March 7, 2022

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Re: CMS-4192-P

We commend CMS for issuing its proposed rule on Medicare Advantage and Part D plans.[1] As currently written, the rule would help save community pharmacies while lowering out-of-pocket costs for Part D patients. While the proposed rule is straightforward and strong, it currently does not address patients in Part D's coverage gap and gives room for PBMs and health plans to continue gaming contracts with pharmacies to their own advantage. We urge CMS to adopt a strong, clear final rule that addresses these loopholes.

PBMs, or Pharmacy Benefits Managers, are corporate middlemen who process pharmaceutical benefits for Medicare and Medicaid plans. In theory, health plans pay PBMs to bargain down the price of drugs and to reimburse pharmacies for patients' prescriptions. In practice, PBMs often abuse their position as middlemen to drive up the cost of drugs, over-charge Medicare and Medicaid, steer patients to their own mail-order pharmacies, and skim as much money as possible from independent pharmacies by under-reimbursing them and charging excessive fees for network access.

PBMs reimburse pharmacies on behalf of Medicare Part D and Medicare Advantage plans, and are vertically integrated within the health insurance companies that own these plans. Since 2006, roughly half of all Part D recipients have been enrolled with UnitedHealth, CVS Health, and Humana – all three of which have their own in-house PBMs and mail-order pharmacies.[2][3] Aetna, Cigna, Humana (also a Part D insurer), and UnitedHealth own the four largest PBMs in the country.[4] The top three PBMs control nearly 80% of the overall prescription drug market.[5] PBMs and their corresponding Part D plans leverage their market dominance to force independent pharmacies into take-it-or-leave-it contracts. These contracts expose community pharmacies to under-reimbursement and excessive, unnecessary fees by PBMs. In a 2021

---

[1] Center for Medicare & Medicaid Services, "CMS Takes Action to Lower Out-Of-Pocket Medicare Part D Prescription Costs," CMS Newsroom, January 6, 2022, https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-out-pocket-medicare-part-d-prescription-drug-costs

[2] Jack Hoadley and Laura Summer, "Medicare Part D in its Ninth Year," Kaiser Family Foundation, August 18, 2014, https://files.kff.org/attachment/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014-report

[3] Juliette Cubanski, "Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021," Kaiser Family Foundation, June 8, 2021, https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/

[4] Adam J. Fein, "The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation," Drug Channels Institute, April 6, 2021, https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html

[5] Ibid.

survey of community pharmacists, PBM fees were ranked as the number-one concern impacting the health of their business.[6]

Over the past decade, most states have passed laws going after unfair point-of-sale tactics by PBMs. These tactics include "spread pricing," where a PBM over-charges health plans while it under-reimburses pharmacies. States have also required PBMs to make their "maximum allowable cost" (MAC) lists available to health plans and pharmacists, allowing both to see what a PBM is charging and reimbursing – this keeps PBMs from utilizing spread pricing at point-of-sale transactions. These state-level laws have been effective in stopping specific types of PBM malfeasance, but over the years PBMs have found new ways to tax independent pharmacies.[7]

Since 2010, PBMs have been charging pharmacies ever-increasing pharmacy price concessions, sometimes known as DIR fees. These are post-point-of-sale adjustments to the negotiated price of a drug. Instead of taking money from pharmacies at point-of-sale, these fees can be levied months after a patient buys a drug at a pharmacy. That is, a patient can go to a pharmacy, and the pharmacist gets a copay from the patient and a reimbursement from a PBM. The copayment from the patient is usually based on the total price then charged. But then, months later, the PBM claws back a portion of the amount reimbursed to the pharmacy. This causes two separate harms. The first is that DIR fees are effectively surprise costs for pharmacists, which are very difficult to plan for. The second is that they increase the copay for the patient, since the patient is paying a portion of the price at the point of sale, but that price is later reduced by the DIR fee.

Post-point-of-sale price concessions obfuscate and drive up the negotiated price of a drug, allowing PBMs and plans to skim money from patients and independent pharmacists. According to CMS, the use of DIR fees increased by more than 90,000% from 2010 to 2019. Pharmacies now pay hundreds of thousands of dollars a year in retroactive price concessions.[8] Because these fees are levied long after the sale, pharmacies are often caught by surprise and have little recourse. They fuel pharmacies going out of business.

In crafting its final rule, CMS must be careful to anticipate any potential contractual game-playing or financial manipulation by PBMs and health insurers. As the past 10 years of increasing DIR fees have shown, if an insurer sees any opportunity to shift costs onto another party to pad its bottom line, it will sieze that opportunity. Finally, the rule currently does not apply to drugs in Medicare Part D's coverage gap. Once a patient on a Part D plan spends a certain amount of money on drugs, their plan will only cover 75% of the patient's drug costs,

---

[6] "Survey of community pharmacy economic health 2021 report," National Community Pharmacists Association, November 2021, https://ncpa.org/sites/default/files/2021-11/November2021-NCPA-Pharmacy.Economic.Health.Survey_0.pdf

[7] Zach Freed, "Reining in Pharmacy Middlemen," Institute for Local Self-Reliance, January 31, 2020, https://ilsr.org/reining-in-pharmacy-middlemen/

[8] "Justification of Estimates for Appropriations Committees, Fiscal Year 2022," Centers for Medicare and Medicaid Services, May 31 2021, https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf

until they've spent a certain amount of money out-of-pocket – this is called the "coverage gap." Because the rule doesn't apply to drugs in Part D's coverage gap, it gives plans and PBMs wiggle room to still skim money. An earlier version of this rule applied to drugs in Part D's coverage gap, and we believe CMS can easily remedy this loophole. We urge CMS to affirmatively address these types of extractive contractual provisions in its final rule, and to fix the coverage gap issue.

Once the coverage gap issue and any potential loopholes are addressed, we believe CMS's new rule will help save community pharmacies across the country, preserve patient choice of pharmacy, give Part D patients a discount on their life-saving medicines, and bring transparency to drug prices.

Sincerely,

American Economic Liberties Project
Institute for Local Self-Reliance