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September 13, 2022

Barb Jones
Rules Coordinator, Office of the Insurance Commissioner
302 Sid Snyder Ave., SW
Olympia, WA 98504

Submitted via email to: rulescoordinator@oic.wa.gov

Re: Comments on R 2022-05 Cost-sharing for prescription drugs CR-102 draft rules.

Dear Ms. Jones:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we are writing to offer comments on the August 23rd CR-102 draft of R 2022-05 relating to prescription drug cost-sharing (the "Draft Rule"). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. We appreciate the opportunity to provide feedback on the implementation for SSB 5610,[1] which requires health plans to apply third-party payments for prescription drugs toward an enrollee's cost-sharing requirements within specific parameters.

1. Definition of "therapeutic equivalent"

The term "therapeutic equivalent" is used in SSB 5610 in determining which drugs are subject to the requirements of the statute.[2] However, we note that the Draft Rule does not include a definition for it. We urge the Office of the Insurance Commissioner (OIC) to include a definition for that term in its implementation of SSB 5610 to avoid confusion or inconsistency. In order to provide a clear standard, PhRMA suggests that OIC adopt a definition for "therapeutic equivalent" consistent with the U.S. Food and Drug Administration's definition under 21 C.F.R. § 314.3(b):

> *Therapeutic equivalents* are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

[1] Enacted as 2022 Wash. Sess. Laws Ch. 228.
[2] 2022 Wash. Sess. Laws Ch. 228, sec. 1(1) (codified at Wash. Rev. Code § 48.43.435(1)).

This federal definition provides a clear and widely understood standard for determining when a prescription drug will be considered to have a therapeutic equivalent.

2. HSA-Eligible High Deductible Health Plans

PhRMA recognizes the removal of Section 5(c) from the Pre-Publication Draft of R 2022-05 as a step in the right direction. That section provided a blanket exclusion for Health Savings Account-eligible High Deductible Health Plans (HSA-eligible HDHPs) from the requirements of SSB 5610. As stated in the preamble of the law, the aim of the legislature in enacting SSB 5610 was to require "cost sharing for prescription drugs to be counted against an enrollee's out-of-pocket costs." The language of the bill makes it clear that the legislature intended this requirement to apply to HSA-eligible HDHPs too, to the maximum extent possible:

> This section does not apply to a qualifying health plan for a health savings account ***to the extent necessary*** to preserve the enrollee's ability to claim tax exempt contributions and withdrawals from the enrollee's health savings account under internal revenue service laws, regulations, and guidance.[3]

To implement the legislature's intent, the rule should make clear that cost sharing amounts paid on behalf of an enrollee by another person must count toward applicable cost-sharing and out-of-pocket maximums *when allowable for HSA-eligible HDHPs*.

Multiple state legislatures have recently addressed this exact issue involving HSA-eligible HDHPs. Just this year, Virginia,[4] Oklahoma,[5] and Illinois[6] enacted explicit language clarifying the circumstances under which similar cost-sharing requirements shall apply with respect to HSA-eligible HDHPs. PhRMA suggests that the OIC incorporate similar language in the Draft Rule to clarify this issue:

> *If under federal law, application of this requirement would cause a Health Savings Account-qualified High Deductible Health Plan to fail to qualify as such a plan under section 223 of the federal Internal Revenue Code, this requirement shall apply with respect to such a plan after the enrollee has satisfied the minimum deductible under section 223, except for with respect to items or services that are preventive care pursuant to section 223(c)(2)(C) of the federal internal Revenue Code, in which case the requirements of this paragraph shall apply regardless of whether the minimum deductible under section 223 has been satisfied.*

[3] 2022 Wash. Sess. Laws ch. 228, sec. 1(5) (S.S.B. 6510, to be codified under ch. 48.43 RCW) (emphasis added).
[4] 2022 Va. Acts ch. 133 (S.B. 433/H.B. 1081, to be codified at Va. Code § 38.2-3407.20(D)).
[5] 2022 Okla. Sess. Laws ch. 266 (H.B. 3495, codified at Okla. Stat. tit. 36, § 1250.5(18)).
[6] 2022 Ill. Pub. Act 102-0704 (H.B. 4433, codified at 215 Ill. Comp. Stat. 134/30(d)).

This proposed language would align with current federal Internal Revenue Service (IRS) guidance with regard to HSA-eligible HDHPs,[7] while also allowing enrollees in these plans to have cost-sharing assistance counted toward their out-of-pocket obligations once they have satisfied the IRS minimum deductible. Further, as permitted by IRS guidance, it would clarify that third-party payments, including manufacturer cost-sharing assistance, will continue to count toward out-of-pocket costs for items and services identified by the IRS as preventive care even if patients have not yet met the IRS minimum deductible.[8]

…

PhRMA and its member companies appreciate the opportunity to comment on these proposed changes. Thank you for your consideration of our feedback related to this matter. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[7] I.R.S. Priv. Ltr. Rul. GENIN-107276-21 (https://www.irs.gov/pub/irs-wd/21-0014.pdf).
[8] *Id.*; *see also* Rev. Proc. 2021-25 (providing minimum deductibles for HSA-eligible HDHPs for CY 2022) (https://www.irs.gov/pub/irs-drop/rp-21-25.pdf).