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Overview of CMS Policy Regarding Copay Accumulators

On May 7, 2020, the Centers for Medicare and Medicaid Services (CMS) released the 2021 Notice of Benefit and Payment Parameters (NBPP) Final Rule, which clarifies CMS policy regarding the use of copay accumulator programs by certain individual market and group health plans.[1] The Final Rule allows issuers and plans to use copay accumulators to exclude the value of a coupon for a brand name drug from an enrollee's annual cost sharing limit, even when there is no medically appropriate generic equivalent available, if doing so is permitted under state law.

Background. Under the Patient Protection and Affordable Care Act (ACA), most individual market and group health plans, including self-insured and insured small and large group health plans, are required to comply with an annual limit on enrollee cost sharing.[2] This limit does not apply to certain plans in existence prior to 2014.[3] Each year, the NBPP sets annual cost sharing limits. For plan or policy years beginning in 2020, the maximum annual cost sharing is $8,150 for self-only coverage and $16,300 for family coverage.[4]

Copay accumulator programs—also called accumulator adjustment programs—exclude the value of drug manufacturer coupons from the enrollee cost sharing limit. Health insurers implement copay accumulator programs to keep the value of drug manufacturer coupons from counting toward the enrollee's maximum annual out-of-pocket costs, which shifts costs from the health plan to the enrollee.

Example of Impact of Copay Accumulator Programs on Patient Out-of-Pocket Costs					
Copay Accumulator?	Drug Cost	Coupon	Out-of-Pocket Cost	Amount Counted Toward Cost Sharing Limit	Remaining Balance on Cost Sharing Limit
No	$100	$20	$80	$100	$8,050
Yes	$100	$20	$80	$80	$8,070

In April 2019, CMS finalized a regulation that permits issuers and health plans to exclude the value of drug manufacturer coupons for brand-name drugs *that have an available and medically appropriate generic equivalent* from the annual limit on enrollee cost sharing, to the extent consistent with state law.[5] The rule applies to plans that are required to comply with the ACA's annual limit on enrollee cost sharing, including most individual market and group health plans (see chart below).[6] The regulatory language did not address whether issuers and health plans are also permitted to use copay accumulators when no generic equivalent is available.

Why Did CMS Issue This Policy? The agency explained that drug manufacturer coupons may cause physicians and patients to choose a brand-name drug when a less expensive generic or other alternative is available, which can lead to unnecessary spending by issuers, increased premiums, and reduced coverage.[7] CMS believes that the use of copay accumulators could reduce the incentive that coupons create to select a more expensive brand-name drug—reduced out-of-pocket cost—when a generic alternative is available.[8]

In August 2019, the Department of Health and Human Services, as well as the Departments of Labor and the Treasury (the Departments), acknowledged that the rule creates ambiguity as to whether issuers and plans are prohibited from using copay accumulators when there is no generic equivalent available. The Departments explained that if the rule did prohibit plans from using copay accumulators under those circumstances, the rule may conflict with guidance for high deductible health plans.[9] The Departments stated that they would clarify in the 2021 NBPP.[10]

Policy Issued in 2021 NBPP Final Rule. In the 2021 NBPP Final Rule, CMS removed language regarding the availability of a medically appropriate generic equivalent from the regulation on copay accumulators to eliminate any implication that issuers and plans are prohibited from using copay accumulators when there is no generic equivalent available. Thus, effective July 13, 2020, the regulation provides that health plans may exclude any direct support from drug manufacturers to a patient from the patient's annual cost sharing limit.[11] Accordingly, issuers and health plans can continue to implement copay accumulators, regardless of whether a generic is available. However, states may issue state-specific laws preventing issuers and health plans from taking such action.[12]

State Laws on Copay Accumulators. Under the 2021 NBPP Final Rule, issuers and health plans are only permitted to implement copay accumulator programs to the extent permitted by state law. States have the authority to impose restrictions on insurers that offer individual and group health plans. However, federal law exclusively governs employee benefit plans, including employer-sponsored self-insured group health plans. Accordingly, states likely cannot prohibit self-insured group health plans from implementing copay accumulators.[13]

The following states have enacted laws that limit the use of copay accumulators by certain issuers and health plans:

- Arizona. Arizona law requires health care insurers and pharmacy benefits managers to count the value of manufacturer drug coupons towards out-of-pocket maximums, deductibles, and any other cost sharing requirements if there is no generic or the patient has accessed the drug through prior authorization, step therapy, or the plan's exception or appeals process.[14]

- Illinois. Illinois law requires health care plans to apply any third-party payments, discounts, vouchers, or other reduction in out-of-pocket expenses made on behalf of the enrollee for a drug toward the enrollee's deductible and out-of-pocket maximum.[15]

- Virginia. Virginia law requires entities providing health care plans subject to state regulation to include any amount paid on behalf of the enrollee in calculating the enrollee's overall contribution to any out-of-pocket maximum or other cost sharing requirement.[16]

- West Virginia. West Virginia requires certain health insurers and pharmacy benefits managers to include any cost sharing amounts paid on behalf of an enrollee in calculating the enrollee's contribution to any applicable cost sharing requirement.[17]

- Georgia. Effective July 1, 2021, Georgia law requires pharmacy benefits managers to include cost sharing amounts paid on behalf of the insured when calculating an insured's contribution to any out-of-pocket maximum, deductible, or copayment when a drug does not have a generic equivalent or was obtained through prior authorization, step therapy, or an exceptions process.[18]

Applicability of Copay Accumulator Policies By Health Plan Type

	Type of Health Plan	Subject to CMS Copay Accumulator Policy?	Subject to State Laws on Copay Accumulators?**			
			AZ	*IL*†	*VA*	*WV*
Individual Market	Qualified Health Plans*	✓	✓	✓	✓	✓
	Certain Individual Market Plans In Effect Prior to 2014		✓	✓	✓	✓
Employer-Sponsored	Insured Group Health Plans	✓	✓	✓	✓	✓
	Self-Insured Group Health Plans	✓				
	Certain Insured Group Health Plans In Effect Prior to 2014		✓	✓	✓	✓
	Certain Self-Insured Group Health Plans In Effect Prior to 2014					
Other	Short-Term Plans		✓	✓	✓	✓

*Qualified Health Plans are individual plans sold on ACA exchanges that provide essential health benefits, follow limits on cost-sharing, and meet other ACA requirements.[19]

**Legislation in Georgia restricts the use of copay accumulators by pharmacy benefits managers—not health plans directly. The bill defines pharmacy benefits managers as entities that administer a program that pays for, reimburses, and covers the cost of drugs, devices, or pharmacy care to insureds on behalf of a health plan, including individual plans, group plans, and plans administered by the state.[20]

†Illinois exempts certain plans from its limitations on copay accumulators, including indemnity health insurance policies and plans that offer only dental or vision coverage.

[1] Centers for Medicare & Medicaid Services (CMS), Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, Final Rule, 85 Fed. Reg. 29,164 (May 14, 2020), https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf [hereinafter "2021 NBPP Final Rule"].

[2] 42 U.S.C. § 300gg–6(b); 42 U.S.C. § 18022(c); Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 40 (Aug. 26, 2019), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf [hereinafter "ACA Implementation FAQs Part 40"].

[3] 84 Fed. Reg. 5,969, 5,970 (Feb. 25, 2019); The Commonwealth Fund, State Regulation of Coverage Options Outside of the Affordable Care Act: Limiting the Risk to the Individual Market at 3–5 (March 2018), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2018_mar_lucia_state_regulation_alternative_coverage_options_rev.pdf. The ACA's cost sharing limitation also does not apply to coverage options that are generally not considered individual market health insurance under the ACA, such as short-term policies.

[4] 84 Fed. Reg. 17,454, 17,542 (April 25, 2019). For the 2021 benefit year, the maximum annual cost sharing will be $8,550 for self-only coverage and $17,100 for family coverage. 2021 NBPP Final Rule at 29,229.

[5] 45 C.F.R. § 156.130(h)(1) ("For plan years beginning on or after January 1, 2020 . . . to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing . . . .").

[6] 84 Fed. Reg. 17,454, 17,545 (April 25, 2019).

[7] *Id.* at 17,545–46.

[8] 2021 NBPP Final Rule at 29,232.

[9] Internal Revenue Service (IRS) guidance states that, to keep drug discounts from affecting an individual's eligibility for a health savings account, high deductible health plans cannot apply the value of drug discounts toward the individual's deductible. IRS Notice 2004-50, Q&A 9, https://www.irs.gov/pub/irs-drop/n-04-50.pdf. The Departments explained that, if CMS required plans to count the value of the discount towards an individual's cost sharing limit when no generic equivalent is available, HDHPs may be unable to comply with both requirements. ACA Implementation FAQs Part 40 at 2.

[10] *Id.* at 2–3.

[11] 2021 NBPP Final Rule at 29,261 ("[T]o the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing . . . .").

[12] 2021 NBPP Final Rule at 29,232.

[13] 29 U.S.C. § 1144. Although federal preemption under the Employee Retirement Income Security Act of 1974 (ERISA) applies to all employee benefit plans, whether insured or self-insured, ERISA does not preempt state law that regulates insurers (except that self-insured employee benefit plans are deemed not to be insurers for this

purpose). *Id.* § 1144(b)(2). Therefore, insured employer-sponsored group health plans would be subject to any state law regarding copay accumulators.

[14] Ariz. Rev. Stat. §§ 20-1126, 20-1379, 20-822, 20-1051.

[15] 215 Ill. Comp. Stat. 134/30(d), 134/10.

[16] Va. Code Ann. §§ 38.2-3407.10, 38.2-3407.20.

[17] W. Va. Code Ann. §§ 33-15-4t(b), 33-16-3ee(b); *see also id.* §§ 33-24-7t, 33-25-8q, 33-25A-8t.

[18] S.B. 313, Gen. Assemb., Reg. Sess. (Ga. 2020), http://www.legis.ga.gov/legislation/en-US/Display/20192020/SB/313.

[19] 42 U.S. Code § 18021; CMS, HealthCare.gov, Qualified Health Plan, https://www.healthcare.gov/glossary/qualified-health-plan/ (last accessed May 16, 2020).

[20] S.B. 313, Gen. Assemb., Reg. Sess. (Ga. 2020).