



July 24, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program (CMS-2434-P)

The National Association of Community Health Centers (NACHC) is the national membership organization for Federally qualified health centers (also known as FQHCs or health centers). Health centers are Federally-funded or Federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 30 million people, including 1 in 6 Medicaid beneficiaries and over 3 million elderly patients. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other “enabling” or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

Health centers serve some of the nation’s most vulnerable patients; nearly 70% of health center patients are under 100 percent of the Federal Poverty Level (FPL), and 90% are under 200 percent FPL. Additionally, nearly half (48%) of health center patients have Medicaid coverage, and 20% of health center patients are uninsured.¹ Therefore, FQHCs heavily rely on the 340B Drug Pricing Program to provide comprehensive services to our medically underserved and often uninsured or underinsured patients. The savings and resources they generate by participating in the 340B program allow them to provide the services their patients most need and for which there is no other funding source.

NACHC welcomes the opportunity to comment on this proposed rule and discuss the anticipated implications of these proposed changes on health centers and the patients they serve. We support the intentions behind this proposed rule to increase the transparency of drug pricing for manufacturers. However, we will focus our comments on the proposal on the following:

- I. Using Identifiers for all Medicaid Managed Care Beneficiary Identification Cards for Pharmacy Benefits;
- II. Drug Cost Transparency in Medicaid Managed Care Contracts;
- III. Conditions that trigger a National Drug Rebate Agreement (NDRA) Suspension; and
- IV. Request for Information—Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment.

¹ <https://www.nachc.org/wp-content/uploads/2023/04/Community-Health-Center-Chartbook-2023-2021UDS.pdf>

I. Using Identifiers for all Medicaid Managed Care Beneficiary Identification Cards for Pharmacy Benefits

NACHC appreciates the Departments' intention to create a more efficient process for pharmacies to identify Medicaid managed care beneficiaries and minimize duplicate discounts under the 340B program through the proposal at § 438.3 (S)(7). Health centers support improving transparency by including BIN/PCN/group numbers (GRP) on Medicaid managed care pharmacy benefit cards to ensure that pharmacies charge patients accurate cost-sharing and provide appropriate drug coverage. This policy change would help pharmacies accurately account for reimbursement and pharmacy fees. However, it's imperative we raise anticipated operational barriers. For states that permit contract pharmacies to dispense 340B drugs to Medicaid managed care patients, NACHC anticipates challenges with the proposal to require a point-of-sale modifier for 340B drugs or drugs ineligible for a Medicaid rebate.

First, we believe this proposal does not consider the data available when a pharmacy fills a prescription. Determining whether a prescription can and should be filled with a 340B purchased drug can be a complicated, data-intensive process that often cannot be completed when the prescription is filled and the claim submitted to the payer or at the point-of-sale. Under the 340B program, pharmacies have the discretion to use a variety of inventory models, including for tracking drugs at contract pharmacies. A covered entity will work with a third-party administrator (TPA) to implement a 340B drug inventory system for contract pharmacy arrangements, usually implementing the pre-purchased inventory model or the replenishment inventory model.² Both systems can run a compliant 340B program to avoid duplicate discounts but track inventory differently. Specifically, under the replenishment model, a contract pharmacy uses its non-340B purchased drugs when filling prescriptions on behalf of the covered entity. Because 340B eligibility is determined retrospectively in a replenishment model, most contract pharmacies do not know at the point of sale if the drug they are dispensing will ultimately qualify as a 340B drug and would have extreme difficulty implementing a point-of-sale modifier for 340B drugs. Additionally, even if a contract pharmacy uses the pre-purchase inventory model, that does not guarantee the pharmacy has 340B price drugs for all their patients' needs.

Second, health centers use several systems and methods to prevent and minimize the risk of duplicate discounts. When registering on the Office of Pharmacy Affairs (OPA) database, they can indicate they will use 340B drugs for fee-for-service patients, if applicable. They also diligently ensure that Medicaid billing numbers and NPIs are accurately reflected in the OPA database and the Medicaid Exclusion File. Health centers perform audits regularly over their in-house and contract pharmacies to ensure their everyday practices reflect their policies and procedures and conform to 340B program requirements. They conduct ongoing internal audits of in-house and contract pharmacy dispenses to verify that 340B accumulations do not include Medicaid patients.

From lessons learned based on similar state policy proposals, we recommend CMS consider these questions when finalizing this policy:

- Does the payer allow a 340B purchased drug to be dispensed?

² <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>

- Is the individual a patient of the FQHC?
- Has the patient been seen at the FQHC recently enough to qualify for a 340B purchased drug?
- Was the prescription written by a provider who works for the FQHC?
 - If yes, was the provider:
 - moonlighting when the prescription was written?
 - providing a service that is under the FQHC’s scope of project?
 - If no, can the FQHC demonstrate that it has assumed responsibility for the care that generated the prescription?
- Is it more cost-effective to dispense a non-340B purchased drug?

Further, we would like to recommend that in addition to requiring the identification by unique BIN/PCN/GRP of Medicaid managed care on pharmacy benefit cards, CMS requires the creation and maintenance of a national database of State Medicaid Fee-For-Service and Manage Care plans (by BIN/PCN/GRP) to enhance transparency and support covered entity and 340B stakeholder efforts to reduce duplicate discounts from occurring.

NACHC appreciates efforts to decrease duplicate discounts and supports the intent of this provision. However, we encourage CMS to implement policies that align with the timeline of identifying 340B drugs.

II. Drug Cost Transparency in Medicaid Managed Care Contracts

NACHC supports the proposed changes in amending § 438.3 to add a new subparagraph (s)(8) requiring Medicaid managed care plans to structure any contract with subcontractors (i.e., PBMs) for the delivery/administration of the covered outpatient drug benefit so that the subcontractors separately report out incurred claims³ and other administrative costs, fees, and expenses of the subcontractor. We appreciate CMS acknowledging Pharmacy Benefit Managers’ (PBM) abusive and discriminatory business practices and seeking to rectify them through this proposal. For years, health centers across the country have been advocating for PBM reforms because of the lack of regulation at both the federal and state levels. Over half of states have instituted protections for 340B covered entities against discriminatory practices by PBMs, including laws prohibiting spread pricing.⁴

We appreciate CMS taking steps to use its regulatory authority to address spread pricing. PBMs have historically charged health plans for prescription drugs more than they reimburse a pharmacy, often well below the cost for a pharmacy to purchase drugs they are dispensing. Instead of passing the entire payment to health center pharmacies, PBMs keep the difference, or “spread,” as profit. Meanwhile, health center pharmacies get reimbursed well below their costs, jeopardizing their financial viability in trying to keep their doors open to care for patients. Furthermore, PBMs have historically engaged in discriminatory contracting practices, such as charging health centers additional fees to misappropriate 340B savings. Outside of 340B, this impacts the ability of the pharmacy to operate a sustainable business. Health centers strive to provide affordable, accessible

³ Including reimbursement for the cost of the prescription drug itself, payments for other patient services and dispensing fees to pharmacies and other providers

⁴ [State Level 340B Laws - NACHC Resource](#)

medications to their patients. These fees also affect health centers and their ability to serve their patients.

NACHC encourages CMS to address spread pricing and avoid any unintended consequences on CHCs ability to retain 340B pricing. For instance, CMS should only create policies that address contracting between PBMs and managed care companies, fees charged, and profits generated by PBMs. We do not support any policies that will impact a pharmacy's reimbursement.

III. Conditions that trigger a National Drug Rebate Agreement (NDRA) Suspension

NACHC supports CMS' proposal at § 447.510 (i), which outlines manufacturers' requirements, including suspending a manufacturer's NDRA for late drug pricing and drug product information reporting. If they fail to adhere to these requirements, it is essential to hold manufacturers accountable by disallowing them from claiming federal financial participation (FFS) for physician-administered drugs in Medicaid.

We appreciate that CMS specifies that this suspension does not curtail a manufacturer's ability to participate in the 340B drug pricing program when their rebate agreement is suspended. Health centers are already facing restrictions from nine pharmaceutical manufacturers, decreasing the number of 340B-priced medications available to patients. However, we want to make CMS aware that manufacturers may still unilaterally decide to suspend 340B pricing, as they have done since August 2020. Health centers have been losing millions of dollars in mission-critical 340B savings, which have historically been used to reinvest in services such as dental care, behavioral health, specialty care, translation services, food banks, housing support, and prescription and co-pay assistance programs. Health centers cannot afford to have more manufacturers restrict access to 340B-priced medications. NACHC recommends that CMS consider other enforcement mechanisms, such as the imposition of civil monetary penalties, if manufacturers stop providing 340B pricing.

IV. Request for Information—Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment

Requiring the inclusion of a diagnosis on prescriptions adds an administrative burden to healthcare providers, including prescribers and pharmacists. This practice could slow down the prescription filling process if:

- The pharmacist must clarify missing diagnoses;
- The pharmacist needs to obtain an alternative prescription from the prescribing provider when the original prescription is not for a medically accepted condition; or
- The pharmacist needs to contact payers when point-of-sale billing of claims with medically accepted conditions are not being paid.

We are concerned these issues may lead to delays in patient care and increased workload for healthcare professionals. Health center pharmacists consistently go above and beyond to help their patients, helping enhance patients' health literacy by providing clinical medication management assistance and support for chronic disease management. Unfortunately, pharmacists are not

recognized Federally as providers, and thus, their services are not reimbursed. Especially given the realities of the continued shortage in the healthcare workforce, this additional requirement would be another service they are not reimbursed for and would increase the administrative burden overall.

Thank you for your consideration of these comments. We appreciate CMS' initiative to increase transparency in the Medicaid Drug Rebate Program and hold actors of the drug supply chain accountable. Health centers and their patients rely on access to affordable medications and are supportive of ways to If you have any questions, please contact Vacheria Keys, Director of Policy and Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

A handwritten signature in black ink that reads "Joe Dunn". The signature is written in a cursive, flowing style.

Joe Dunn
Senior Vice President, Public Policy and Research
National Association of Community Health Centers