acts outside of its authority.

Conclusion

The Legislative Assembly's respect for clinical judgment reflected in HB 2002 will accommodate the evolution of the evidence and understanding of gender incongruity and its treatment, including the long-term benefits and harms of these treatments. In not exhibiting the same restraint, the Division exceeds its statutory authority.

Respectfully yours,

Brenna K. Legaard

Brenna K. Legaard
Partner

BKL