The pharmacy benefit manager (PBM) industry recently has come under significant scrutiny by the Trump administration. Historically, payments from manufacturers to PBMs receive protection under the group purchasing organization safe harbor, and down-stream payments to end users are protected under the discounts safe harbor. The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) made this position clear in its pharmaceutical manufacturer compliance guidance in 2003. Sixteen years later, the regulatory agencies are beginning to question whether existing safe harbors that seek to achieve transparency work.

approved, may have broad implications for pharmaceutical manufacturers and PBMs, and may change the structure for drug pricing. OIG is seeking comments on the proposal by April 7, 2019 in advance of issuing a final rule.

OIG’s proposed rule would make three main changes to the current regulations governing pricing of prescription pharmaceutical products. It would: (1) eliminate safe harbor protection under the Anti-Kickback Statute (AKS) for rebates paid by manufacturers to PBMs; (2) create a new safe harbor for discounts provided directly to beneficiaries at the point of sale; and (3) create a second new safe harbor for certain fixed administrative fees paid by manufacturers to PBMs. The elimination of safe harbor protection for rebates paid to PBMs is slated to go into effect on January 1, 2020, while the point-of-sale safe harbor will take effect 60 days after promulgation of a final rule. No effective date has been set for the administrative-fee safe harbor.

In the fact sheet (available at: https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf) accompanying the release, OIG characterizes the proposal as the “most sweeping change to how Americans’ drugs are priced at the pharmacy counter, ever, by delivering discounts directly to patients at the pharmacy counter and bringing much-needed transparency to a broken system.” This proposal is one of a series of initiatives undertaken by OIG to advance the president’s May 2018 Blueprint (available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf) to Lower Drug Prices and Reduce Out-of-Pocket Costs, including a rule proposed in October 2018 (available at: https://www.federalregister.gov/documents/2018/10/18/2018-22698/medicare-and-medicaid-programs-regulation-to-require-drug-pricing-transparency), which requires pharmaceutical manufacturers to include the list prices of their drugs in all direct-to-consumer advertisements. Both proposals seek to increase transparency into drug pricing and create incentives for lower list prices.

OIG contends that the current pricing structure is hurting beneficiaries because the rebates between manufacturers and PBMs are generally not applied at the point of sale to offset the beneficiary’s deductible or coinsurance or otherwise reduce the price paid at the pharmacy counter. OIG also notes that the current system leads PBMs to favor drugs with higher rebates over drugs with lower costs, and discourages the use of lower-cost brand and generic drugs, all of which increase the burden on federal health care programs. OIG also opines that, to the extent rebates are paid to buy formulary position, these payments are not protected by the AKS statutory exemption for discounts, and will no longer have protection under the rebate safe harbor.
The proposed rule raises many questions and is likely to have far-reaching implications. For example, even OIG’s impact statement predicts that the changes will cause health insurance premiums to rise for all Medicare Part D participants and out-of-pocket costs to rise for 70 percent of those participants, but OIG predicts that, in the aggregate, costs will decrease. In addition, although the new rules only directly apply to Medicare and Medicaid plans, many states will apply these rules to private plans, making it necessary for manufacturers to apply the rules to both government and commercial plans. Further, HHS Secretary Alex Azar has called on Congress to pass legislation applying the rule changes to private payers. Not only will pharmaceutical manufacturers be required to restructure their agreements with PBMs, they will also need to analyze the impact the changes will have on their list prices and their obligations under other federal programs, such as AMP and best-price calculations under the Medicaid Drug Rebate Program.

OIG is seeking comments from stakeholders on multiple issues relating to the proposed rule and its impact, including whether the amendments will have their intended effect (e.g., will the point-of-sale discount safe harbor incentivize manufacturers to provide such discounts; will declining to protect PBM rebates affect beneficiary access to prescription medications due to cost or formulary placement) and whether the amendments will have any unintended collateral consequences (e.g., will the transparency requirements in the new safe harbors implicate competitive concerns, and how might OIG address them). Manufacturers and PBMs should review the rule and consider submitting comments on how the changes will affect their agreements and prices, any concerns regarding the timing and structure of the amendments, and any insight into the overall impact on federal government programs and beneficiaries.

John W. Jones Jr. and Hyung P. Steele are partners in Pepper Hamilton’s Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. Suzanne Forbis Mack is an associate in the Health Sciences Department.