February 9, 2024

From: Paul Terdal, Health Consumer Advocate
To: Karen Winkel, Rules Coordinator, Division of Financial Regulation
Brooke Hall, Senior Health Care Policy Analyst
Lisa Emerson, Senior Policy Advisor
Re: Draft Rules for HB2002, Gender Affirming Treatment

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

Thank you for the opportunity to provide public comment on the draft administrative rules for HB2002, on Gender Affirming Treatment. I have appreciated the opportunity to participate in the rule-making process as an "interested observer."

As part of my comment on the draft rules, I am also attaching the comment that I submitted in December on the Interim Guidance for House Bill 2002. My general comments and recommendations there form the foundation for my comments today.

The Nature of HB2002: A Modest Restatement of Existing Law

Before walking through each section of the draft rules, I would like to revisit my comments on the Interim Guidance regarding the nature of HB2002.

As described in those comments, I believe the Division should interpret HB2002 as a "Modest Restatement of Existing Law' – and not as a new mandate for coverage.

Oregon and Federal Law already required coverage of medically necessary care for Gender Dysphoria, as described in bulletins INS 2012-1, INS 2014-1, DFR 2016-1.

There is NOTHING in HB2002 that was not already legally required:

HB2002:	**Prior Laws / Bulletins:**
SECTION20(2)(a) (2) 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.	INS 2014-1: "The guidance of INS 2012-1 is supplemented by the provisions of this bulletin to the extent that this bulletin provides additional guidance for the treatment of all mental health conditions including gender dysphoria." "…gender dysphoria are subject to the mandate" (Mental Health Parity) "If a mental or nervous condition is encompassed by the mandate, an insurer must provide coverage for medically necessary treatments for the condition. Recent judicial opinions have indicated that if a plan excludes a therapy regardless of whether it is medically necessary, the blanket exclusion violates the

HB2002:	Prior Laws / Bulletins:
	mental health parity requirements if the therapy may be medically necessary to treat a mental disorder"
SECTION20(2)(b) and (c) (b) Apply categorical cosmetic or blanket exclusions to medically necessary gender affirming treatment. (c) 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:	INS 2014-1: "An insurer may not apply a categorical exclusion (such as exclusions for developmental, social, or educational therapies) to a class of mental health conditions that results in the denial of medically necessary care or otherwise results in one of the mandates being effectively meaningless." *A "cosmetic exclusion" is a "categorical exclusion" already prohibited by INS 2014-1*.
SECTION20(2)(d) (d) Issue an adverse benefit determination denying or limiting access to gender-affirming treatment unless a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment has first reviewed and approved the denial of or the limitation on access to the treatment.	*I don't have a specific citation for this, but we have often raised this exact issue regarding autism services – if an insurer is going to deny coverage as "not medically necessary" or "experimental / investigational" they need to have a licensed health care provider acting within their license and professional scope of competence making that decision*.
SECTION20(3) (3) A carrier described in subsection (2) of this section must: (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.	ORS 743B.505 (1) An insurer offering a health benefit plan in this state that provides coverage to individuals or to small employers, as defined in ORS 743B.005 (Definitions), through a specified network of health care providers shall: (a) Contract with or employ a network of providers that is sufficient in number, geographic distribution and types of providers to ensure that all covered services under the health benefit plan, including mental health and substance abuse treatment, are accessible to enrollees for initial and follow-up appointments without unreasonable delay. *The HB2002(20)(3) requirement literally references this existing statute and then proceeds to duplicate it almost verbatim*.

I urge you to recognize that HB2002 is not a "new" mandate:

- This would exempt the State of Oregon from significant financial obligations under 45 CFR 155.170, as described in my comment on the Interim Guidance.
- This also addresses the issue I raised in the Interim Guidance about the inapplicability of HB2002 to Health Care Service Contractors – since Bulletin INS 2014-1 is based on ORS 743A.168 and the Wellstone Domenici Mental Health Parity and Addiction Equity Act (MHPAEA), both of which do apply to Health Care Service Contactors.
- Preserves the rights of individuals with gender dysphoria who were seeking treatment prior to the effective date of HB2002

Bear in mind that recognition that HB2002 is not a "new" mandate – but is really restating rights derived from ORS 743A.168 and MHPAEA – also requires a more modest and less "radical" implementation that would establish special rights for individuals with gender dysphoria that don't exist for individuals with other medical or mental health conditions. Your rules should be fully consistent with the authority you have under those other statutes.

Review of Draft HB2002 Rules:

(1) (b) "Accepted standards of care"

The draft rule states:

> (1) For purposes of this rule: …
>
> (b) "Accepted standards of care" includes, at a minimum and without limitation, the World Professional Association for Transgender Health's Standards of Care for Transgender and Gender Diverse People, Version 8, which is incorporated as Exhibit 1 to this rule.

As described in my comments regarding the Interim Guidance, I strongly object to the proposal to define "accepted standards of care" to mean "the World Professional Association for Transgender Health's Standards of Care for Transgender and Gender Diverse People, Version 8" (WPATH SOC 8) and to incorporate that 260 page document into the Oregon Administrative Rules – giving ever word the full force of Oregon law.

By defining WPATH SOC 8 as the "standard of care" for the purposes of HB2002, you aren't merely identifying a list of services that carriers must cover – you are also prescribing the medical decision-making criteria that licensed health care professionals working for carriers must follow when reviewing prescriptions to confirm that they meet the "standard of care" for medical necessity.

In a meeting with TK Keen and Jesse O'Brien last month, they expressed surprise at the notion that anyone would interpret the rules as directing physicians how to practice medicine – but that is exactly what you would be doing by defining "standard of care" in this way.

Further, any licensed heath care provider seeking insurance reimbursement would be required to follow all of the requirements of WPATH 8 as a condition for reimbursement – even if in their

professional judgment some aspects of WPATH 8 were contraindicated by the latest published research.

As described in my comment on the interim guidance, WPATH 8 is quite controversial in the medical community – even among proponents of gender-affirming treatment. Even within the WPATH organization, there was considerable controversy about provisions for children and adolescents, and recommendations by Beaverton, Oregon Psychologist Dr. Laura Edwards-Leeper Ph.D. – an original author of the early drafts of WPATH SOC 8 – to be cautious in prescribing medical interventions for youth with gender dysphoria were overturned.[1]

In adopting HB2002, the Oregon Legislature made a point of not defining a specific standard of care for gender-affirming treatment. The Division has never done so for any other condition – and it shouldn't now.

Instead, you should define "standard of care" as it is used in Oregon law (ORS 677.265):

Recommendation:

Define "accepted standard of care" as follows:
"Accepted standard of care" means that degree of care, skill and diligence that is used by ordinarily careful physicians in the same or similar circumstances in the community of the physician or a similar community.
ORS 677.265(1)(c)

Disagreements about the "accepted standard of care" for gender-affirming treatment should be resolved the way they are for any other condition – by External Review under ORS 743B.252.

For reference, see also the attached article on the Standard of Care, published in the Journal of the American Academy of Psychiatry and the Law.

(3) Adverse Benefit Decisions

The draft rule states:

> (3) Prior to issuing an adverse benefit determination that denies or limits access to gender-affirming treatment, a carrier offering a health benefit plan must have the adverse benefit determination reviewed and approved by a physical or behavioral health care provider with experience prescribing gender-affirming treatment. This subsection does not require a health care provider to review or approve an adverse benefit determination that only involves the application of cost sharing, such as deductibles, coinsurance, or copays, to gender-affirming treatment.

The text is fine as is, but it is important to remember that a carrier can still deny coverage on grounds that it is not medically necessary or is experimental / investigational – provided that the

[1] "The Battle Over Gender Therapy," Emily Bazelon, New York Times, June 15, 2022. https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html

determination is reviewed and approved by a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment.

This is (or should be) standard practice for all medical conditions.

There was some discussion in the last Rules Advisory Committee meeting about requiring these providers to have taken a course approved by WPATH, a private organization. That requirement goes well beyond what HB2002 authorizes.

I suggest that you consider the existing administrative rules regarding External Medical Review as a baseline for qualifications of a carrier's reviewer – that they have expertise, and are a clinical peer:

> OAR 836-053-1325
>
> Procedures for Conducting External Reviews
>
> (6) The following standards govern the assignment by an independent review organization of appropriate medical reviewers to a case: …
>
> (b) An independent review organization shall assign one or more medical reviewers to each case as necessary to meet the requirements of this subsection. The medical reviewer assigned to a case, or the medical reviewers assigned to a case together, must meet each of the following requirements:
>
> A) Have expertise to address each of the issues that are the source of the dispute.
>
> (B) Be a clinical peer. For purposes of this paragraph, a clinical peer is a physician or other medical reviewer who is in the same or similar specialty that typically manages the medical condition, procedures or treatment under review. Generally, as a peer in a similar specialty, the individual must be in the same profession and the same licensure category as the attending provider. In a profession that has organized, board-certified specialties, a clinical peer generally will be in the same formal specialty.

New Provision: coverage for medical procedures associated with a gender detransition.

Please refer to the attached letter from DCBS Directo Andrew Stolfi to Speaker Dan Rayfield regarding coverage for medical procedures associated with a gender detransition:

> This definition would apply for purposes of HB 2002. Importantly, this definition does not focus solely on an individual's subjective sense of his or her own gender, but includes other objective facets of gender identity such as "appearance, expression or behavior."
>
> Given this definition, we believe that detransition procedures would be included in the definition of "gender affirming treatment" under HB 2002. To illustrate, an individual who previously received gender affirming treatment and who is now seeking to reverse the effect of that treatment would be seeking treatment for an incongruence between their gender identity (namely, their appearance) and their sex assigned at birth. This conclusion is supported by HB 2002's explicit inclusion of "revisions to prior forms of gender affirming treatment" in the same section's list of prohibited exclusions.
>
> Finally, HB 2002 specifically requires the department to adopt rules implementing the bill. If a question remains on this issue after HB 2002 becomes law we would be glad to address that as part of such rulemaking.

Consistent with Director Stolfi's commitment, please add a provision to the rule clarifying that detransition procedures would be included in the definition of "gender affirming treatment" under HB 2002.

Sincerely,

/s

Paul Terdal

Attachments:

- TerdalP Comment on Interim Guidance for HB2002 2023-12-20.pdf: public comment submitted in December on the "interim guidance" for HB2002
- 358.full.pdf: Cooke BK, Worsham E, Reisfield GM. The Elusive Standard of Care. J Am Acad Psychiatry Law. 2017 Sep;45(3):358-364. PMID: 28939735.
- Rayfield_ltr_signed.pdf: letter that DCBS Director Andrew Stolfi sent to Speaker Dan Rayfield on April 20, 2023, regarding coverage for medical procedures associated with a gender detransition

December 20, 2023

From: Paul Terdal, Health Consumer Advocate
To: TK Keen, Administrator, Division of Financial Regulation
Oregon Department of Consumer and Business Services
Re: Public Comment on Interim Guidance for House Bill 2002 (Gender-Affirming Treatment)

Dear Mr. Keen,

Thank you for the opportunity to provide public comment on the proposed "Interim guidance for health benefit plans for Section 20 of 2023 Oregon House Bill 2002 (gender-affirming treatment)."

For the past decade, I have been working as a volunteer health consumer advocate for individuals with autism and other disabilities. In recent years, there has been a surge in comorbidity between autism and gender dysphoria, for reasons that remain unclear. I have a long-standing interest in ensuring that health consumers can access the medically necessary, evidence-based care that they need to thrive.

In 2014, after the landmark decision in AF v Providence, I worked closely with the Division on development of bulletins INS 2014-1 ("Mental Health Parity") and INS 2014-2 ("Autism Spectrum Disorder; Applied Behavior Analysis Therapy"). As part of that process, I worked with a broad coalition of stakeholders, including LGBTQ advocates, to ensure that the INS 2014-1 bulletin was as broadly applicable as legally possible, and applied the Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act, 29 U.S.C. 1185a (MHPAEA) to strengthen the protections for patients with gender dysphoria that the Division had previously described in bulletin INS 2012-1 ("Application of Senate Bill 2 (2007 Legislative Session) to Gender Identity Issues in the Transaction and Regulation of Insurance in Oregon").

In the 2023 legislative session, I also requested and facilitated enactment of HB2421, which included an enhancement of Oregon's existing prohibition on conversion therapy, extending the prohibition to providers of Applied Behavior Analysis (ABA) therapy.

The Nature of HB2002: A Modest Restatement of Existing Law

In reviewing the Division's draft interim guidance, it is important to start with the statute.

After carefully reviewing the text and context of HB2002, including the legislative history, it is clear that – despite the uproar -- the insurance coverage provisions were actually very modest: they largely restated rights under existing laws, and consolidated some rights derived from federal laws (like MHPAEA) into state law. In context, this can be seen both as a clarification to make it easier for the Division to enforce, and a preemptive move to preserve these existing rights in State law in the event of future changes to Federal law. HB2002 does not significantly change coverage requirements for gender-affirming treatment – because coverage of that treatment was already required.

Definition of "Gender Affirming Treatment"

HB2002 Section 20 defines "gender affirming treatment" as:

> **(b) "Gender-affirming treatment" means a procedure, service, drug, device or product that a physical or behavioral health care provider prescribes to treat an individual for incongruence between the individual's gender identity and the individual's sex assignment at birth.**

DSM-5 describes "gender dysphoria" as "the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender."[1]

This definition of "gender affirming treatment" can thus be best interpreted as any sort of medical or behavioral health service to treat an individual for gender dysphoria – which was already required by Oregon's Mental Health Parity law (ORS 743A.168), as elaborated upon in bulletin INS 2014-1 – with the exception of conversion therapy, which is prohibited under Oregon law (ORS 675.850).

Restrictions on Adverse Benefit Decisions:

HB2002 Section 20 subsections 2(a) and (d) provide specific restrictions on adverse benefit decisions:

> **(2) 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.**
> *** * ***
> **(d) Issue an adverse benefit determination denying or limiting access to gender-affirming treatment unless a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment has first reviewed and approved the denial of or the limitation on access to the treatment.**

It is important to recognize that carriers may still issue adverse benefit decisions on grounds that a treatment is not medically necessary, or is experimental / investigational, provided that the decision is based on a deviation from the accepted standards of care, and is reviewed and approved by a provider with experience prescribing or delivering treatment for gender dysphoria.

My concerns regarding the Division's proposed definition of "accepted standards of care" are described in more detail below.

Recommendations:

- The bulletin should include guidance on when and how carriers may issue benefit denials, such as for:
  - Patients without a well-documented diagnosis of gender dysphoria
  - Prescriptions for services that are not in accordance with accepted standards of care, including because the patient's condition doesn't meet the medical necessity criteria in the accepted standards of care
- This guidance would be helpful to patients and providers as well as to carriers, because patients and providers need to know when and how a carrier can deny coverage.

[1] Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), American Psychiatric Association, Washington DC, 2013. Page 451.

Mandated Coverage:

HB2002 Section 20 subsections 2(b) and 2(c) provide specific requirements to cover a few key services:

> **(2) A carrier offering a health benefit plan in this state may not:**
> *** * ***
> **(b) Apply categorical cosmetic or blanket exclusions to medically necessary gender affirming treatment.**
> **(c) 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; and**
> **(E) Any combination of gender-affirming treatment procedures.**
> *** * ***

Enumeration of these services is not a "new" mandate – because coverage of all of these services was already required before HB2002. As described in INS 2014-1, Mental Health Parity:

- Gender dysphoria is a "mental or nervous condition" subject to both Oregon Mental Health Parity (MHP) and the Federal MHPAEA.
- "If a mental or nervous condition is encompassed by the mandate, *an insurer must provide coverage for medically necessary treatments for the condition*. Recent judicial opinions have indicated that if a plan excludes a therapy regardless of whether it is medically necessary, the blanket exclusion violates the mental health parity requirements if the therapy may be medically necessary to treat a mental disorder." (*emphasis* added)

Since Gender Dysphoria is encompassed by the MHP / MHPAEA mandate, an insurer must provide coverage for medically necessary treatments for the condition.

If the kinds of services described in HB2002 Section 20 subsections 2(b) and 2(c) are medically necessary for treatment of gender dysphoria, then they were already required for coverage by MHP and MHPAEA.

If for any reason the services are not medically necessary for a patient – as per "accepted standards of care" – then they are not covered by HB2002 either.

This is not, therefore, a "new" mandate.

(It was disappointing to hear patients describe their troubles with inappropriate denials of coverage for these services during the public hearing on HB2002 – this coverage was already mandated, and the Division already had all the authority it needed to enforce).

Importance of Recognition that HB2002 Is Not a "New" Mandate:

It is important to recognize that HB2002 doesn't require any new benefits that were not already required, because if it did then the State of Oregon would face significant financial requirements under the Affordable Care Act (45 CFR 155.170) to make payments to defray the increased cost of coverage, either to each individual enrollee in the state of Oregon, or to the policy issuers.

In addition, consumers who have been improperly denied coverage of these benefits in the past should still be able to pursue those claims – and the Division should help them.

The final Fiscal Impact Statement for HB2002 was for "minimal expenditure impact' – indicating that the Legislature was not expecting to make these payments under 45 CFR 155.170.

Recommendations:

- The bulletin should reiterate that HB2002 does not require coverage of any new benefits that were not already required under Oregon's Essential Health Benefits Package.
- In the event that the Agency's bulletin or eventual rules do require some new, additional coverage then the State must analyze the increased cost, and make payments to every individual enrollee in Oregon, or to policy issuers as required by 45 CFR 155.170.

HB2002 Doesn't Apply to Health Care Service Contractors or MEWAs:

The bulletin should clearly specify which types of carriers colloquially considered "health insurers" are subject to the provisions of HB2002. A close reading of the bill and the insurance code makes plain that it applies only to health insurers fully regulated by the insurance code – and NOT to health care service contractors or multiple-employee welfare arrangements (MEWA). Both consumers and carriers should have a clear understanding of their particular rights and responsibilities under this bill.

The key section of HB2002 regarding insurance coverage – section 20 – is added to and made a part of the Insurance Code:

> **SECTION 19. Section 20 of this 2023 Act is added to and made a part of the Insurance Code.**

Oregon's insurance code does not automatically apply to all types of organizations that the general public thinks of as "health insurers." See in particular ORS 731.026:

> **731.026 Application of Insurance Code to particular insurers.** The Insurance Code applies to:
> (1) A fraternal benefit society complying with ORS chapter 748, only as provided in such chapter.
> (2) A *health care service contractor complying with ORS 750.005 to 750.095, only as provided in such sections.*
> (3) A legal expense organization complying with ORS 750.505 to 750.715, only as provided in such sections.
> (4) A *multiple employer welfare arrangement complying with ORS 750.301 to 750.341, only as provided in such sections.*
> (*emphasis* added)

The insurance code *only* applies to health care service contractors and multiple employer welfare arrangements as provided in the specified sections of ORS Chapter 750.

Within Chapter 750, ORS 750.055 provides a very specific, detailed and comprehensive list of the sections of the insurance code that apply to health care service contractors. This list includes many – but not all – of the health benefit mandates that apply to other types of health insurers.

HB2002 Section 20 was *NOT* added to this list – and therefore does *NOT* apply to health care service contractors.

Likewise, ORS 750.333 specifies the sections of the insurance code that apply to multiple employer welfare agreements – and HB2002 Section 20 wasn't added to the list.

I recognize that HB2002 Section 20 references definitions of the terms "carrier" and "health benefit plan" that otherwise refer to health care service contractors and MEWAs. But the construction of the insurance code is very clear – the insurance code applies to health care service contractors and MEWAs "only as provided" in the applicable sections of ORS Chapter 750. Most health coverage mandates I have seen over the past dozen years have been careful to include updates to these provisions of Chapter 750, and I was surprised to see that HB2002 did not.

There is substantial legislative history on this, and precedent for past agency decision-making. In 2016 (after I made a series of inquiries to the Division about the applicability of specific sections of the insurance code to health care service contractors), the Division spent many months analyzing the insurance code, and consulting with stakeholders (including insurers, health care service contractors, and consumers such as myself) to review and update Chapter 750. We literally walked through the list line by line to discuss which sections should – and should not – apply to health care service contractors and MEWAs. This bill was requested by the agency as HB2340 (2017), and passed unanimously.

These specific provisions of the Insurance Code and Chapter 750 aren't merely a "quick reference guide" about the provisions applicable to health care service contractors and MEWAs – they are the law of the land, and they are binding.

Recommendations:

- The bulletin *must* clarify that HB2002 *doesn't apply* to Health Care Service Contractors and Multiple Employee Welfare Arrangements

If – as I suspect – the proponents wish to apply HB2002 to health care service contractors and MEWAs, there are multiple paths forward:

- The bulletin could describe how the same coverage required under HB2002 was already required for coverage by health care service contractors and MEWAs under Oregon's Mental Health Parity law (ORS 743A.168) and the Federal Mental Health Parity and Addiction Equity Act – so the coverage will still be the same
- The legislature could amend ORS Chapter 750 to include the necessary references to HB2002 Section 20 in ORS 750.055 and 750.333 – ensuring that the HB2002 is applied uniformly. This could be a standalone bill, or amended into any other bill with an appropriate relating clause. Prompt action in the February 2024 legislative session would resolve this gap.

HB2002 *DOES* apply to PEBB and OEBB:

I was pleased to see that HB2002 *does* apply to both the Public Employees Benefits Board (PEBB) and Oregon Educator's Benefits Board (OEBB) – but only because Sections 25 and 26 were included to specifically require this coverage.

For legislative history behind the creation of these two sections, refer to SB1523(2014), the first bill to propose specific insurance mandates for PEBB and OEBB. In particular, see the email from then

Insurance Commissioner Laura Cali on the inapplicability of the insurance code to PEBB on page 3 of the Autism Society of Oregon's testimony.

(The fact that PEBB and OEBB didn't project a fiscal impact for this coverage – despite the very clear requirements for compliance – underscores that the provisions in HB2002 don't represent a new mandate for coverage that wasn't already required).

Concerns with Proposed Definition of "Accepted Standards of Care"

I have serious concerns with the Division's proposed definition of "Accepted Standards of Care:"

> "Accepted standards of care" includes the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.

I realize that it would be easier for the Division's upcoming market conduct examination (HB2002 Section 21) if there were a single, concrete reference for the "accepted standard of care" required by HB2002 Section 20.

However, defining the statutory term to include this one standard (WPATH SOC8) to the exclusion of others is premature, would be harmful to the public, and expose the Division, its personnel, and the State of Oregon to substantial legal liability.

Legal Definition of "Accepted Standard of Care" in the Context of HB2002

In drafting and adopting HB2002, the legislature prohibited carriers from denying coverage of gender-affirming treatment "[p]rescribed in accordance with accepted standards of care" – but did not include a definition of "accepted standards of care" and didn't define a specific protocol that must be covered. Even where HB2002 identified a few specific services (like hair electrolysis), it didn't insist that they must be covered – only that coverage couldn't be denied if medically necessary and consistent with the "accepted standards of care."

This legislative deference was clearly intentional. During the testimony and discussion on the bill, several legislators and proponents of HB2002 emphasized the importance of evidence-based gender-affirming treatment decisions made by physicians and their patients – not by courts of legislatures.

As Dr. Marianne C. Parshley, MD, the President of the Oregon Medical Association, testified:

> "The Oregon Medical Association strongly supports this bill. ***Legislation that will ensure the evidence-based in quality healthcare is not decided by courts or legislatures***. As one of the over 80 stakeholders that helped draft HB 2002, the OMA supports the bill because it supports patients and their clinicians. We believe that all reproductive and gender affirming healthcare decisions should be discussed and determined by patients together with their clinicians in the privacy of an exam room…."
> (*emphasis* added)

The Division of Financial Regulation has expertise in financial services, including banking, insurance, and securities – not health care. The Division should not tread where the legislature wisely did not by

attempting to define accepted standards of care for a highly specialized, rapidly evolving medical specialty that is very far outside of the Division's area of financial expertise. The Division has no staff with medical licensure who are qualified to evaluate the clinical evidence and make such a determination.

Within Oregon law, standards of care for medical professionals are delegated to the licensing boards that regulate them. For instance, the Oregon Medical Board is empowered to adopt and enforce rules regarding standards of care:

> ORS 677.265 Powers of board generally
> (1)Adopt necessary and proper rules for administration of this chapter including but not limited to:
> * * *
> (c) Enforcing the provisions of this chapter and exercising general supervision over the practice of medicine and podiatry within this state. *In determining whether to discipline a licensee for a standard of care violation, the Oregon Medical Board shall determine whether the licensee used that degree of care, skill and diligence that is used by ordinarily careful physicians in the same or similar circumstances in the community of the physician or a similar community.*

This includes a clear definition of "standard of care" in Oregon law ("whether the licensee used that degree of care, skill and diligence that is used by ordinarily careful physicians in the same or similar circumstances in the community of the physician or a similar community") – and clearly delegates authority over physicians to the Board of Medicine, not to the financial experts at the Division of Financial Regulation.

WPATH SOC8 Is NOT Broadly Accepted as the Standard of Care

The ORS 677.265 definition of "standard of care" (above) is consistent with national standards. For highly specialized practices like gender-affirming treatment, the practice is to apply a national standard of care – where the "community of physicians" is interpreted as the "national community of physicians" engaging in the same field, as described by Drs. Cooke, Worsham and Reisfield in the Journal of the American Academy of Psychiatrist and the Law. [2]

There is not, at present, a consensus on the standards of care for gender-affirming treatment.

As noted above, HB2002 effectively defines "gender-affirming treatment" to mean any medical or behavioral health service to treat an individual for gender dysphoria – except for conversion therapy, which is legally prohibited in Oregon.

WPATH SOC8 was developed by one professional association – the "World Professional Association for Transgender Health" and endorses the practices by its members. As Drs. Cooke et al note, guidelines issued by professional medical societies are not "immune from bias."[3] The American Psychiatric

[2] Cooke BK, Worsham E, Reisfield GM. The Elusive Standard of Care. J Am Acad Psychiatry Law. 2017 Sep;45(3):358-364. PMID: 28939735; available for download at https://jaapl.org/content/45/3/358.long
[3] Ibid, p. 363

Association takes a more modest approach with its own Practice Guidelines, by stating that they "are not intended to service or be construed as a "standard of medical care.""[4]

The American Academy of Pediatrics (AAP) has also issued "practice guidelines" on gender-affirming treatment that are similar to WPATH SOC8 – but has recently commissioned "a systematic review of medical research on the treatments, following similar efforts in Europe that found uncertain evidence for their effectiveness in adolescents," as described in the New York Times last August.[5] Earlier this month, as reported in the New York Sun, the AAP cancelled publication of a book offering doctors "practical guidance and overview on access" to pediatric gender medicine – citing their "upcoming policy review on this topic." This also comes in the wake of multiple medical malpractice lawsuits naming the AAP as a defendant, filed by patients who underwent medical transition as minors.[6]

As the New York Times Magazine wrote in a detailed article in 2022, "the medical community that treats them is deeply divided about why" there is a large surge in the number of teens seeking gender transition "and what to do to help them." The article notes that major medical associations including "the Endocrine Society, the American Psychological Association, the American Psychiatric Association and the American Academy of Pediatrics have endorsed gender-affirming care as the only acceptable approach" – as has the Oregon legislature, in passing HB2002 – but that, like the HB2002, "the major medical groups tended to speak in broadly supportive terms without specifying how providers should actually do it."[7]

Internationally, the disagreement with WPATH SOC8 regarding standards of care for gender-affirming treatment is even stronger. As a group of 21 clinicians and researchers from nine countries wrote in the Wall Street Journal in July 2023:[8]

> "Every systematic review of evidence to date, including one published in the Journal of the Endocrine Society, has found the evidence for mental-health benefits of hormonal interventions for minors to be of low or very low certainty. By contrast, the risks are significant and include sterility, lifelong dependence on medication and the anguish of regret. For this reason, more and more European countries and international professional organizations now recommend psychotherapy rather than hormones and surgeries as the first line of treatment for gender-dysphoric youth."

[4] Ibid, p. 362

[5] "Doctors Back Youth Gender Treatments but Call for Review of Data," Azeen Ghorayshi, New York Times, August 4, 2023, Section A, Page 14. https://www.nytimes.com/2023/08/03/health/aap-gender-affirming-care-evidence-review.html

[6] "Lawsuits by Regretful 'Detransitioners' Take Aim at Medical Establishment's Support for Gender-Transition Treatments for Minors," Benjamin Ryan, New York Sun, December 5, 2023. https://www.nysun.com/article/lawsuits-by-regretful-detransitioners-take-aim-at-medical-establishments-support-for-gender-transition-treatments-for-minors

[7] 'The Battle Over Gender Therapy," Emily Bazelon, The New York Times Magazine, June 19, 2022, page 30. https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html

[8] "Youth Gender Transition Is Pushed Without Evidence," Prof. Riittakerttu Kaltiala, M.D., Ph.D. et al, Wall Street Journal, July 14, 2023, https://www.wsj.com/articles/trans-gender-affirming-care-transition-hormone-surgery-evidence-c1961e27

In recent years, Norway, Finland, Sweden, the United Kingdom and other European countries have imposed more restrictions on access the kinds of hormonal and surgical interventions promoted by WPATH SOC8, out of concerns for the lack of clinical evidence and risk of harm. As a recent Forbes article reports, "… progressively the message emanating from European gender experts is that until there is reliable long-term evidence that the benefits of youth gender transition outweigh the risks, it is prudent to limit most medical interventions to rigorous clinical research settings." These countries continue to provide other forms of gender-affirming treatment, with "a less medicalized and more conservative approach that addresses possible psychiatric comorbidities and explores the developmental etiology of trans identity."[9]

The Agency for Healthcare Research and Quality (AHRQ), the lead Federal agency for patient research in the United States, was created by Congress to develop evidence-based, specialty-specific practice guidelines.[10] In 2020, the American Academy of Family Physicians (AAFP) petitioned AHRQ to develop a "clinical practice guideline for family physicians to provide high value and appropriate care of the child and adolescent who identifies as transgender.'[11]

After carefully reviewing the AAFP's nomination, AHRQ's Evidence-based Practice Center decided NOT to develop a new systematic review – because it found "an insufficient number of primary studies" to address key questions about the safety and efficacy of hormone therapy and surgical affirmation.[12] The AHRQ noted that "[t]here is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation. While there are some existing guidelines and standards of care, most are derived from expert opinion or have not been updated recently. A comprehensive evidence review is currently not available."

The inability of this critical federal agency to find sufficient evidence to support the kinds of hormone therapy and surgical affirmation recommended by WPATH SOC8 should make it clear to the Division of Financial Regulation that endorsing WPATH SOC8 as the "Accepted Standard of Care" – when the Oregon Legislature pointedly declined to intervene by setting a standard in HB2002 – would be a mistake. It would risk being overturned by judicial review – or even subjecting the Division and its personnel to the kinds of legal liability for malpractice currently faced by the American Academy of Pediatrics.

[9] "Increasing Number Of European Nations Adopt A More Cautious Approach To Gender-Affirming Care Among Minors," Joshua Cohen, Forbes, June 6, 2023. https://www.forbes.com/sites/joshuacohen/2023/06/06/increasing-number-of-european-nations-adopt-a-more-cautious-approach-to-gender-affirming-care-among-minors/

[10] Cooke BK, et al, p. 362.

[11] Treatments for Gender Dysphoria in Transgender Youth. Content last reviewed February 2021. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. https://effectivehealthcare.ahrq.gov/get-involved/nominated-topics/treatments-gender-dysphoria-transgender-youth

[12] "Topic Brief: Treatments for Gender Dysphoria in Transgender Youth," Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. https://effectivehealthcare.ahrq.gov/system/files/docs/topic-brief-gender-dysphoria.pdf

The Solution – Medical Technology Assessment by HERC

While the Division of Financial Regulation shouldn't attempt to define a medical standard of care for gender-affirming treatment – or any other medical condition – there is a well-established solution in Oregon law: the Health Evidence Review Commission (HERC) can conduct a formal Medical Technology Assessment. This process, defined in ORS 414.695 and 414.698, is rigorous and requires a public hearing, and solicitation of testimony and information from health care consumers. HERC's Evidence-based Guidelines Subcommittee (EbGS) can follow its coverage guidance process[13] to develop and publish evidence-based policy that can serve as Oregon's recommended "standard of care" for gender-affirming treatment.

HERC's research could end up endorsing WPATH SOC8 – if it finds that it meets Oregon's standards for evidence-based medicine – or HERC could, after its thorough and transparent process, develop other standards consistent with its evaluation of other technologies.

HERC apparently began evaluating WPATH SOC8 in early 2023 to update its evidence review of treatment for gender dysphoria – but abandoned that review when HB2002 was passed by the legislature. Instead of completing the formal medical technical assessment process prescribed by ORS 414.695 and 414.698, HERC simply adopted WPATH SOC8 on advice of "several individuals (including patients and a health plan representative)." HERC's decision to abort its evidence review of WPATH SOCC8 was legally erroneous, based on a misinterpretation of its responsibilities under HB2002. I will follow up with HERC directly.

In the absence of a clear consensus in the medical community – backed by the analysis of evidence-based medicine that has long been the hallmark of Oregon health policy – Oregon simply cannot declare WPATH SOC8 (or any other guideline) to be the "accepted standard of care" for gender-affirming treatment.

Recommendations:

- The bulletin should NOT define "accepted standard of care" for "gender-affirming treatment" to mean "the World Professional Association for Transgender Health's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8" at this time.
- The Health Evidence Review Commission's Evidence-based Guidelines Subcommittee should be charged with developing an Evidence-based Guideline for Gender-Affirming Treatment, using the medical technology assessment process established in ORS 414.695 and 414.698 and HERC's rules and policies.

Sincerely,

Paul Terdal,
Health Consumer Advocate

[13] HERC Coverage Guidance Process: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Coverage-Guidance-Process.aspx

The Elusive Standard of Care

Brian K. Cooke, MD, Elizabeth Worsham, MD, and Gary M. Reisfield, MD

In medical negligence cases, the forensic expert must explain to a trier of fact what a defendant physician should have done, or not done, in a specific set of circumstances and whether the physician's conduct constitutes a breach of duty. The parameters of the duty are delineated by the standard of care. Many facets of the standard of care have been well explored in the literature, but gaps remain in a complete understanding of this concept. We examine the standard of care, its origins, and who determines the prevailing standard, beginning with an overview of the historical roots of the standard of care and, using case law, tracing its evolution from the 19th century through the early 21st century. We then analyze the locality rule and consider local, state, and national standards of care. The locality rule requires a defendant physician to provide the same degree of skill and care that is required of a physician practicing in the same or similar community. This rule remains alive in some jurisdictions in the United States. Last, we address the relationship between the standard of care and clinical practice guidelines.

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A medical negligence case is the result of a clinical situation that has had an adverse outcome. The task of the forensic expert is to determine what actions a defendant physician should have taken and whether a breach of duty has occurred, in accordance with the parameters set forth by the standard of care. Thus, the forensic expert must both define the standard of care and opine whether it has been properly applied.[1]

Scholars have examined the standard of care and provided guidance for those involved in these forensic cases. For example, Recupero and Harms[2] studied whether psychiatrists treating outpatients agree about the standard of care for requesting records from a patient's past clinician. Rogers *et al.*[3] provided commentary on the differences between legal and clinical standards of care and offered suggestions on incorporating medicolegal aspects of standard of care in psychiatry residency curricula. Simon[4] wrote an editorial on standard-of-care testimony for *The Journal*.

Experiences with clinicians and a personal review of expert witness testimony suggest that a complete understanding of the standard of care is still elusive. What is a "standard of care"? From whence does it arise? Who determines the prevailing standard? Our aim is to examine these questions, beginning with an overview of the historical roots of the standard of care and using case law to trace its evolution from the 19th century through the 20th and early 21st centuries. We analyze the locality rule and consider local, state, and national standards of care. Finally, we address the relationship between the standard of care and concepts with which it is often conflated, such as best practices, expert opinions, and the now-pervasive clinical practice guidelines.

The Genesis of the Standard of Care

Through most of the first half of the 19th century, there was little scientific foundation for the practice of medicine. It was based largely on a received ancient wisdom, and bore practically no resemblance to the medicine of today.[5] Early American physicians, like their European counterparts, attempted to establish professional authority based on education, licensing, and membership in professional societies, but there was little legitimate basis for their claims.[6] This disjunction was brought into stark relief during Andrew Jackson's administration, which was marked by egalitarian, antielitist sentiments. Under Jackson, all state medical licensing laws were repealed, replaced by a "marketplace professionalism" in which anyone, trained or not, was free to offer their services in an unregulated marketplace.[5]

This situation began to change around the mid-19th century, as traditional medicine began to reas-

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sert its authority. The American Medical Association (AMA), founded in 1847, worked for reforms in medical education, standardization of medical practice, and reinstitution of licensing laws.[5] As well, medical authority began to be asserted on the basis of the legitimacy of practice and scientific breakthroughs in, for example, ether anesthesia (1846), introduction of antisepsis by Lister (1867), and immunology, including the development of vaccines (cholera, 1879; anthrax, 1881; and rabies, 1882). Medical doctors were the primary emissaries of these advances, and their growing competence began to bestow legitimate authority upon them.[7]

Through the first third of the 19th century, medical malpractice lawsuits were extremely rare.[8] These actions, originally derived from English jurisprudence, were comprised chiefly of common law writ proceedings. The middle third of the century, dubbed by Spiegel and Kavaler[8] as America's first medical malpractice crisis, coincided with this era of marketplace professionalism. During this period of unlicensed, unregulated practice, in which medical doctors ("regulars") openly competed both with members of their own profession and with their "irregular" counterparts (e.g., homeopaths, hydropaths, and botanists, among others), medical care was sometimes regarded by the courts as comprising a contract between individuals and malpractice as a breach of contract. Gradually, during the final third of the century, tort emerged as an independent branch of the law and, with it, the concept of medical negligence evolved as a genuine tort doctrine, conditioned on a policy determination that a standard of care had been breached.[9]

White[9] argued that the writ system collapsed of its own weight, devolving into an unwieldy classification system, chiefly because of the growing diversity of American law. Little academic attention has been paid to the reasons for the shift from contract to tort.[10] Certainly, both medical and legal factors were responsible. Mohr[5] asserted that the change was brought about, in large part, by the medical profession's efforts to achieve professional status and to distinguish medical care from ordinary commercial transactions. Medicine argued that contracts assumed equal footing between parties, and the increasing complexity of medicine created asymmetries in knowledge, risk evaluation, and bargaining power that made contract law unsuitable to the evolving nature of the physician–patient relationship.[5] As well, Atiyah[10] argued that medical misadventures, comprising unforeseen and accidental events, could not reasonably be accommodated by contract law.

In any event, the result was that, by the end of the 19th century, medical malpractice was firmly rooted in the principles of tort law. Whereas contract actions are evaluated based on agreed-upon outcomes, tort actions are evaluated by the integrity of processes.[11] The integrity of processes, in turn, are adjudged by the adherence to standards. To be liable for breaching standards of care, accepted standards must first be established.[11] Thus, the adoption of tort law required the establishment of standards by which medical care could be evaluated, standards that the AMA played a role in developing.[5] Although physicians would be protected from claims based on failure to achieve contracted outcomes, it left them vulnerable to whatever deficiencies in adherence to standards of care plaintiffs could demonstrate.[11] The medical establishment was willing to pay this price for its professional status.

The Locality Rule

As malpractice law evolved, courts began comparing a physician's practice to those of similarly situated professionals in their community. The applicable standard of care in medical malpractice lawsuits varies somewhat among jurisdictions in the United States. Expert witnesses should understand whether a locality rule applies in the jurisdiction of the case in which they have been retained. Black's Law Dictionary defines the locality rule as "a term in medical jurisprudence where the physicians of an area must maintain standards of practice."[12] The locality rule requires defendant physicians to provide the same degree of skill and care that is required of other physicians practicing in the same or similar community. It places a geographical dimension on the professional standard of care in medical negligence litigation.[13] The strictest form of the locality rule would require expert witnesses to practice in the same or a similar community of the case in which they are offering opinions.[14]

Once widely adopted in the United States, the locality rule was originally designed to protect rural physicians from having to uphold the same standard of care as that provided in the academic health science centers and modern clinics of the city.[15] It was believed that rural practitioners lacked the equipment of the urban health centers and did not benefit from the latest advances in science and practice that emanated from medical research conducted at urban

hospitals. There is controversy, however, because some critics have called extant locality rules "archaic, anachronistic, and in fact, insulting to modern medicine" (Ref. 13, p 324–5).

Landmark Cases

The origin of the locality rule is often attributed to *Small v. Howard*,[16] an 1880 opinion of the Supreme Judicial Court of Massachusetts that endured until overruled by the same court in 1968. This case is cited as the first appellate decision requiring the use of a locality rule. In *Small*, Dr. Howard was sued by a patient in Massachusetts for alleged "malpractice in dressing and caring for a wound upon the [patient's] wrist" (Ref. 13, p 322). Dr. Howard was a general practitioner in a country town with a population of 2,500. He was consulted by the plaintiff, Mr. Small, to treat a severe wound, a serious injury caused by glass, that required a considerable degree of surgical skill. The wrist wound "extended to the bone, severing all the arteries and tendons" (Ref. 13, p 328). In *Small*, the plaintiff proposed, and the trial court refused, an instruction suggesting "that the skill required of the defendant was merely the average skill of all practitioners, educated and uneducated, permanent and occasional, regulars and interlopers alike" (Ref. 13, p 329). The Supreme Judicial Court of Massachusetts rejected this form of instruction and offered the following, which is often credited as the origin of the locality rule:

> The defendant . . . being the practitioner in a small village . . . was bound to possess that skill only which physicians and surgeons of ordinary ability and skill, practi[c]ing in similar localities, with opportunities for no larger experience, ordinarily possess; and he was not bound to possess that high degree of art and skill possessed by eminent surgeons practi[c]ing in large cities, and making a specialty of the practice of surgery [Ref. 13, p 329].

In *Brune V. Belinkoff*,[17] the Supreme Judicial Court of Massachusetts overturned their prior ruling in *Small*. *Brune* was a malpractice case of Ms. Theresa Brune who sought to recover from the defendant because of alleged negligence in administering a spinal anesthetic. Ms. Brune delivered a baby in 1958 at St. Luke's Hospital in New Bedford, Massachusetts. During the delivery, Dr. Belinkoff, a specialist in anesthesiology practicing in New Bedford, administered a spinal anesthetic to the plaintiff containing 8 mg of pontocaine in 1 cc of a 10% solution of glucose. When Ms. Brune attempted to get out of bed 11 hours later, she slipped and fell on the floor. She subsequently complained of numbness and weakness in her left leg, which appeared to have persisted to the time of trial.

Eight physicians provided testimony, much of which was related to the plaintiff's condition. There was ample evidence that her condition resulted from an excessive dosage of pontocaine. Others testified that it was an appropriate dose and a customary dose for New Bedford vaginal deliveries.[17]

The Supreme Judicial Court of Massachusetts offered:

> A general medical practitioner is to be held to the standard of care and skill of the average qualified practitioner, and a medical specialist is to be held to the standard of care and skill of the average practitioner of the specialty, taking into account with respect to either the general practitioner or the specialist the advances in the profession and the medical resources available to him [Ref. 17, p 798].

Thus, a specialist should be held to the standard of care and skill of the average member of the profession practicing the specialty, taking into account the advances in the profession.

The last case we review redefined the standard of care but was heard in a different jurisdiction than the previously two described cases. In *Hall v. Hilbun*,[18] Terry Hall was admitted to the hospital in Mississippi in May 1978 complaining of abdominal pain. Dr. Hilbun, a general surgeon, was consulted and performed surgery for a small bowel obstruction. Mr. Hall had provided adequate consent, and surgery was performed with apparent success. However, Mr. Hall later died in the hospital of respiratory failure.

Two areas of fault suggested were Dr. Hilbun's failure to make inquiry regarding his patient's postoperative course before retiring on the night of May 20 and his alleged failure to give appropriate postoperative instructions to the hospital nursing staff. The plaintiff called Dr. S. O. Hoerr, a retired surgeon from Cleveland, Ohio, as an expert witness. Through that testimony, the plaintiff sought to establish that there is a national standard of surgical practice and surgical care of patients in the United States to which all surgeons, including Dr. Hilbun, are obligated to adhere. Dr. Hoerr conceded that he did not know for a fact the standard of professional skill, including surgical skills and postoperative care, practiced by general surgeons in Pascagoula, Mississippi, but that he did know what the standard should have been. The Mississippi Supreme Court provided the following:

> [G]iven the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options [Ref. 18, p 873].

Emergence of Professional Standards

The locality rule was established before the standardization of medical training and certification, which, critics argue, obviated the need for a locality rule. The Liaison Committee on Medical Education (LCME) is recognized by the U.S. Department of Education as the reliable authority for the accreditation of medical education programs leading to a Doctor of Medicine degree.[19] The LCME was founded at a 1942 meeting of the Association of American Medical Colleges and the AMA.[20] The accreditation of allopathic medical schools in the United States is granted by the LCME through compliance with national standards. The locality rule is now difficult to justify, as medical education has become more standardized, and modern technology provides rural physicians with the same access to information for patient care as is available to urban ones.

The Accreditation Council for Graduate Medical Education (ACGME) was founded in 1981 and accredits all U.S. clinical residency and fellowship programs.[21] The ACGME accredits organizations that provide continuing medical education that has a national focus. Medical board certification examinations, administered by the member boards of the American Board of Medical Specialties since its founding in 1933, are national in scope. Although medical school training, medical licensing requirements, and board certification requirements are based on national standards, some states continue to rely on local practice standards to determine the applicable standard of care in medical malpractice lawsuits.

Toward a National Standard of Care

Although *Brune* overturned *Small* and there is an established national basis to the training and certification of medical education, the locality rule remains alive in the United States. Lewis and colleagues[22] delineated which states had established different standards of care. At the time of that publication in 2007, 21 states maintained a version of the locality rule, in which physicians are judged by the standard of care in their locality; 29 states followed a national standard. Of the 21 states that followed a version of the locality rule, 3 followed a statewide standard, 2 the same-community standard, 11 the same- or similar-community standard, and 5 the similar-community standard for general practitioners and a national standard for specialists. These counts were updated in 2014 (M. H. Lewis, personal communication, July 6, 2015); 45 states are now believed to follow a national standard, whereas only 5 states (Arizona, Arkansas, Idaho, New York, and Pennsylvania), still follow a version of the locality rule. Notably, medical schools operate in all states that adhere to the locality rule except Idaho.

A national standard of care presupposes that rural physicians will have the same training, and exercise the same level of judgment and diligence, as urban practitioners. It does not require that rural physicians have the same available medical facilities. For example, if the community does not have facilities for emergency surgery, physicians cannot be found negligent for failing to perform this surgery within the amount of time that might constitute the standard in a well-equipped urban hospital. Because there would still be differences in available resources, physicians practicing under a national standard would need to alert patients to the lack of necessary facilities or resources, should they exist. Advances in modern medicine and the ease of access to those advances regardless of practice location give further support for the eradication of the last vestiges of the locality rule in United States.

Clinical Practice Guidelines

In the 1970s and 1980s, the literature regarding health care costs, common practices, and outcomes surged.[23–26] Research demonstrated that medicine was practiced differently depending on location. For example, patients in Miami spent twice as much time in the hospital and intensive care units as similar patients in Minneapolis.[26,27] In addition, costs for comparable populations differed markedly across the United States. Gawande[24] reported that, in 2006, the average Medicare enrollee in McAllen, Texas, received approximately $15,000 per year in medical services, twice as much as comparable patients in the nearby and sociodemographically similar El Paso. Such disparities represent, in part, local differences in medical culture, including the degree to which communities practice defensively, especially if the science is unclear.

Because of these marked health care delivery inconsistencies, the United States Congress heeded the call for improvements in 1989 by creating the Agency for Healthcare Quality and Research, now called the Agency for Healthcare Research and Quality (AHRQ).[28] This agency was charged with creating specialty-specific clinical practice guidelines to align the fragmented practice of medicine in America. The AHRQ defined practice guidelines as "systematically developed statements [to] assist health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances."[29]

Professional medical societies, state governments, liability insurers, and health insurance companies followed suit and created their own guidelines. The AHRQ hoped that practice guidelines would result in a more uniform practice of medicine. In addition, the guidelines would provide a host of other benefits, including effective dissemination of research findings into clinical practice, promotion of patient safety, and reduction in the rising cost of health care.[30,31] With regard to health care costs, the goal was to reduce the practice of both defensive and offensive medicine. The latter refers to reducing the frequency of unnecessary interventions performed by physicians purely for financial gain. In establishing these guidelines, the intent was not to establish the standard of care. In fact, each American Psychiatric Association (APA) practice guideline clearly defines the proper use of the guide. For example, the APA Practice Guidelines for the Psychiatric Evaluation of Adults states:

> The American Psychiatric Association Practice Guidelines are not intended to serve or be construed as a "standard of medical care." Judgments concerning clinical care depend on the clinical circumstances and data available for an individual patient and are subject to change as scientific knowledge and technology advance and practice patterns evolve [Ref. 32, p 799].

Nonetheless, many states hoped that, through the creation of these guidelines, adherent practitioners could be shielded from frivolous litigation, eventually reducing the practice of defensive medicine.[26] Most notably, Maine promised in the 1990s that strict adherence to practice guidelines would shield practitioners as an affirmative defense to medical malpractice. However, this one-way street would not allow plaintiffs to use nonadherence to the guidelines as evidence in a malpractice case. Despite similar programs and intents in Florida, Minnesota, and Vermont, none of the state programs was successful, nor did they control costs. Furthermore, Florida and Minnesota failed to issue practice guidelines.[30]

As of April 2017, there were 8,228 individual guideline summaries for all medical specialties according to the AHRQ.[33] Of those, there were 229 individual guideline summaries for psychiatry and psychology. With this surfeit of guidelines, it is easy to conclude that, at best, many provide redundant information and, at worst, they provide conflicting information, thus undermining their primary intent. These guidelines have at least four significant pitfalls that limit their usefulness in unifying the practice of medicine and providing a concise summary of appropriate medical care for a specific clinical circumstance. More have been explicated by Recupero.[28]

First, many guidelines quickly become outdated because of new research and practices. After approximately six years, only half of all practice guidelines on the AHRQ website were valid.[34] Replacing a guideline costs an average of $350,000. The rapid expiration of guidelines requires large expenditures of time and money that can hamper effective dissemination of concise recommendations.

Second, many of the guidelines conflict with each other, even when created contemporaneously. Saddichha and Chaturvedi[35] highlighted how some preeminent psychiatric institutions' guidelines differ from one another. For example, in the management of schizophrenia, the duration of treatment and recommended psychosocial interventions differed significantly. These clashes confuse patients and may cause clinicians to ignore the weight of the recommendations.

Third, many of the guidelines lacked the requisite scientific evidence to support their recommendations. One study found that 90 percent of guidelines failed to describe formal methods of how guideline authors reconcile scientific evidence with expert opinion, and more than 25 percent of guidelines failed to cite any references.[36] Furthermore, some guidelines note that relevant older literature was explicitly excluded from the guidelines for practical purposes, to streamline literature review. For example, the authors of the APA's Major Depressive Disorder practice guideline acknowledged that the recommendations emphasize newer treatments, minimizing helpful information regarding tricyclic antidepressants and monoamine oxidase inhibitors.[37] To mitigate these omissions, the authors encouraged readers to consult older versions of the practice guidelines. However, these older versions are not available on the website.

Finally, guidelines established by private health insurance companies, liability insurers, and the pharmaceutical industry, groups without fiduciary responsibilities to patients, may be biased. Guidelines created by these entities should be considered with skepticism because of inherent conflicts. Nor are guidelines that are issued by professional medical societies immune from bias, as many authors have significant relationships with industry. Choudhry and colleagues[38] discovered that only seven percent of guideline authors believed that their own relationship with the pharmaceutical industry influenced their recommendations. Yet, of that same group of authors, 19 percent believed that their coauthors' recommendations were influenced by pharmaceutical relationships.

Notwithstanding these many pitfalls, the question remains of whether physicians adhere to their specialty's practice guidelines with the goal of unifying and improving the practice of medicine. Even with free online access to over 8,200 individual guidelines, the behavior of physicians has not measurably changed.[30] More than half of the physicians surveyed did not know that guidelines existed online. Even those aware of the guidelines objected to following them for various reasons, including an aversion to practicing "cookbook" medicine, the wish to adhere to non–evidence-based recommendations, and the perception that guidelines represented a threat to their practice autonomy.[39]

Even though the creation of practice guidelines was not intended to set the standard of care, artful attorneys have found that these widely published standards, despite their many pitfalls, could be persuasive to juries in malpractice litigation, especially those guidelines created by professional medical societies. The Federal Rules of Evidence[40] and landmark cases of *Reilly v. Pinkus*[41] and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[42] paved the way for entering medical treatises as evidence. Plaintiff attorneys attempt to use CPGs as a "sword," or as inculpatory evidence. Defense attorneys attempt to use CPGs as a "shield," or as exculpatory evidence.[43] Although malpractice cases rarely make it to trial,[44] the cases that do may involve use of CPGs as evidence on either side of the courtroom.

Hyams and colleagues[43] assessed how often and how successfully CPGs were used as evidence in malpractice cases. In a computerized search of U.S. courts from 1980 through 1994, there were 37 instances in which CPGs were used as either a shield or sword, whether successful or not. CPGs were used successfully in 28 cases, 22 times by plaintiffs, and 6 times by the defense. Generally, when CPGs were used successfully, the guidelines originated from strong, evidence-based sources, such as the APA, American College of Obstetrics and Gynecology, American Heart Association, AMA, American Academy of Pediatrics, and the American Society of Anesthesiologists. However, nine times the guidelines were used unsuccessfully: seven times by plaintiffs and twice by the defense. In those instances, the guidelines originated principally from liability carriers or federal institutions, not professional medical societies, likely contributing to their failure to persuade. It should be noted that these outcomes hinged on the verdict at trial and CPGs were just one part of the larger body of evidence. In addition, because of the age of that study, the findings may be limited; it is unclear if this pattern of CPG use in the courtroom persists today.

Discussion

This historical review of the development of the standard of care reminds mental health experts that despite case law and the national standards of medical training and certification, the locality rule remains alive in some jurisdictions of the United States. The distinction between a generalist and a specialist still prevails. For example, a family medicine practitioner in the rural southern United States will not be expected to possess the same knowledge of viruses as an infectious disease specialist at an academic institution in a major city in the southeast.

When retained in medical malpractice cases, the expert must remember that the standard of care may vary among jurisdictions in the United States. Practice guidelines, although intended to unify and improve the practice of medicine, often fail to provide sufficient clarity because of age, conflicting recommendations, various levels of evidential support, and underutilization by practitioners. In many cases, the standard of care is determined *de novo* and is a moving target. This is one reason why static documents, guidelines, and algorithms are not quite coextensive with the requirements of the legal system. Furthermore, learned medical treatises do not constitute evidence *per se*. Rather, they are elements of the experts' opinions that may be introduced into evidence at trial.

Expert witnesses must carefully consider whether to use CPGs in reports or testimony, for example in personal-injury cases. Newer technologies and data analytics, including standards built into the elec-

tronic health record, may also shape the modern standard of care. Future research should examine the current use of practice guidelines and emerging technologies as evidence in malpractice cases.

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April 29, 2023

Representative Dan Rayfield
Oregon House Speaker
District 16
900 Court St. NE
Salem, OR 97301

Delivered via email to: rep.danrayfield@oregonlegislature.gov

Speaker Rayfield:

Thank you for your question regarding House Bill 2002 (2023). You asked whether HB 2002, which generally requires health insurance carriers to provide coverage for medically necessary gender-affirming treatment, would also require coverage for medical procedures associated with a gender detransition.

As you know, Section 20 of the B-Engrossed version of HB 2002 defines the phrase "gender-affirming treatment" as follows:

> *"Gender-affirming treatment" means a procedure, service, drug, device or product that a physical or behavioral health care provider prescribes to treat an individual for incongruence between the individual's gender identity and the individual's sex assignment at birth.*

The reference to an "incongruence" between an individual's gender identity and that person's sex assigned at birth has raised a question of whether this definition would exclude detransition procedures. We do not believe it does.

ORS 174.100(4) provides the following definition of "gender identity" that applies to Oregon statutes unless the context or a specially applicable definition requires otherwise:

> *"Gender identity" means an individual's gender-related identity, appearance, expression or behavior, regardless of whether the identity, appearance, expression or behavior differs from that associated with the gender assigned to the individual at birth."*

This definition would apply for purposes of HB 2002. Importantly, this definition does not focus solely on an individual's subjective sense of his or her own gender, but includes other objective facets of gender identity such as "appearance, expression or behavior."

Given this definition, we believe that detransition procedures *would be* included in the definition of "gender affirming treatment" under HB 2002. To illustrate, an individual who previously received gender affirming treatment and who is now seeking to reverse the effect of that treatment *would be* seeking treatment for an incongruence between their gender identity (namely, their appearance) and their sex assigned at birth. This conclusion is supported by HB 2002's explicit inclusion of "revisions to prior forms of gender affirming treatment" in the same section's list of prohibited exclusions.

Finally, HB 2002 specifically requires the department to adopt rules implementing the bill. If a question remains on this issue after HB 2002 becomes law we would be glad to address that as part of such rulemaking.

Please feel free to contact me if you have any further questions or concerns.

Sincerely,

Andrew R. Stolfi
Oregon Insurance Commissioner
Director, Oregon Department of Consumer and Business Services

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