

Oregon Department of Consumer and Business Services Division of Financial Regulation, Bulletin No. DFR 2023-X

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To: All entities offering health benefit plans in Oregon

Date: November XX, 2023

RE: Director's expectations for health benefit plans under the Oregon Reproductive Health Equity Act

I. Definitions

As used in this bulletin:

"Cost sharing" means any expenditure required by or on behalf of an enrollee with respect to a covered benefit. Cost sharing includes deductibles, coinsurance, copayments, and any similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

"Director" means the director of the Oregon Department of Consumer and Business Services.

"FDA" means the United States Food and Drug Administration.

"Reproductive Health Equity Act" or "RHEA" means the Oregon Reproductive Health Equity Act as enacted under Chapter 721, Oregon Laws 2017 (Oregon House Bill 3391 (2017)) and any subsequent amendments.

"RHEA listed service" means a service, drug, device, product or procedure described in ORS 743A.067(2)(b) through (l). The term does not include well woman care under ORS 743A.067(2)(a) and additional preventive services for women under ORS 743A.067(2)(m).

"Therapeutic equivalent" means a contraceptive drug, device or product that the FDA Has classified as being therapeutically equivalent to another contraceptive drug, device or product in the most recent edition of the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as "The Orange Book."¹)

¹ As of the date of this bulletin, the 2023 Edition of the Orange Book is available for download at: <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>

II. Scope of RHEA covered services generally

The Oregon Reproductive Health Equity Act (RHEA) requires a health benefit plan to provide coverage without cost sharing for each service, drug, device, product and procedure described in ORS 743A.067(2). Importantly, the scope of services that must be covered without cost sharing under RHEA is broader than the scope of preventive services that must be covered in accordance with the federal preventive services mandate at 42 USC § 300gg–13 and ORS 743A.262.

In cases where a service described in ORS 743A.067(2) is also a federal preventive service, the director considers RHEA to be inclusive of, but not limited to, the coverage that is required under federal law. Accordingly, if a health benefit plan fails to provide coverage for a federal preventive service that is also described under ORS 743A.067(2), the director would consider that plan to have violated both RHEA and the federal preventive services mandate. At the same time, however, a health benefit plan's obligation to comply with RHEA is not limited to solely providing federal preventive services without cost sharing in accordance with 42 USC § 300gg–13 and ORS 743A.262.

Q1 - To what extent may a health benefit plan deny or restrict coverage for a service that must be covered under RHEA?

ORS 743A.067(4) provides that "Except as authorized under this section, a health benefit plan may not impose any restrictions or delays on the coverage required by this section." In accordance with this provision, a health benefit plan may only deny or restrict coverage for a service described under ORS 743A.067(2) if another provision of ORS 743A.067 specifically authorizes the denial or restriction.

ORS 743A.067(7) lists certain types of treatments for which RHEA does not require coverage. Specifically, under ORS 743A.067(7), RHEA does not require a health benefit plan to cover:

- Experimental or investigational treatments;
- Clinical trials or demonstration projects (except as provided in ORS 743A.192);
- Treatments that do not conform to acceptable and customary standards of medical practice;
- Treatments for which there is insufficient data to determine efficacy; or
- Abortion if the carrier offering the health benefit plan is exempt from abortion coverage under RHEA.

When a carrier offering a health benefit plan denies a claim for a service described under ORS 743A.067 for a reason listed in ORS 743A.067(7), the director expects that the carrier will document the reason for the denial and be able to demonstrate why it was appropriate to apply that criterion to a particular claim. The director also expects that the carrier will provide the enrollee who submitted the claim with all appeal rights required under ORS 743B.250.

In addition to ORS 743A.067(7), ORS 743A.067(12) permits “reasonable medical management” for services other than abortion and contraception. The scope of medical management permitted under this provision is discussed in section IV. of this bulletin. ORS 743A.067(2)(j) establishes additional requirements for contraception coverage under RHEA, which are discussed in sections V. through VII. of this bulletin.

Q2 – With respect to “screening” for a condition listed under ORS 743A.067(2)(c), does RHEA require health benefit plans to reimburse the cost of diagnostic tests?

Yes. To the extent that a screening described under ORS 743A.067(2)(c) is performed on an enrollee by means of a diagnostic or other form of test, a health benefit plan must provide coverage for the test without cost sharing. Consistent with ORS 743A.067(7), RHEA does not require a health benefit plan to cover tests for which there is insufficient data to determine efficacy or in cases where the use of a diagnostic test does not conform to acceptable and customary standards of medical practice.

Q3 – With respect to well woman care under ORS 743A.067(2)(a) and preventive care for women under ORS 743A.067(2) (m), are RHEA’s coverage requirements consistent with federal requirements for preventive coverage under the ACA?

Yes. ORS 743A.067(2)(a) requires health benefit plans to provide coverage for “well-woman care prescribed by the Department of Consumer and Business Services by rule consistent with guidelines published by the United States Health Resources and Services Administration.” The director has adopted OAR 836-053-0435 to implement this provision.

Similarly, ORS 743A.067(2)(m) requires health benefit plans to provide coverage for “any additional preventive services for women that must be covered without cost sharing under 42 U.S.C. 300gg-13, as identified by the United States Preventive Services Task Force or the Health Resources and Services Administration of the United States Department of Health and Human Services as of January 2, 2017.” The director expects that health benefit plans will provide coverage for any services described under ORS 743A.067(2)(m) that are not also described under ORS 743A.067(2)(b) through (l) in accordance with federal requirements.

III. Prohibition on cost sharing under RHEA

ORS 743A.067(3) provides that “A health benefit plan may not impose on an enrollee a deductible, coinsurance, copayment or any other cost sharing requirement on the coverage required by this section.” This provision prohibits a health benefit plan from imposing cost sharing on a service described in ORS 743A.067(2) *any time* the plan provides coverage for that service. Accordingly, whenever a health benefit plan subject to RHEA provides coverage for a RHEA service, the plan must do so without any member cost sharing.

Q4 – May a health benefit plan impose cost sharing on a RHEA listed service when it is provided outside of a preventive context?

No. As described above, RHEA prohibits the imposition of cost sharing on a service described in ORS 743A.067(2)(b) through (l) regardless of whether the service was provided as preventive care.

IV. Reasonable medical management under RHEA for services other than contraception and abortion

ORS 743A.067(12) makes clear that, except in the case of contraception and abortion, RHEA does not prohibit a carrier offering a health benefit plan from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for the coverage of services, drugs, devices, products and procedures described in ORS 743A.067(2).

However, the allowance under ORS 743A.067(12) is not unlimited. ORS 763A.067(12)(a) and (b) provide that RHEA does not permit the application of medical management techniques if the techniques are inconsistent with the coverage requirements of ORS 743A.067(2) or result in the wholesale or indiscriminate denial of coverage for a service.

The following types of medical management are inconsistent with the coverage requirements of ORS 743A.067(2) and/or would result in the wholesale or indiscriminate denial of a RHEA service:

- Failing to provide coverage for, or imposing cost sharing upon, a RHEA listed service based on strict numerical limits that do not take into consideration the medical needs of the enrollee. For example, limiting the number of times an individual may receive a particular STI screening to once per year when more frequent tests would be medically appropriate.
- Failing to provide coverage for, or imposing cost sharing upon, a RHEA listed service on the basis that the service was not provided to the enrollee as a preventive measure. For example, imposing cost sharing on a RHEA service because the enrollee who received the service is in “active treatment” for a previously diagnosed condition.
- Failing to provide coverage for, or imposing cost sharing upon, a RHEA listed service that was medically appropriate for an individual on the basis that an enrollee is not included in the population for which the service has been recommended or supported by the United States Preventive Services Task Force, the Health Resources and Services Administration, or any similar body that issues recommendations or guidelines regarding preventive care. For example, imposing cost sharing upon a RHEA service because the enrollee who received the service is not considered “at risk” for a particular condition or outcome.

- Failing to provide coverage for, or imposing cost sharing upon, a RHEA listed service to an individual based on age or gender criteria.² For example, failing to cover voluntary sterilization without cost sharing for males.

V. Coverage of contraceptives under RHEA

ORS 743A.067(2)(j) requires a health benefit plan to provide coverage for “any contraceptive³ drug, device or product approved by the United States Food and Drug Administration.” ORS 743A.067(5)(a) makes clear that the scope of contraceptive coverage required under RHEA includes coverage for contraceptive drugs, devices or products that are prescribed by a health care provider for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause. Similarly, ORS 743A.067(5)(b) makes clear that RHEA requires coverage for contraception that is prescribed as being necessary to preserve the life or health of an enrollee.

These provisions require health benefit plans to provide coverage for the full range of FDA-approved contraceptives, including contraception that is prescribed for reasons other than preventing pregnancy.

In addition to the requirements to cover contraceptive drugs, devices and products under ORS 743A.067(2)(j), ORS 743A.067(2)(L) provides that a health benefit plan must also cover, as a single claim or combined with other claims for covered services provided on the same day, patient education and counseling on contraceptives and services related to the administration and monitoring of contraceptive drugs, devices and products.⁴

As discussed above, unlike other services required under RHEA, ORS 743A.067(12) does not permit the use of reasonable medical management techniques to determine the frequency, method, treatment or setting for contraceptives. In addition, ORS 743A.067(2)(j)(D) provides that “a health benefit plan may not infringe upon an enrollee’s choice of contraceptive drug, device or product and may not require prior authorization, step therapy, or other utilization review techniques for medically appropriate covered contraceptive drugs, devices, or other products approved by the United States Food and Drug Administration.” These provisions make clear that RHEA prevents a health benefit plan from conducting medical management with respect to its coverage of contraceptives.

² In addition to exceeding RHEA’s allowance for reasonable medical management, restrictions or limitation on RHEA coverage that are based solely on age or gender may violate the prohibitions on age and sex discrimination under RHEA and the Insurance Code. See Section 7, Oregon House Bill 3391 (2017) and ORS 746.021.

³ For purposes of RHEA, ORS 743A.067(1)(a) provides that “contraceptives” means health care services, drugs, devices, products or medical procedures to prevent pregnancy.

⁴ As provided under ORS 743A.067(2)(L)(B), coverage for services related to contraception includes, but is not limited to, (1) management of side effects resulting from contraceptives, (2) counseling for continued adherence to a prescribed regimen of contraception, (3) insertion and removal of contraceptive devices, and (4) where appropriate, the provision of alternative contraceptive drugs, devices or products deemed medically necessary in the judgement of an enrollee’s provider.

VI. Therapeutically equivalent contraceptives under RHEA

While RHEA generally requires health benefit plans to cover all FDA approved contraceptives without medical management, the law provides an exception in the case of a contraceptive that has one or more therapeutic equivalents. ORS 743A.067(2)(j)(A) provides that, “if there is a therapeutic equivalent of a contraceptive drug, device, or product approved by the United States Food and Drug Administration, a health benefit plan may provide coverage for either the requested contraceptive drug, device or product or for one or more therapeutic equivalents of the requested drug, device, or product.”

ORS 743A.067(2)(j)(A) effectively authorizes a health benefit plan to exclude coverage for one or more therapeutic equivalents of a covered contraceptive, so long as the plan provides coverage for at least one therapeutically equivalent version of that contraceptive. For example, when there is a therapeutically equivalent generic version of a name brand contraceptive (both of which are FDA approved), a health benefit plan may choose to provide coverage for only the generic version.

A health benefit plan’s ability to exclude therapeutic equivalents is not unlimited, however. ORS 743A.067(2)(j)(B) provides that “if a contraceptive drug, device or product covered by a health benefit plan is deemed medically inadvisable by the enrollee’s provider, the plan must cover an alternative contraceptive drug device or product prescribed by the provider.”

The director expects that carriers will treat the provisions of ORS 743A.067(j)(2)(B) as superseding the provisions of ORS 743A.067(j)(2)(A). In other words, even when a health benefit plan generally excludes coverage for a given therapeutic equivalent in accordance with ORS 743A.067(2)(j)(A), the director expects that the plan will still cover that therapeutic equivalent for a particular enrollee when the requirements of ORS 743A.067(2)(j)(B) are met.

Specifically, when 1) an enrollee’s provider has notified a health benefit plan that a covered therapeutic equivalent is medically inadvisable for a particular enrollee, and 2) the provider has prescribed an alternative FDA approved therapeutic equivalent for the enrollee, a health benefit plan must cover the prescribed therapeutic equivalent, even if the plan would otherwise consider the prescribed therapeutic equivalent to be excluded under ORS 743A.067(2)(j)(A). For example, a health benefit plan that generally limits coverage to generic contraceptives would have to cover a brand name contraceptive in cases where a provider has prescribed the brand version after determining that the generic version would be medically inadvisable for an enrollee.

Because ORS 743A.067(2)(j)(D) prohibits health benefit plans from infringing upon an enrollee’s choice of contraception, the director expects that any carrier offering a health benefit plan that excludes certain therapeutic equivalents will establish a process by which a health care provider may notify the health benefit plan that a covered therapeutic equivalent is medically inadvisable for an enrollee and through which the plan will provide coverage for the therapeutic equivalent prescribed by the provider. The

director expects that carriers will operate this process according to a timeframe and in a manner that takes into account the nature of the provider's request and any medical exigencies involved.

Moreover, to the extent the process described in the previous paragraph constitutes an "exceptions process" as described in federal sub-regulatory guidance,⁵ the director expects that a carrier's process for accommodating requests for alternative therapeutic equivalents under ORS 743A.067(2)(j)(B) will be easily accessible, transparent, and sufficiently expedient and will not be unduly burdensome on the enrollee, the enrollee's provider, or any other individual acting as a enrollee's authorized representative.

Finally, because ORS 743A.067(2)(j)(B) provides that a health benefit plan must cover any prescribed alternative, the director expects that carriers offering health benefit plans will generally defer to the provider's determination regarding the medical necessity and appropriateness of the requested alternative contraceptive and that any requests for alternative therapeutic equivalents will be freely granted, except as provided under ORS 743A.067(7).

Q5 – Under RHEA, may a health benefit plan require an enrollee or an enrollee's provider to request an exemption before providing coverage for an FDA approved contraceptive for which there is no therapeutic equivalent?

No. As described above, RHEA generally requires health benefit plans to cover the full range of FDA approved contraceptives. ORS 743A.067(4) prohibits health benefit plans from imposing any restrictions or delays on the coverage of contraception that are not specifically authorized under RHEA. While ORS 743A.067(j)(2)(A) allows a health benefit plan to provide coverage for a therapeutic equivalent instead of a requested contraceptive, RHEA does not include any similar allowance for contraceptives that have no therapeutic equivalent.

Moreover, ORS 743A.067(2)(j)(D) specifically prohibits health benefit plans from requiring "prior authorization, step therapy or other utilization review techniques for medically appropriate covered contraceptive drugs, devices or other products." For purposes of RHEA, ORS 743A.001 defines prior authorization as "a form of utilization review that requires a provider or an enrollee to request a determination by an insurer, prior to the provision of health care that is subject to utilization review, that the insurer will provide reimbursement for the health care requested."

In light of this definition, the director concludes that a health benefit plan that requires an enrollee or an enrollee's provider to request an exemption before the plan will provide

⁵ See FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf; and FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022), available at <https://www.cms.gov/files/document/faqs-part-54.pdf>

coverage for an FDA approved contraceptive would, in both form and substance, be requiring prior authorization for that contraceptive in violation of ORS 743A.067(2)(j)(D). Accordingly, the director expects that health benefit plans will provide coverage for all FDA-approved contraceptive products for which there are no therapeutic equivalents as prescribed and without limitation, delay or any requirement for prior authorization.

VII. Examples of impermissible restrictions on contraceptive coverage under RHEA

The director finds that the following types of conduct are inconsistent with the coverage requirements of ORS 743A.067(2)(j):

- Failing to provide coverage for, or imposing cost sharing upon, a dispensing of a prescription contraceptive drug on the basis that an enrollee is seeking to refill a prescription too early if the enrollee's use of the contraceptive requires more frequent refills, as prohibited by ORS 743A.067(2)(j)(D). For example, oral contraception typically comes in packages of 28 pills, with 21 pills containing active hormones and 7 placebo pills. When an enrollee has been prescribed such a product for continuous use (without taking the placebos), that enrollee would require a new package every 21 days rather than every 28 days. In this scenario, a carrier that denies a refill prior to 21 days would infringe upon the enrollee's choice of contraception in violation of ORS 743A.067(2)(j)(D). The director expects carriers and their pharmacy benefit managers to administer "refill too soon" policies in a manner that ensures each enrollee can use oral contraception as directed by their health care provider.
- Failing to provide coverage for the full amount of a prescription contraceptive drug that was prescribed by the provider. For example, failing to cover a 12 month supply of a prescription contraceptive drug in accordance with ORS 743A.066 and as prohibited by ORS 743A.067(2)(j)(D).
- Failing to cover, or imposing cost sharing upon, a contraceptive drug, device or product on the basis that the contraceptive was prescribed for a reason other than avoiding pregnancy, as prohibited by ORS 743A.067(5).
- Failing to cover, or imposing cost sharing upon, a prescribed therapeutic equivalent after an enrollee's provider has notified a health benefit plan that the covered version of an FDA-approved contraceptive is medically inadvisable for a particular enrollee, as prohibited by ORS 743A.067(2)(j)(B) and (D). For example, refusing to provide coverage for a prescribed brand contraceptive after an enrollee's provider has notified the plan that the generic equivalent is medically inadvisable.
- Failing to establish or maintain an easily accessible, transparent, and sufficiently expedient process by which a health care provider may notify a health benefit plan that a covered contraceptive is medically inadvisable for a particular enrollee, as required by ORS 743A.067(j)(B) and (D) and as described in this bulletin. For

example, requiring an enrollee to appeal an adverse benefit determination using a plan's internal claims and appeals process before covering an alternative therapeutic equivalent contraceptive.

VIII. Coverage of abortion under RHEA

As discussed above, ORS 743A.067(4) prohibits health benefit plans from imposing restrictions or delays on the coverage that are not explicitly authorized by RHEA and the allowance for reasonable medical management under ORS 743A.067(12) does not apply to the coverage of abortion. Accordingly, the director expects that when a carrier offering a health benefit plan is required to cover abortion under RHEA, the carrier will defer to the provider's determination of appropriateness of the frequency, method, treatment, or setting of an abortion and will not impose cost sharing.

This bulletin is effective upon issuance.

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

Date