AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Re: 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 (OIG-0936-P)

Dear Secretary Azar and Inspector General Levinson:

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to offer comments on the Department's proposed rule, "*Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-Of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.*" The rapid escalation of prescription drug prices in our nation is a significant concern to patients and their physicians, and the AMA applauds the Administration for its attention to this serious issue. We support efforts to increase the transparency of arrangements between pharmaceutical manufacturers and pharmacy benefit managers (PBMs)/health plans, and agree that patients should see the benefit of discounts, rebates, and other price concessions on prescription drugs.

Patient Impact

The AMA supports the Administration's proposal to remove safe harbor protection for reductions in price of prescription pharmaceuticals to Medicare Part D plan sponsors or PBMs under contract with these plans. We are pleased to see the proposed creation of a new safe harbor to protect price reductions for prescription pharmaceuticals paid at the point-of-sale. Prescription drug prices are reaching levels that are unsustainable for both patients and the health care system. The cost of new therapies is increasing every year, leaving patients in potentially untenable situations where their out-of-pocket costs—impacted by the list price of a drug—are simply unaffordable. Skyrocketing prices, coupled with a completely opaque system for drug pricing and contracting, have created a set of potentially perverse incentives to keep drug prices increasing with limited opportunity for review or oversight by policymakers and limited relief for patients.

The Administration's proposal to change the current drug "rebate" system for beneficiaries is a major step towards increasing transparency in this opaque system and should help to provide patients relief at the pharmacy counter. Where discounts or other reductions in price are available on certain prescription

drugs, patients should see the benefit of those rebates directly. Price reductions on certain products should not serve as an opportunity for PBMs and Part D plan sponsors to profit while patients pay co-pays and other co-insurance amounts based on high list prices that even the plans themselves are not paying. Further, the proposed changes to the current safe harbor protections could assist in removing incentives for prescription drug manufacturers to keep list prices higher than necessary. Policy experts seem to agree that the current system of providing rebates or other price reductions to health plans/PBMs has kept drug prices inflated, as a health plan/PBM can negotiate a larger rebate on a higher-priced product. We are hopeful that removing discounts/rebates from the drug pricing equation may help to alleviate the consistent upward pressure on drug list prices.

While we support the proposed changes to bring price reductions directly to patients at the point-of-sale, we urge the Administration to carefully consider the potential impact on beneficiaries to avoid any unintended negative consequences prior to and after finalizing these proposals. If finalized, the changes included in this proposed rule would significantly alter the current system used by manufactures and health plans/PBMs to contract for and price prescription drug products. Due to the significant and unprecedented nature of this change, there is a high degree of uncertainty about how exactly prescription drug manufacturers and health plans/PBMs will react and how these changes will ultimately impact the prescription drug marketplace. The AMA has questions and concerns about possible unintended consequences, including an increase in premiums, uncertainty regarding impacts on drug list prices, lack of availability of the price reductions for patients, and increased Medicaid drug expenditures. We urge the Administration to carefully consider the potential negative impacts of this proposed rule and consider what strategies may be available to address these unintended consequences. Specifically, we request that the Administration outline what steps it will take to actively monitor and address the impact of the proposed rule in the final rule.

- Impact on Premiums: Under the current contracting and pricing structure utilized by manufacturers and health plans/PBMs, plans have stated that they utilize savings achieved through negotiating with manufacturers for rebates and other price reductions to lower premiums for all beneficiaries enrolled in those plans. Should the proposals put forth by the Administration be finalized, it is likely that premiums for all beneficiaries enrolled in Part D plans or Medicaid Managed Care Organizations could increase, as acknowledged by the Department in the proposed rule. At the same time, some beneficiaries could benefit through a reduction in the amount that they must pay in cost-sharing versus paying a larger share of the actual cost of a drug—especially vital for beneficiaries that are high utilizers of prescription drugs with associated discounts. We urge the Administration to carefully consider the potential impact of this proposal on beneficiaries across the board and consider what strategies may be available to mitigate impacts on premiums.

- Impact on Drug List Prices: We are concerned about the significant uncertainty surrounding this proposal and its potential impact on drug list prices. While the current system of negotiated price reductions can serve to drive prices higher, we see little incentive for drug manufacturers to lower prices under this proposal. Although representatives from several major pharmaceutical manufacturers have stated they would lower list prices under this proposal, these pledges were conditioned on this proposal moving to the commercial market as well, and it is not clear that there will be success in mandating changes to the discount/rebate system in the commercial market. Also, should there be success in mandating these changes for the commercial marketplace, the extent to which manufacturers would reduce list prices is uncertain. For many

prescription drugs, significant reductions to list prices would be needed to ensure meaningful financial impacts for patients and this proposal falls short of ensuring meaningful list price reductions.

- Impact on Available Price Reductions: The AMA has questions about the potential impact of this proposal on the availability of prescription drug price reductions in the form of discounts made available to patients at the point-of-sale. Currently, manufacturers offer price reductions in the form of rebates or other discounts to health plans and/or PBMs in exchange for benefits such as preferred formulary placement. This type of negotiation has traditionally provided a benefit for both manufacturers and health plans/PBMs. However, the current proposal would make significant changes to the traditional way of doing business and remove the traditional incentives for both parties. Given the proposed changes, it would follow that there would be little incentive for drug manufacturers to continue to offer price reductions on their products, especially if health plans/PBMs are no longer offering incentives such as preferred formulary placements for doing so. Should manufacturers either cease to offer discounts to patients, or greatly reduce the amount of the discount on prescription drug products, patients will potentially see higher out-of-pocket costs, as premiums will have likely increased with little relief in the form of discounts at the pharmacy counter.

- Impact on Medicaid Drug Expenditures: Several key Medicaid policy experts have recently noted concerns about the proposal's potential impact on drug expenditures by state Medicaid programs. The Medicaid and Children's Health Insurance Program Payment and Access Commission in particular has noted that there is significant potential for Medicaid drug expenditures to increase should the changes in this proposal limit the ability of Medicaid programs to negotiate rebates as they currently do. As you know, state Medicaid programs serve some of our most vulnerable patients and do so on extremely limited budgets. This makes it crucial to carefully examine the potential impact on Medicaid programs before finalizing changes that would also be applicable to this population.

Transparency

The AMA recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders—but not patients. Thus, the AMA supports applying manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale. This policy would add much needed transparency and ensure that beneficiaries benefit from discounts. To further improve transparency in this space, the AMA highlights the need to disclose rebate and discount information, financial incentive information, and pharmacy and therapeutics committee information.

As requirements for the proposed PBM Service Fees safe harbor, the AMA recommends that PBMs should be required to disclose additional information about the fee arrangements including information about valuation and valuation methodology, information demonstrating that fee arrangements are not duplicative of other arrangements for which the PBM might receive duplicative payments, and information demonstrating that fee arrangements meet the volume and value criteria. Providing this information would provide additional and much needed transparency regarding PBM service fees. While the AMA appreciates the requirement that the fee arrangements must be provided to the Secretary upon request, this information should either be made public or PBMs must be required to annually submit

this information to the Secretary. The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. Pharmaceutical manufacturers, PBMs, and health insurers contribute to the prescription drug cost equation, ultimately impacting patient cost-sharing, drug tiering decisions, prior authorization policies, and decisions whether to change formularies in the middle of a plan year. These practices and policies of pharmaceutical manufacturers, PBMs, and health insurers warrant steps by the Administration to interject much needed transparency.

Mere reporting to the Secretary upon request is insufficient. With other regulatory safe harbors, the Department has the capability to request records.[1] Yet the AMA is unaware of any requests or public reports based off any requests from the Secretary. Given the push for greater price and cost transparency and the lack of recent data, the AMA recommends that the federal government renew efforts to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures involving drug pricing.

Proposed Safe Harbor for Point-of-Service Discount

Application of the Point-of-Service Discount

The AMA seeks clarification as to whether the point of service discount is applied to reduce the negotiated price, the patient's cost sharing, or both. If the discount is applied to the negotiated price, how will the Department address the potential unintended consequence of Part D plans capturing most of a discount by changing benefit designs to use fixed copayments versus coinsurance? Alternatively, if the discount is applied to the patient cost-sharing amount, how will the Department address the potential unintended consequences of manufacturers unilaterally electing to provide these discounts similar to a copayment coupon program?

Zero Cost-Sharing

The Department solicits feedback on how the safe harbor would apply during periods of 100 percent beneficiary cost sharing. The AMA believes that in these circumstances the point-of-sale discount apply equally because at 100 percent cost sharing the negotiated price is equal to the cost-sharing amount. A $100 negotiated price would have a $100 cost-sharing amount. Thus, a $30 point-of-sale discount applies equally and the patient owes $70. That said, the AMA seeks clarification as to how the discount applies in a situation where there is zero cost-sharing and seeks clarification from the Department.

Interaction with Existing Regulatory Safe Harbors

The AMA believes that the Department either needs to eliminate the application of the Group Purchasing Organization (GPO) regulatory safe harbor to PBMs or clarify its application only to administrative fees and define what fees are covered. Otherwise, PBMs will potentially be able to continue to operate under the current rebate structure.

[1] *See, e.g.*, 42 CFR § 1001.952(j).

The Departments only formal pronouncement on PBMs and the application of the GPO regulatory safe harbor is found in sub-regulatory guidance: Compliance Program Guidance for Pharmaceutical Manufacturers issued in 2003.[2] "Any rebates or other payments by drug manufacturers to PBMs that are based on the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor."[3] Through this language, the Department potentially extended the GPO regulatory safe harbor (which is meant to cover administrative fees) to include "any rebates or other payments."[4] Even if the Department finalizes the rule as proposed, PBMs can argue that the current rebate structure still has protection under the GPO regulatory safe harbor. Thus, the AMA recommends eliminating the application of the GPO regulatory safe harbor to PBMs.

Furthermore, PBMs may be able to avail themselves to existing regulatory safe harbors including the GPO safe harbor, the personal services and management contracts safe harbor, managed care safe harbor, and the proposed certain PBM services safe harbor. The AMA requests that the Department clarify what PBM fees and services apply to both the proposed and existing safe harbors. Otherwise, the AMA is concerned that the lack of clarity may provide further opportunity for exploitation.

Technical Edits

Change "reduced price" to "reduction in price" in proposed 1001.952(cc)(i)

The AMA recommends that the Department change "reduced price" to "reduction in price" to not introduce ambiguity and inconsistency within the requirements of the Point-of-Sale Reductions safe harbor (42 C.F.R. § 1001.952(cc)). This safe harbor uses the term "reduction in price" at (cc)(1), (cc)(1)(ii), and (cc)(1)(iii), while (cc)(i) uses "reduced price." The Department does not provide any explanation as to this difference. Thus, to remove this unnecessary ambiguity, proposed 42 CFR § 1001.952(cc)(i) should read as follows:

(i) The reduction in price ~~reduced price~~ must be set in advance with a plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either;
Change "health benefits plan" to"health plan" in proposed 1001.952(h)(8)

The AMA recommends that the Department change "health benefits plan" to "health plan" to not introduce a new term in the regulatory safe harbors and inconsistency. In defining "pharmacy benefit manager," the proposed regulation uses the term "health benefits plan." This term is not used anywhere in any of the current safe harbors. Moreover, in this proposed rule, the Department proposes that the PBM services fee safe harbor includes PBM services that are furnished to a "health plan" and defines that term as it is ascribed in 1001.952(l). Thus, to remove ambiguity, proposed 42 CFR § 1001.952(h)(8) should read as follows:

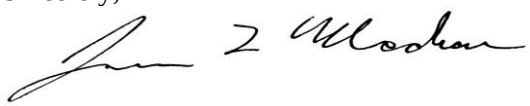
[2] HHS, *Compliance Program Guidance for Pharmaceutical Manufacturers* (Apr. 2003), p. 24-25, https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.
[3] *Id.*
[4] *Id.*

(8) For purposes of this paragraph (h), the term pharmacy benefit manager or PBM means any entity that provides pharmacy benefits management on behalf of a health ~~benefits~~ plan that manages prescription drug coverage.

Conclusion

The AMA appreciates the Administration's focus on this important issue and efforts towards ensuring the affordability of prescription drugs for all Americans. With drug prices reaching new extremes, every possible effort must be made to ensure that patients can afford the treatments they need most. Ensuring that patients directly benefit from any available price reductions on their prescription medications will help to alleviate financial burdens at the pharmacy counter for many beneficiaries. However, uncertainty exists as to how the pharmaceutical marketplace will react to these changes put forth in this proposal, and we urge the Administration to carefully consider and attempt to mitigate the potential negative consequences for Medicare and Medicaid beneficiaries. As always, we look forward to continuing to work with you to take meaningful steps towards ensuring the affordability of prescription drugs for our patients. If you would like to discuss further or have any questions, please contact Shannon Curtis, Assistant Director, Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,



James L. Madara, MD