Court Vacates HHS Regulation on Counting Drug Manufacturer Assistance in ACA Cost-Sharing Limit

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HIV and Hepatitis Policy Inst. v. HHS, 2023 WL 6388932 (D.D.C. 2023)

Available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_22-cv-02604/pdf/USCOURTS-dcd-1_22-cv-02604-0.pdf

A court has set aside a 2021 regulatory provision that changed how direct drug manufacturer assistance accrues toward the Affordable Care Act (ACA) annual limits on cost-sharing. As background, some drug manufacturers provide patients with direct financial support for certain prescription drugs, such as coupons that direct a pharmacy to bill all or part of the patient's copayment or coinsurance obligations to the manufacturer instead of the patient. Under the 2021 regulations, HHS permitted, but did not require, plans and insurers to count the amount of this direct support toward the annual limits on cost-sharing, regardless of whether a generic equivalent was available. Several individuals and patient advocacy groups sued, contending that the provision conflicted with cost-sharing definitions in the ACA and prior regulations, which they argued unambiguously include manufacturer assistance.

The court vacated the challenged provision, directing the agencies to interpret the statutory definition of cost-sharing. Concluding that the ACA's definition "does not speak clearly" as to manufacturer assistance and that the agencies have not adopted a single interpretation (because the provision in the 2021 regulations allow insurers to either count or not count the assistance), the court held that the provision is arbitrary and capricious because it interprets the term as having two different meanings, to be chosen at the discretion of the regulated parties.

EBIA Comment: This case has important implications for HSA-compatible high-deductible health plans (HDHPs). The now-vacated provision followed an earlier HHS announcement that manufacturer assistance need not be counted toward a plan's annual cost-sharing limit when a medically appropriate generic equivalent was available, which some stakeholders viewed as implying that support must be counted absent a medically appropriate generic equivalent. The preamble to the 2021 regulations explained that the change was necessary to avoid a potential conflict with the HDHP rules, under which only amounts actually paid by the individual may be taken into account when determining whether the HDHP deductible is satisfied. This case appears to revive that conflict. For more information, see EBIA's Health Care Reform manual at Section IX.B ("Cost-Sharing Limits") and EBIA's Self-Insured Health Plans manual at Section XI.E ("Trends in Self-Insured Health Plan Design"). See also EBIA's Consumer-Driven Health Care manual at Section X.J ("Issues Raised by the HDHP Minimum Deductible").

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