

COMPLIANCE ALERT

FEDERAL AGENCIES RELEASE GUIDANCE ON DRUG MANUFACTURER COUPONS

October 1, 2019

QUICK FACTS

- The DOL, HHS, and Treasury have jointly issued FAQs to address group health plan concerns regarding the application of drug coupons towards annual cost-sharing limits under the ACA.
- The FAQs recognized potential conflicts with prior agency guidance.
- The agencies will address these inconsistencies in upcoming regulations in 2021.
- In the interim, the agencies have stated that they will not initiate enforcement against health plans or insurers for excluding the drug coupon amounts from the annual cost sharing limits, even in circumstances in which there is no medically appropriate generic equivalent available.

The Department of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively the “Departments”) recently released new guidance delaying the enforcement of a new drug manufacturer coupon rule (“New Rule”) included in the HHS Notice of Benefit and Payment Parameters for 2020 (2020 NBPP Final Rule). The Departments issued the new guidance as part of a FAQ on the 2020 NBPP Final Rule addressing large group and self-insured health plan questions about conflicting compliance issues created between the New Rule and existing Internal Revenue Service (IRS) guidance regarding high-deductible Health Plans (HDHPs) (“IRS HDHP Rules”). According to the FAQ, the Departments will not initiate enforcement actions relating to the New Rule until at least such time as the Departments’ issue further rules that resolve the conflicts. The Departments expect to include these additional rules in the Final 2021 NBPP Rule that should issue in early-2020.

The New Rule, designed to encourage plan enrollees to use less-expensive generic drugs, permits plans to decide whether to exclude the manufacturer coupon discount amount for a brand-name drug from the annual limit on cost-sharing if the plan covers a medically appropriate and available generic equivalent. This implies that plans must count the value of coupons towards the annual cost-sharing limit under the following circumstances:

- When only a brand-name drug is available;
- If a generic equivalent is unavailable; or
- Should a generic be medically inappropriate.

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If the New Rule does require plans to count the value of coupons in certain circumstances, it would conflict with the IRS HDHP Rule. [2004 IRS guidance](#) stipulates that plans must disregard discounts, including drug coupons, in determining whether a plan participant has satisfied his or her minimum deductible.

Accordingly, plans would possibly need to choose to either comply with the New Rule or the IRS HDHP Rule. Stakeholders, such as self-insured group plans, submitted questions to the Departments about how to deal with the New Rule's conflicts with the IRS HDHP Rules.

The recently issued FAQ notes that the goals and interpretations of the New Rule created ambiguities including whether and when HDHPs must count a coupon's value toward the annual limitation on cost-sharing for enrollees. The Departments affirmed that if the New Rule was interpreted to require group health plans to count coupon amounts to the annual cost-sharing limits, it would put the New Rule and IRS HDHP Rule at odds.

Thankfully, the FAQ stated that the HHS, in conjunction with DOL and Treasury, will review the rules to clarify any ambiguities and address any conflicts in the upcoming 2021 NBPP Rule. Until the Final 2021 NBPP Rule's release, the Departments will suspend all enforcement action against plans that exclude the value of drug manufacturers' coupons from the annual limitation on cost-sharing, including when no medically appropriate generic equivalent is available.

NEXT STEP FOR EMPLOYERS

Employers should be on the lookout for the Final 2021 NBPP Rule and be prepared for potential additional compliance considerations. Employers may wish to consult legal counsel about how to structure their plans based on the release of recent FAQ and Guidance.

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