



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Testimony Before the United States Senate Special Committee on Aging

***“The Complex Web of Prescription Drug Prices, Part III:
Examining Agency Efforts to Further Competition
and Increase Affordability”***

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Chairman Collins, Ranking Member Casey, and other distinguished members of the Committee, I am Vicki L. Robinson, Senior Counselor for Policy at the Department of Health and Human Services (HHS), Office of Inspector General (OIG). Thank you for the invitation to testify today about the Department's recent proposed rule addressing rebates and other price reductions on prescription drugs.

Introduction

My testimony will describe the Department's proposal to change the safe harbor framework under the Federal anti-kickback statute as it applies to certain rebates and other price reductions on prescription pharmaceutical products from manufacturers to Part D plan sponsors and Medicaid managed care organizations (MCOs).¹

Specifically, the proposed rule would:

1. remove existing protection from anti-kickback statute liability under the discount safe harbor (42 CFR 1001.952(h)) for rebates and other reductions in price on prescription drugs from a manufacturer to a Part D plan sponsor, Medicaid MCO, or pharmacy benefits manager (PBM) under contract with them;
2. add new safe harbor protection for point-of-sale discounts that are completely applied to the price of the prescription drug at the time the pharmacy dispenses it to the beneficiary; and
3. add new safe harbor protection for fixed fees paid by manufacturers to PBMs for services the PBMs perform for the manufacturers.

As stated in the proposed rule, the Secretary is concerned that existing rebate arrangements have proven to be ineffective at, and counterproductive to, putting downward pressure on drug prices and that rebates may be harming Federal healthcare programs by increasing list prices, preventing competition to lower drug prices, discouraging the use of lower-cost brand or generic drugs, and skewing formularies. The proposed rule further explains concerns about PBMs favoring drugs with higher rebates over drugs with lower costs and basing formulary decisions on rebate potential rather than the quality or effectiveness of the drug. The Department's goals for the proposed rule are to curb list price increases, reduce financial burden on beneficiaries, improve transparency, and reduce the risks associated with rebates inappropriately influencing formulary placement or inducing business payable by Medicare Part D or Medicaid.

Because we are in active rulemaking, my testimony is limited to what the Department proposed in the Notice of Proposed Rulemaking published in the *Federal Register* on February 6, 2019 (84 FR 2340) and the public comments we received in response. My testimony is not intended to predict, and should not be viewed or interpreted as predicting, what might be in a final rule. A final rule is currently pending review at the Office of Management and Budget.

¹ Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2,340 (Feb. 6, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf>.

Legal Background

1. The Federal Anti-Kickback Statute and Safe Harbors

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act, serves an important role in ensuring that medical decision-making is not improperly influenced by financial interests. Broadly speaking, the statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration (generally, anything of value) to induce or reward the referral of business reimbursable under any of the Federal healthcare programs (as defined in section 1128B(f) of the Act). Among other things, the statute applies to remuneration offered or paid in return for arranging for or recommending the purchase of products.

The statute contains certain exceptions describing payment practices that are not violations of the law, including one that protects discounts or other reductions in price. Given the broad reach of the anti-kickback statute, Congress enacted legislation that required the Secretary to develop and promulgate regulations, the so-called safe harbor regulations, that would specify various payment and business practices that are not subject to sanctions under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business for which payment may be made under a Federal healthcare program.² The safe harbor regulations are evolving rules intended to be updated periodically to reflect changing business practices and technologies in the healthcare industry. In crafting safe harbors, the Secretary may consider a variety of factors, including increases or decreases in access to healthcare services, increases or decreases in the cost to Federal healthcare programs, and increases or decreases in competition among healthcare providers.³ Congress gave the responsibility for the development of safe harbors to the Secretary, and the Secretary has further delegated the authority to OIG.

Healthcare providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any anti-kickback statute enforcement action. The fact that a business practice does not fit in a safe harbor does not mean it is necessarily unlawful. Rather, it would be examined for compliance under the anti-kickback statute on the basis of its facts and circumstances, including the intent of the parties.

2. The Discount Safe Harbor

The original discount safe harbor regulation at 42 CFR 1001.952(h) was promulgated in 1991 and amended in 1999 and 2002.⁴ The discount safe harbor recognizes that a price reduction is an

² Specifically, section 1128B(b)(3) of the Act protects from the anti-kickback statute “any payment practice specified by the Secretary in regulations promulgated pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987.”

³ See Section 205 of the Health Insurance Portability and Accountability Act of 1996.

⁴ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991), available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm>; Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute 64 Fed. Reg. 63518 (Nov. 19, 1999), available at <https://www.govinfo.gov/content/pkg/FR-1999-11-19/pdf/99-29989.pdf>; Medicare and Federal Health

inducement to purchase a product and therefore implicates the anti-kickback statute. In its current form, the discount safe harbor—which is available broadly across the healthcare industry—protects discounts and other reductions in price to a buyer, including rebates, provided that all conditions of the safe harbor are satisfied.

Summary of the Proposed Rule

To address the Department’s concerns with the current rebate system in the pharmaceutical supply chain, the Department proposed and solicited comments on revisions to the safe harbor regulations. The stated intent of the proposed rule is to eliminate rebates from manufacturers to plan sponsors under Part D, Medicaid MCOs, and PBMs operating on their behalf, and replace them with discounts that would benefit beneficiaries at the point of sale. In addition, the Department proposed a new safe harbor to protect certain fixed fees that pharmaceutical manufacturers pay to PBMs for certain services rendered to the manufacturers.

1. Proposed Amendment to the Discount Safe Harbor to Remove Protection for Discounts to Part D Plans and Medicaid MCOs

First, the Department proposed to amend the current discount safe harbor to exclude from the definition of “discount” at paragraph 1001.952(h)(5) all price reductions (including rebates) from manufacturers on prescription pharmaceutical products in connection with their sale to or purchase by plan sponsors under Medicare Part D, Medicaid MCOs, directly or through PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, unless the reduction in price is required by law (*e.g.*, rebates under the Medicaid Drug Rebate Program). This change would have the effect of removing safe harbor protection under the anti-kickback statute for these price reductions.⁵ The proposed effective date of this change is January 1, 2020. The proposed rule solicited comments on the proposed exclusion and the proposed establishment of a new safe harbor for point-of-sale price reductions, including impact on beneficiaries, states, pharmacies, commercial markets, and others.

2. Proposed Safe Harbor for Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products

Second, the Department proposed to add a new safe harbor at 42 CFR 1001.952(cc) to protect certain point-of-sale price reductions that benefit patients when they fill prescriptions at the pharmacy counter. Three proposed criteria would apply. The reduction in price would need to be set in advance in writing; the reduction in price could not be a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback, or the rebate is required by law; and the reduction in price would need to be completely applied to the price the pharmacy charges to the beneficiary at the point of sale. The proposed rule solicited comments on how best to frame the new safe harbor to foster point-of-sale price reductions while minimizing any fraud or abuse risks to programs and patients.

Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 67 Fed. Reg. 11928 (March 18, 2002), available at <http://www.federalregister.com/Browse/AuxData/9F5C6DD8-FF39-4FB6-85C0-DBC24659C3B2>.

⁵ The proposed rule would not alter any rules or obligations under the Part D or Medicaid programs.

3. Proposed Safe Harbor for Pharmacy Benefit Manager Service Fees

Third, the Department proposed to add a new safe harbor at 42 CFR 1001.952(dd) specifically designed to protect certain fees a pharmaceutical manufacturer pays to a PBM. These fees would pay for services rendered by the PBM to the manufacturer that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans. Among other conditions, protected fees would need to be fixed (*i.e.*, not based on a percentage of sales); be set out in advance in writing; be fair market value for the service rendered; and not be determined in a manner that takes into account the volume or value of referrals or business generated between the parties). The services rendered would be disclosed to plans. The proposed rule recognized the possibility that certain types of remuneration that manufacturers might pay to PBMs either would not implicate the anti-kickback statute or could be protected using another safe harbor. However, the proposed safe harbor would provide a pathway, specific to PBMs, to protect certain low risk service fee arrangements. The proposed rule solicited comments on the proposed criteria and specifically highlighted as goals for the proposed criteria the importance of furthering transparency and avoiding risks connected with waste, fraud, and abuse.

4. Estimated Impacts of the Proposed Regulation

As described more fully in the proposed rule, due to the complexity and uncertainty of stakeholder response, it is difficult to accurately quantify the potential benefit of the proposed regulation. The Department engaged the Centers for Medicare & Medicaid Services' (CMS's) Office of the Actuary (OACT) and two independent actuarial firms (Milliman and Wakely)⁶ with experience working with Part D plan bid preparation to assess the potential effects on both premiums and out-of-pocket expenses. As described in the proposed rule, certain behavioral responses to the regulation by industry actors and beneficiaries would potentially affect benefit design, plan bids and, ultimately, beneficiary and government spending. The proposed rule presented six scenarios analyzed by OACT, Wakely, and Milliman. The scenarios made different assumptions about how plans might change benefit offerings or how manufacturers might change pricing processes.

Broadly speaking, the analyses show potential for beneficiaries, on average, to experience lower costs (combined premiums and out-of-pocket drug spending), although the impact on individual beneficiaries would vary greatly. Some beneficiaries, such as sicker beneficiaries with high drug costs, would see savings, while others would experience increases in out-of-pocket spending, such as increased plan premiums. Similarly, the analyses show variation in potential impact on Federal spending, with one scenario that assumed behavioral changes predicting potential decreased Federal spending, while other scenarios show substantial increases. The proposed rule solicited comments on the estimated impacts.

⁶ These analyses are available at <https://aspe.hhs.gov/pdf-report/prescription-drug-pricing-aspe-resources-related-safe-harbor-rule>.

Overview of Public Comments

The public comment period for the proposed rule closed on April 8, 2019. We received approximately 26,000 comments from a wide range of stakeholders, including PBMs, pharmaceutical manufacturers, Part D plan sponsors, pharmacies, wholesalers, Medicaid MCOs, states, consumers, and trade associations representing various individuals and entities. We received extensive, thoughtful comments, and we appreciate the engagement of the public in this rulemaking process. We have read, and are continuing to consider closely, all comments received. We are also coordinating closely with CMS, the HHS agency that administers the Part D and Medicaid MCO programs.

The comments address a broad range of topics and issues, from legal concerns to policy goals to practical implementation. Key themes in the public comments include:

- Beneficiary Out-of-Pocket Spending on Drugs. Comments reflected broad support across stakeholders for reducing beneficiaries' out-of-pocket spending on drugs.
- Formularies. Commenters made suggestions related to ensuring beneficiary access to drugs, raised concerns about plans using more restrictive formularies to keep premiums down, and supported eliminating rebates as an incentive for preferred formulary placement of brand name drugs over less costly, equally effective drugs (e.g., generics or biosimilar products).
- Implementation. Stakeholders raised both concerns about and support for the proposed implementation timeframe, as well as concerns about needed infrastructure to operationalize point-of-sale discounts and chargebacks.
- Additional Guidance. Commenters requested additional guidance and clarity regarding key terms and provisions, including how the chargeback process would work in the proposed point-of-sale price reductions safe harbor.
- Medicaid MCOs. Commenters requested we remove Medicaid MCOs from the amendments to the discount safe harbor given that most patients in these programs have nominal, if any, cost-sharing obligations.
- Impacts. Commenters offered feedback on the estimated impacts of the proposed rule on programs and beneficiaries.

Conclusion

I appreciate the opportunity to testify about the Department's proposed rule and would be happy to discuss the issues raised more fully after completion of the rulemaking process.

Since 1976, OIG has provided objective, independent, credible oversight to drive positive change for the Department of Health and Human Services' programs and the people they serve. OIG is at the forefront in preventing and detecting fraud, waste, and abuse in health and human services programs and, where necessary, enforcement to address violations of law. OIG carries out its mission through audits, evaluations, inspections, investigations, and legal actions in accordance with established professional standards.

OIG's past and current work speaks to the integrity and effectiveness of critically important benefits on which senior citizens depend and that taxpayers fund, such as prescription drugs, hospice, and nursing homes. OIG has a rich body of work focused on ensuring that HHS prescription drug programs work as intended. Protecting the integrity of prescription drug programs, fostering prudent payments for prescription drugs, and ensuring appropriate access to prescription drugs drive our efforts in this space. Our goal is to identify opportunities to limit the impact of high drug prices on Federal programs and senior citizens, while protecting access to medically necessary drugs. OIG will continue to work diligently to promote the effective and efficient operation and fiscal soundness of HHS's programs and to protect the health and welfare of the people they serve.

OIG greatly appreciates the support of this Committee for its oversight and program integrity work. Thank you again for the invitation to testify. I would be happy to take your questions.