Kilpatrick

AUGUST 27, 2019

# Departments Delay Implementation of Controversial HHS Prescription Drug Rule

In ACA FAQ Part 40, HHS, IRS and DOL (the "Departments") delayed the implementation of the controversial rule in HHS 2020 Notice of Benefit and Payment Parameters requiring health plans to credit to the out-of-pocket maximum the amount of certain financial assistance received from drug manufacturers. The delay continues at least until January 1, 2021.

**Background**

In a prior blog post, we discussed that in the 2020 Notice of Benefit and Payment Parameters, HHS amended the regulations implementing the ACA cost-sharing requirements to address drug manufacturer coupons. Under the new rule, financial assistance which is provided to plan participants by drug manufacturers to reduce or eliminate out-of-pocket costs for specific brand name drugs does not have to be counted towards the annual cost-sharing limits if there is an available and medically appropriate generic equivalent. Conversely, in all other situations (e.g., the participant uses a coupon but there is no generic equivalent available or the generic equivalent is determined not to be medically appropriate), the financial assistance must be counted towards the ACA out-of-pocket maximum.

Many large self-insured employers have begun to utilize manufacturer drug coupons as part of their prescription drug plans. These coupon programs are sometimes referred to as “copay assistance programs” and typically apply to high-cost specialty drugs for which a generic is not available. Under these programs, when a health plan participant purchases the drug, the participant typically pays no copay at all. If the drug was purchased normally under the employer plan without the copay assistance, the participant might have to pay several hundreds of dollars more for the same drug.

In the past, most employer-sponsored health plans did not apply the amount of financial assistance provided by drug manufacturers to either the participant’s deductible or the participant’s out-of-pocket maximum. The reason behind this rule stems from the basic tenant that if a participant is not responsible for the payment for a product, the dollar value of the product should not be added to a deductible or out-of-pocket maximum. It is treated merely as if the participant received a free sample of the drug from a physician.

In a later blog post, we noted how it will be difficult to apply the new HHS rule to high deductible health plans (“HDHP”). IRS guidance regarding HDHPs requires that only amounts actually paid by the individual shall be taken into account for purposes of satisfying the HDHP deductible and out-of-pocket maximum. Because the HHS rule requires crediting of amounts not paid by the individual, complying with the HHS rule is at odds with complying with the HDHP rules.

**ACA FAQ Part 40**

In ACA FAQ Part 40, the Departments noted that the HHS rule in the 2020 Notice of Benefit and Payment Parameters could cause issues with HDHP compliance. Specifically, FAQ Part 40 notes that Q&A-9 of IRS Notice 2004-50 requires an HDHP to disregard drug discounts and other manufacturers discounts in determining whether the minimum deductible for an HDHP is satisfied.

ACA FAQ Part 40 notes there is confusion about whether the 2020 HHS rule requires health plans to count the value of drug manufacturers' coupons toward the out-of-pocket maximum, other than in circumstances in which there is a medically appropriate generic equivalent available, particularly with regard to large group market and self-insured group health plans. Based on this feedback, the Departments note that the interpretation of how drug manufacturers' coupons apply with respect to the out-of-pocket maximum is ambiguous.

ACA FAQ Part 40 indicates that the 2021 HHS Notice of Benefit and Payment Parameters will address the issue of financial assistance from drug manufacturers in greater detail. Therefore, until the 2021 Notice is issued and effective, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of drug manufacturers' coupons from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic alternative.

This means that the HHS rule regarding drug manufacturer financial assistance will not apply at least until January 1, 2021. Further, reading between the lines of the ACA FAQ Part 40, the 2021 HHS Notice of Benefit and Payment Parameters is likely to contain different requirements than the 2020 HHS Notice.