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AGENCIES WON'T ENFORCE ACA RULE ON DRUG COUPONS AND OUT-OF-POCKET COSTS

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Citing a possible conflict with existing health savings account (HSA) guidance, the federal government won't enforce an Affordable Care Act (ACA) regulation on drug coupons and enrollees' annual out-of-pocket (OOP) costs, according to new guidance ([FAQ 40](#)). The [2020 HHS Notice of Benefit and Payment Parameters](#) (payment notice) created confusion about the circumstances in which health plans may exclude participants' drug coupon savings from counting toward the annual OOP cost limits. In the new FAQ, the departments of Labor (DOL), Health and Human Services (HHS), and IRS say they won't enforce the drug coupon provision for nongrandfathered plan years or policies beginning in 2020. Instead, the agencies intend to address this issue in the 2021 payment notice.

2020 PAYMENT NOTICE LEFT OPEN QUESTIONS

The 2020 payment notice issued earlier this year includes a new provision on how drug manufacturers' discount coupons affect the ACA's annual OOP cost-sharing limits. Section 2707(b) of the Public Health Service Act (PHSA) requires nongrandfathered group health plans and issuers to adhere to the ACA's annual OOP limits for in-network essential health benefits (42 USC [§ 18022\(c\)](#); ACA [§ 1302\(c\)\(1\)](#)).

The 2020 payment notice allows plans to exclude enrollees' savings from drug manufacturer coupons for brand medications when calculating costs for the annual OOP limits if the brand drug has a generic equivalent. In light of the increasing cost of prescription drugs, the rule aims to encourage the use of lower-cost generics over the higher-cost brands.

Confusing Regulatory Language

When read together, the preamble and the actual text of the regulation seem to indicate that the only time a plan's OOP cost calculation could exclude enrollees' savings from a coupon for brand medications is when the medication has no generic equivalent. The preamble text states:

... [T]he final regulation limits the discretion to exclude manufacturer coupons from counting towards the annual limitation on cost sharing for specific prescription brand drugs that have a generic equivalent, as the availability of a coupon may cause physicians and patients to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. Where there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market ... Therefore, under those circumstances, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers *must* be counted toward the annual limitation on cost sharing. (*emphasis added*)

The actual text of the final regulation, however, is unclear whether the availability of a generic equivalent is the only circumstance in which a plan can exclude drug coupon savings when calculating costs toward the annual OOP maximum. The regulation simply addresses “any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs” for a medication that has a generic equivalent.

This has left open questions for plans that have or are considering copay accumulator programs that subtract the value of brand-name drug coupons from costs credited toward the OOP maximum — even when no generic equivalent is available. The regulation also raises questions about how to apply this rule in HSA-compatible high-deductible health plans (HDHPs).

Application to Large Employer-Sponsored Plans

The 2020 payment notice modified only the PHSA regulations, not ERISA or the Internal Revenue Code (IRC). However, ACA provisions that amend the PHSA generally are incorporated by reference into ERISA and the IRC, so they apply to large group health plans, including self-insured plans. As a result, HHS can issue rules related to the amended ACA provisions that affect ERISA plans. Accordingly, the preamble to the 2020 payment notice and a companion HHS [fact sheet](#) say that the prescription drug provision will apply to self-insured group plans under ERISA and the IRC, along with individual, small- and large-group insured plans.

Some have raised concerns that because HHS alone — rather than jointly with DOL and IRS — issued the proposed and final 2020 payment notice, employers did not have an adequate opportunity to comment on the changes. A similar complaint arose in 2015 when HHS unilaterally modified the rules on embedded out-of-pocket maximums, prompting later tri-agency FAQs clarifying that the revised rules apply to all nongrandfathered group health plans, including self-insured and large-group plans.

NEW FAQ POINTS TO CONFLICT WITH HSA GUIDANCE

The new FAQ acknowledges that the HHS rule “can be read to imply that, in any other circumstances, group health plans and issuers are required to count such coupon amounts toward the annual limitation on cost sharing.” The agencies state that this interpretation may conflict with [Q&A-9](#) in IRS [Notice 2004-50](#). That guidance allows individuals who have a pharmacy discount card to remain HSA eligible as long as they pay discounted drug costs until the deductible is met. The agencies maintain that this conflict makes the HHS rule “ambiguous,” warranting future clarification.

Possible Conflict

The agencies say that plans and issuers might not be able to meet both the HHS drug coupon rule and the HSA guidance on pharmacy discount cards in Notice 2004-50. Under the IRS notice, individuals who have a pharmacy discount card can remain HSA eligible despite receiving a discount before meeting the HDHP deductible. They still must pay the full deductible out of their own pocket — their OOP costs include only what they actually pay after the discount.

To preserve a participant's HSA eligibility under the IRS notice, an HDHP sponsor or issuer would want to exclude discounts for any brand drug — even if no generic is available — from counting toward the HDHP deductible. However, an interpretation of the HHS rule would require that unless a generic is available, the plan must count the full drug cost — disregarding any discount — toward the ACA OOP cost-sharing limits.

NONENFORCEMENT POLICY

Until a final rule clarifying this issue takes effect, HHS, DOL and IRS will not bring any enforcement action if a plan or issuer excludes the value of drug manufacturer coupons from counting toward a participant's OOP maximum, even if no medically appropriate generic is available. This nonenforcement policy applies to self-insured plans and all individual and group insurance policies, not just HSA-compatible HDHPs.

EMPLOYER ISSUES

The nonenforcement policy should bring some relief to employers concerned that their current practices violate the ACA's rules on cost-sharing limits. The high cost of some medications — especially specialty drugs — that have no generic equivalent has been an ongoing concern for plan sponsors and participants. Drug manufacturers provide copay assistance through coupons that reduce patients' out-of-pocket costs. Crediting a drug's undiscounted cost toward the out-of-pocket limits — as the 2020 Payment Notice seems to require — would shift some of the expense for certain brand drugs from participants to group health plans and issuers. Employers could potentially shift these increased costs by raising premiums for all covered employees.

Pharmacy benefit managers (PBMs) and issuers have offered employers a variety of designs to address the cost-shifting increases created by manufacturer coupons, including "copay accumulator" or "accumulator adjustment" programs. These programs take many different approaches but generally credit toward the out-of-pocket maximum or deductible only a participant's costs after any coupon or other discount. Some of these programs require little or no copay for specific medications until participants have exhausted any drug coupons.

Despite the enforcement relief, employers using or considering copay accumulator programs need to evaluate several issues with counsel:

- **Risk of private litigation.** The FAQ just discusses government enforcement of the new rule on drug coupons and ACA cost-sharing limits. The guidance does not rescind that part of the 2020 payment notice or prevent or prohibit private litigation concerning the drug coupon rule. For some participants with chronic illnesses, whether a drug's full or discounted cost applies toward their OOP maximum may affect their ability to afford the medication and finance other healthcare expenses. So some

patients may rely on the drug coupon provision in the 2020 payment notice to assert a claim against a group health plan using a copay accumulator.

- **Other potential compliance issues.** The design of a copay accumulator program could raise issues under ERISA fiduciary and other rules. If the health plan shares in any coupon savings that a participant receives under an agreement with a drug manufacturer's patient-assistance program, the plan sponsor should confirm that the arrangement is consistent with the ERISA fiduciary duty to act solely in the best interest of plan enrollees. Sponsors may also want to compare the required copays for certain medications under the copay accumulator program vs. other programs for compliance with the financial requirements under the federal Mental Health Parity and Addiction Equity Act or other nondiscrimination rules.
- **Implications of certain HSA-compatible HDHP designs.** The FAQ does not address how IRS Notice 2004-50 applies to current copay accumulator programs. Q-A-9 of that notice addresses an employer-provided pharmacy discount card that provides discounts at "managed care market rates" of 15% to 50% off the usual and customary charge. Copay accumulator programs have a more complicated structure and can result in much more significant discounts, sometimes reducing a participant's out-of-pocket costs to zero for a certain time. Can plans rely on Notice 2004-50 for copay accumulator programs, or are these programs different from a discount card? More information on this would be welcome, as the new nonenforcement policy does not alter IRS rules requiring HSA-qualified HDHPs to cover only preventive care before the minimum deductible is met.
- **Impact of state laws that prohibit copay accumulators.** According to the FAQ, states may adopt a similar nonenforcement policy for health insurance issuers' annual OOP limits. However, the FAQ does not mention recent state laws that go in the opposite direction and generally require insurers to apply drug coupons to deductibles and out-of-pocket maximums for insured coverage. States with these types of laws, which can vary considerably, include [Arizona](#), [Illinois](#), [Virginia](#) and [West Virginia](#). Employers with insured coverage in these states should watch for regulations implementing these laws and review how or whether they apply alongside the federal HSA rules.

While the new FAQ may address immediate stakeholder concerns, the Trump administration and some members of Congress believe more significant structural changes are needed to address the escalating cost of prescription drugs and its impact on individuals' medical and financial wellness. Debate over how best to tackle this issue will continue in the months ahead.

RELATED RESOURCES

Non-Mercer Resources

- [FAQs About Affordable Care Act Implementation Part 40](#) (DOL/HHS/IRS, Aug. 26, 2019)
- [Final Rule: HHS Notice of Benefit and Payment Parameters for 2020](#) (Federal Register, April 25, 2019)

- [Press Release: CMS Issues Final Rule for the 2020 Annual Notice of Benefit and Payment Parameters](#) (CMS, April 18, 2019)
- [Fact Sheet: Final HHS Notice of Benefit and Payment Parameters for 2020](#) (CMS, April 18, 2019)
- [FAQs about Affordable Care Act Implementation \(Part XXVII\)](#) (DOL/HHS/IRS, May 26, 2015)
- [Notice 2004-50](#) (IRS, Aug. 9, 2004)

Mercer Law & Policy Resources

- [Top 10 Compliance Issues for 2020 Health and Fringe Benefit Planning](#) (June 25, 2019)
- [2020 ACA Cost-Sharing Caps Set, Pay-or-Play Penalties Projected](#) (May 8, 2019)
- [Senate Bill Would End Drug Rebates in Employer Plans](#) (March 20, 2019)
- [Mercer Shares Views With Senators on Controlling Healthcare Costs](#) (March 6, 2019)

Other Mercer Resources

- [US Health News: Prescription Drugs](#)
- [Employers Weigh in on Drug Rebates](#) (April 11, 2019)
- [State and Federal Rx Actions Have Implications for Employers](#) (Aug. 29, 2018)
- [Addressing the Drug Cost Problem Is a Thorny Issue](#) (July 25, 2018)

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