Issue Brief

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CMS Proposes to Lower Drug Costs by Targeting "Backdoor Rebates" and Encouraging Direct Discounts to Patients

The Centers for Medicare & Medicaid Services has released a proposed rule that would amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, Section 1128B(b) of the Social Security Act. The amendment would revise the discount safe harbor to explicitly exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under Section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them.

The proposed rule would affect the operations of entities that are involved in the distribution and reimbursement of prescription drugs to Medicaid beneficiaries and Medicare Part D prescription drug benefit enrollees.

Also, the proposed rule, if finalized, would affect Medicare prescription drug enrollees. CMS reports there were 44,491,003 Medicare prescription drug enrollees in December 2018.

Please note that the document has not yet been placed on public display or published in the *Federal Register*.

The proposed rule would amend the discount safe harbor at 42 CFR 1001.952(h) by adding an explicit exception to the definition of "discount" such that certain price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D, and Medicaid MCOs would not be protected under the safe harbor. In addition, the proposed rule would add one new safe harbor to protect discounts between those same entities if such discounts are given at the point of sale and meet certain other criteria. Finally, the proposed rule would add a second new safe harbor specifically designed to protect certain fees pharmaceutical manufacturers pay to PBMs for services rendered to the manufacturers that relate to PBMs' arrangements to provide pharmacy benefit management services to health plans.

"The proposed rule would not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Social Security Act, including without limitation the provisions related to best price, the additional rebate amounts for certain drugs if the rate of increase in average

4712 Country Club Drive
Jefferson City, MO 65109

P.O. Box 60
Jefferson City, MO 65102

573/893-3700
www.mhanet.com

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manufacturers price and the increase in the consumer price index for all urban consumers (CPI-U), or provisions regarding supplemental rebates negotiated between states and manufacturers. Nor would this proposed rule alter the regulations and guidance to implement Section 1927 provisions, although the Department may issue separate guidance if this proposal is finalized to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price. This proposed rule recognizes that rebates paid by manufacturers to Medicaid MCOs should be treated differently than supplemental rebates paid by manufacturers to states because of the differing risk posed under the Federal anti-kickback statute."

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

CMS notes "that nothing in this proposed rule changes the discount safe harbor's provision that excludes from protection price reductions offered to one payer but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products."

The department intends for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payers in other Federal health care programs.

The proposed effective date for the new safe harbor would be 60 days after publication of the final rule. The department intends for this new safe harbor to protect reductions in price for prescription pharmaceutical products without regard to what phase of the benefit the beneficiary is in.

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