DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



OFFICE OF THE ADMINISTRATOR

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Dear Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans:

The Centers for Medicare & Medicaid Services (CMS) values your partnership in providing health care coverage and access to essential treatments, including prescription medications, to millions of people. However, we are hearing an increasing number of concerns about certain practices by some plans and pharmacy benefit managers (PBMs) that threaten the sustainability of many pharmacies, impede access to care, and put increased burden on health care providers. We are writing to share these concerns and to encourage you to work with providers and pharmacies to alleviate these issues and safeguard access to care. This is especially important for vaccines and treatments that can prevent and treat influenza, COVID-19, and RSV as we enter the winter respiratory virus season.

Pharmacies serve a critical role in delivering health care and providing access to medications across the country. CMS is concerned about the sustainability of these businesses, especially small and independent pharmacies, and their potential closures that may leave pharmacy services out of reach for many people, especially those in rural and underserved areas. With respect to the Medicare Part D program, CMS finalized a pharmacy price concessions provision in the Contract Year 2023 Medicare Advantage and Part D final rule that is expected to lower total beneficiary out-of-pocket costs, provide meaningful price transparency, better reflect pharmacy payment arrangements, and enable CMS to assess the payment practices of Part D plan sponsors and PBMs with respect to pharmacies under the Medicare Part D program. This provision takes effect January 1, 2024, and requires the application of all pharmacy price concessions to the negotiated price at the point of sale. CMS has heard many concerns regarding the potential impact on pharmacy cash flow upon implementation of this provision, and we finalized a oneyear delay in the effective date of the policy to provide sufficient time for implementation. We continue to hear urgent concerns from pharmacies, and we strongly encourage Part D plan sponsors and their PBMs to make necessary cash flow arrangements with network pharmacies in preparation for these upcoming changes. In addition, we will closely monitor

¹ See final rule titled, "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-F) (87 FR 27704) at: https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.

plan compliance with pharmacy access and prompt payment standards to ensure that all people with Medicare Part D continue to have access to pharmacies and medications.²

We have also heard from pharmacies that the amount plan sponsors and PBMs that serve plans in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), and plans offered through the Marketplaces pay pharmacies for some vaccine administrations is causing many pharmacies and other providers of vaccines to lose money administering vaccines, discouraging them from providing these vaccines. Particularly as we encourage people to get vaccinated against influenza, COVID-19, and RSV this year, CMS is very concerned about payment practices that may impede access to recommended vaccinations, and it is imperative that plans and PBMs take immediate steps to ensure adequate payment for and access to vaccines.

In addition, we know that the increasing level of vertical integration that is occurring among plans, PBMs, and their own pharmacies has the potential to result in anticompetitive behavior and place independent pharmacies at a disadvantage. We urge plans and PBMs to engage in sustainable and fair practices with all pharmacies – not just pharmacies owned by PBMs – and we are closely monitoring plan compliance with CMS network adequacy standards and other requirements.

We have also heard of concerns from stakeholders and consumers that privately insured patients and providers continue to experience a difficult time navigating plan and issuer exceptions processes for medically necessary contraceptive drugs, items, and services required to be covered under the Affordable Care Act. In addition, we have seen plans and issuers impose cost sharing on coverage of preventive services due to claims being submitted with unrelated diagnostic codes or because the provider did not use a specific preventive care procedure code required by the plan or issuer. We are investigating these concerns within our jurisdiction. We urge plans, issuers, and PBMs to check their processes and systems to ensure they are providing full coverage, without cost sharing, of preventive services, as required by federal law.

We also want to highlight that most children enrolled in Medicaid and CHIP have coverage of all routine Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and vaccinations determined to be medically necessary for beneficiaries eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit without cost sharing. Most adults enrolled in Medicaid and CHIP have coverage of FDA-approved and ACIP-recommended vaccinations without cost sharing because requirements established in the Inflation Reduction Act (IRA) became effective on October 1, 2023. This new IRA adult vaccine coverage applies to all types of ACIP recommendations. Additional information can be found in our recent guidance and fact sheet on the new IRA vaccine coverage for adults. Additionally, COVID-19 vaccinations are mandatorily covered for nearly all Medicaid and CHIP beneficiaries through September 30, 2024, in accordance with the American Rescue Plan Act of 2021. We urge plans, as well as states, to ensure that their guidance and systems reflect this coverage.

² See Health Plan Management System (HPMS) memo titled, "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024" at: https://www.cms.gov/about-cms/information-systems/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10.

Finally, we often hear concerns about the impact of plans' utilization management tools, including prior authorization. The inappropriate use of these tools can impede access to needed care for people and delay essential treatments, as well a take clinician time away from direct care. Providers, especially those in rural areas, report that these plan practices have become increasingly unsustainable and burdensome. Earlier this year, CMS finalized vital protections that will be effective on January 1, 2024, to ensure Medicare Advantage enrollees have timely access to needed care and to crack down on harmful disruptions to care. We have also proposed new requirements to improve access to patient health information and to address avoidable delays in patient care by streamlining the electronic exchange of health care data and processes related to prior authorization for Medicare Advantage organizations, state Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans and CHIP managed care entities, and Qualified Health Plan issuers on the Federally Facilitated Marketplaces. We remind plans that CMS will be conducting robust oversight to ensure Medicare Advantage organizations are complying with these new requirements, and we continue to review comments received on the additional proposals from the second rulemaking.

Thank you for your attention to these issues.

Sincerely,

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