It is no surprise that the Trump administration did what it had been promising to do for the past year: tear up the get-out-of-jail-free card from the federal anti-kickback law, which PBMs have been enjoying since 1991. That “safe harbor” allows PBMs to take rebates from drug manufacturers in return for favorable placement of products on PBM formularies. The administration has been inveighing against rebates in statements and policy exhortations over the past 18 months. Its argument against rebates is that they encourage drug manufacturers to inflate list prices, resulting in higher costs for Medicare and Medicaid, not to mention consumers. The current rebate system also results in pressure on P&T committees to make formulary decisions based on rebate potential, not on the quality or effectiveness of a drug.

But the proposed rule that the Department of Health and Human Services (HHS) issued on February 6 did more than simply threaten to ban the PBM safe harbor by disqualifying “rebates” as allowable discounts: It announced two new safe harbors. One protects discounts between manufacturers and PBMs if such discounts are given to consumers at the point of sale at the pharmacy counter. For a rebate to be legal, the whole amount must be passed on to the dispensing pharmacy through a chargeback(s).

The second new safe harbor protects certain fees that pharmaceutical manufacturers pay to PBMs for services rendered, such as utilization management, medical education, medication monitoring, data management, and so on. But those would have to be flat fees, not a percentage of the list price, which is usually the case now, leading to the Office of Inspector General’s (OIG) concern that soaring list prices lead to PBM fees becoming kickbacks. The current safe harbor would continue to protect discounts on prescription pharmaceutical products offered to wholesalers, hospitals, physicians, pharmacies, and third-party payors in other federal health care programs.

Whether the new safe harbors would accomplish what the administration hopes is uncertain. The OIG’s proposed rule says as much, noting that it is “difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response” and that it is “difficult to predict manufacturer and Part D plan behavior in response to this regulation.”

Brian Bohnenkamp, a King & Spalding attorney with drug manufacturer clients, says OIG’s proposed rule is a thoughtful attempt to remove some of the perceived incentives that have driven up list prices. Bohnenkamp, who follows federal pharmaceutical policy, continues: “But I don’t necessarily believe this will solve the problem or that it’s a silver bullet. And [it could] upend a large swath of the drug-purchase paradigm as we know it.”

The PBMs, led by their Pharmaceutical Care Management Association (PCMA) lobby, have been unenthusiastic about any proposed changes to current rebate rules. PCMA president and CEO J.C. Scott says, “We are concerned that eliminating the long-standing safe harbor protection for drug manufacturer rebates to PBMs would increase drug costs and force Medicare beneficiaries to pay higher premiums and out-of-pocket expenses, unless there is a viable alternative for PBMs to negotiate on behalf of beneficiaries.”

The PCMA argues that Part D premiums have remained lower than initially projected since the program began and that enrollees are highly satisfied with their prescription-drug coverage. The group cites a number of studies demonstrating that rebates have reduced costs in Medicare Part D and says that Part D premiums for 2019 show a negative trend for the first year since 2007.

Pharmacies have decrified the current rebate system and are supportive of the Trump administration’s plan to force rebates to be translated into point-of-sale discounts. Andie Pivarunas, Director of Public Affairs, National Community Pharmacists Association, says, “The administration’s latest drug pricing proposal contains a meaningful change that community pharmacists have long supported and advocated for—moving certain types of remuneration to the point of sale so that the benefits of those price reductions are passed along to patients. While we were initially encouraged by the latest administration proposal, which would help keep PBMs from using rebates to line their own pockets, we will continue to analyze the proposal for impacts on our members.”

Drug manufacturers have been the leading proponent of removing the safe harbor protection for PBMs. Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen Ubl says, “We applaud the administration for taking steps to reform the rebate system to lower patients’ out-of-pocket costs. Our health care system results in patients...paying cost-sharing based on the list price, regardless of the discount their insurer receives. We need to ensure that the $150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy.”

There is no guarantee this proposed rule will be translated into a final rule in every detail. The OIG has asked for industry comments on various aspects of the rule. If it is finalized in whatever form, it could become effective on January 1, 2020.