The Trump administration takes another tentative but controversial step toward corralling high drug prices paid by consumers in its proposed rule laying out prospective changes for the Medicare Part D drug program in 2019. The Centers for Medicare and Medicaid Services (CMS) wants to make a number of changes in the Part D and Part C (Medicare Advantage) programs and includes among the potential regulatory changes a nonregulatory “request for information” (RFI). That focuses on whether the agency should require Part D plans to provide a discount at the pharmacy counter so enrollees benefit from rebates plans pay to manufacturers and payments pharmacies make to pharmacy benefit managers (PBMs). It is not clear what percentage of those two revenue streams would end up in Medicare recipient pockets when they pay for prescriptions at the pharmacy counter.

A requirement to pass along discounts to consumers—which would unfortunately have the effect of increasing premiums—will not be mandated for the plan year 2019. But like the potential changes the CMS is considering for the federal health insurance exchanges (another proposed rule—see the article on page 89), including a new, national benchmark plan for formularies, the Part D proposal reflects the Trump administration’s efforts to iron out pricing kinks in the drug distribution system, kinks it believes hurt consumers.

The RFI on pharmacy counter rebates is just one small part of the broader 2019 proposed rule for Part D and Part C plans and arguably one of the less significant ones, at least in the near term, but probably the most controversial. However, the proposed rule includes a number of important changes that will go into effect in 2019. For example, the CMS gives a boost to medication therapy management programs by allowing those expenditures to be included in a plan’s calculations for quality improvement activities (QIA). QIA spending is the numerator for the medical loss ratio (MLR) calculation. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. An MLR lower than 85% results in a plan paying penalties, so plans want to include as many activities as possible in the numerator. The proposed rule for 2019 also touches on pharmacy inclusion in networks, biosimilars, and two formulary issues, the first on tiering exceptions, the second on substitution of newly released equivalent generic drugs for brand-name drugs at the same or lower cost-sharing.1

Perhaps the most notable change will allow Part D plans to voluntarily implement a drug-management program that limits “at-risk” beneficiaries’ access to opioids—the so-called “lock-in” mechanism—to a selected prescriber and/or network pharmacy. CMS also proposes to exempt beneficiaries who have cancer or are in hospice or long-term care from the drug-management program.1

Given the national attention to opioid abuse, the fact that Congress mandated this new voluntary program and the fact that the CMS has allowed Part D plans since 2011 to engage in case management where an enrollee is found to be taking a very high dose of opioids, this extension of the current policy is probably not going to be overly controversial, especially because the use of a lock-in program is voluntary.

But just the prospect of a pharmacy counter rebate mandate sometime in the future has set off fireworks. Recently, the Pharmaceutical Research and Manufacturers of America (PhRMA) has pushed the point that PBMs and Part D plans are making a killing off rebates. The CMS appears to sign on to this belief and throws in an added claim that PBMs are making a second, though smaller, killing off direct and indirect remuneration (DIR) payments they receive from pharmacies. The CMS argues that between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24% per year, about twice as fast as total Part D gross drug costs. Rebates constitute most of this growth. When the Medicare drug benefit was established in 2005, the CMS expected that a high percentage of rebates and DIR payments would be passed back to consumers at the pharmacy counter. That hasn’t happened. In some cases, plan premiums have been moderated to reflect the payments, and that has been welcomed by consumers. But the Trump administration clearly believes that too much of total payments are being pocketed by the PBMs and the Part D plans.

The Pharmaceutical Care Management Association (PCMA) issued a press release soon after the proposed rule came out, and long before comments were due, pointing out that the CMS itself estimated a move to pharmacy counter discounts would cause premiums to spike by up to $28 billion and taxpayer costs by up to $82 billion over the next decade. Such a requirement would also create a windfall for drug-makers, the PCMA argued, who would pay up to $29 billion less in doughnut-hole discounts.2

Congress has already been pulled in to this debate on consumer drug discounts and manufacturer rebates, with PhRMA, continued on page 115

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the manufacturers lobby, running a campaign to highlight the alleged refusal of PBMs to share their discounts. This issue is just heating up. The CMS will likely bring it to a boil.

REFERENCES
