Priority Policy Recommendations to Expand Issuer Discretion to Minimize Distortion of Drug Manufacturer Coupons

CMS should amend the regulatory language related to coupons and the annual limitation on cost-sharing. As noted in FAQs about ACA Implementation Part 40, the new regulatory language at 45 CFR 156.130(h)(1) has created confusion about the treatment of coupons and the potential conflict between the regulation and IRS guidance regarding high-deductible health plans (HDHPs). Health plans appreciate the FAQ guidance and CMS' willingness to reevaluate the new regulatory provision related to drug manufacturer coupons and the annual limitation on cost-sharing. Amendments to this regulation, as suggested below, will create a unified, aligned policy with current HDHP guidance where third-party discounts are excluded from such cost-sharing towards a maximum out-of-pocket.

Drug manufacturers provide coupons and other direct patient assistance to insured patients to circumvent tiered formularies and undercut issuers' ability to negotiate prices based on inclusion of a drug on a formulary. In fact, the HHS-OIG found that coupons used in government programs are a violation of the anti-kickback statute as they "induce the purchase of Federal health care program items or services" – that is, the drug manufacturer offering the coupon is directly benefiting from its use.[1]

Some issuers are leveraging "accumulator programs" to calculate true out-of-pocket spending without treating drug manufacturer coupons as enrollee spending towards deductibles or out-of-pocket maximums. Accumulator programs help to balance the effect of coupons and restore the ability of issuers to encourage the use of lower-cost effective medicines.

We urge CMS to continue extending issuers the flexibility to use a wide range of pharmacy benefit tools, including copay accumulator programs, to address high prescription drug prices. We ask CMS to clarify that the regulatory language allowing issuers to exclude coupons and other direct assistance from deductibles and out-of-pocket maximums applies broadly to all situations when an insured patient receives financial assistance to purchase a drug. This can be accomplished by excluding language in the regulation related to drugs that have an "available and medically appropriate generic equivalent."

Also, we request CMS explore mechanisms by which it can require real-time transparency from drug manufacturers and pharmacies to issuers about when financial assistance such as copay coupons are presented. One possible approach would be to require pharmacies to submit information about any coupons or financial assistance provided for each transaction on the National Council for Prescription Drug Programs' (NCPDP) claim transaction. This would provide issuers with more visibility into the coupons that are available to consumers so they can design consumer tools and prescription drug benefits to encourage patients to consider lower cost options that can effectively treat their conditions. This level of transparency also would allow Medicare Part D prescription drug plan sponsors to track when coupons are used, which would enhance CMS' oversight of and compliance with the HHS-OIG's finding that coupons used in government programs are a violation of the anti-kickback statute, as noted above.

[1] Department of Health and Human Services, Office of the Inspector General. Special Advisory Bulletin. September 2014. https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.