NATIONAL ASSOCIATION OF Community Health Centers

December 20, 2024

Meena Seshamani, M.D., Ph.D.,
Centers for Medicare & Medicaid Services
Deputy Administrator and Director of the Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10912)

Dear Deputy Administrator Seshamani:

The National Association of Community Health Centers (NACHC) is the leading national membership organization dedicated to promoting Federally Qualified Health Centers (also known as FQHCs or health centers) as the Employer, Provider, and Partner of choice in all communities, as well as the foundation of an equitable health care system, free from disparities.

Community Health Centers are the best, most diverse, most innovative, and most resilient part of our nation's health system. For nearly sixty years, health centers have provided high-quality, comprehensive, affordable primary and preventive care, dental, behavioral health, pharmacy, vision, and other essential health services to America's most vulnerable, medically underserved patients in urban, rural, suburban, frontier, and island communities. Today, health centers serve 1 in 11 people at over 15,000 locations. This includes more than 5 million uninsured people, over 15 million Medicaid patients, over 3 million Medicare patients, and over 1 million patients experiencing homelessness.

In addition to medical services, health centers provide dental, behavioral health, pharmacy services, and other "enabling" or support services that facilitate access to care for individuals and families in medically underserved communities, regardless of insurance status or ability to pay. NACHC maintains its role as the national voice for health centers and believes that high-quality primary health care is essential in creating healthy communities. The collective mission and mandate of NACHC and the 1,487 health centers around the country is to close the primary care gap and provide access to high-quality, cost-effective primary and preventative medical care.

Health centers strive to make medications affordable for all their patients. Because patients aged 65+ are the fastest growing patient population for health centers, we applaud CMS as it implements the Inflation Reduction Act (IRA) provisions to help decrease financial barriers for Medicare patients for prescription drugs and seek to continue partnering with the agency. NACHC, however, remains concerned about how health centers will get access to 340B-priced drugs, especially with the rollout of the Medicare Transaction Facilitator (MTF), and how manufacturers will reconcile differences in the Maximum Fair Price (MFP) and the 340B price. We understand provisions have been finalized via Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. We seek to share reiterate concerns around the burden of participating in the MTF, especially because the MTF Payment Module (PM) does not have mandatory participation and guidance allows manufacturers leeway on how to furnish the MFP price to entities.

NACHC recommends CMS create more flexibility to permit entities to identify 340B drugs through a retroactive process.

We believe most of the data processed through the MTF is reasonable; we further appreciate CMS allowing dispensing entities the option of including a 340B Claims Indicator for the MTF Data Module. 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 is submitted to the payer or at the point of sale. Point-of-sale identification for 340B drugs is difficult because it would require the pharmacy to resubmit claims that were classified incorrectly at the point-of-sale, leading to an increased administrative burden.

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.[1] 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 the health center patients' needs.

We continue to request the ability for health center pharmacies to use both prospective and retrospective claim identification to accommodate all types of pharmacy models, which is currently how a model in Oregon functions, and appreciate CMS' acknowledgement of exploring said model. The state's retroactive 340B claims file process allows 340B covered entities to avoid duplicate discounts when contracting with retail pharmacies to dispense 340B-stocked medications to patients of the covered entity. Retroactively identifying which pharmacy encounter claims were filled with 340B drugs allows those claims to be excluded from the Medicaid Drug Rebate process by the Oregon Health Authority.[2] This clearinghouse model can enhance accurate claims identification while easing provider burden by minimizing disruptions to pharmacy workflow and allowing claim identification after submission, given the difficulty of placing a claims modifier on 340B drugs at the point of sale as mentioned previously.

NACHC continues to harbor significant concerns about health center pharmacies getting retrospective reimbursement (i.e., MFP rebates) and needing to pay a higher price for drugs upfront, given the thin financial margins health centers operate on.

At 40.4, CMS guidance states that manufacturers can provide access to MFP to covered entities in one of two ways: 1. Prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP (Sections 40.4.1 and 90.2 draft guidance), or 2. Retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (section 40.4.3 draft guidance), which includes a 14-day prompt pay window after a verified dispense. Many 340B covered entities, including health centers, operate with a physical inventory. They seek to ensure they have the medications their patients need, highlight any recurring inventory issues, reduce waste, and identify differences between inventory stock and actual stock.[3] Additionally, health centers operate on razor-thin

[1] https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
[2] https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc
[3] https://dclcorp.com/blog/inventory/physical-inventory-count/#:~:text=Physical%20inventory%20counts%20can%20help,help%20to%20improve%20customer%20satisfact

financial margins while serving some of the most vulnerable, lower-income populations. Health center patients are four times more likely to have income at or below the Federal Poverty Level (FPL) and twice as likely to have income under 200% of FPL as compared to the U.S. population. Health center patients are also more than twice as likely to be uninsured as compared to the U.S. population. Around 11% of patients at a health center have Medicare, with over 4% being dually eligible for Medicaid as well.[4] [5] Health centers provide healthcare services to all patients, regardless of their ability to pay, and evaluate patients, both those without insurance and those underinsured, on a sliding fee scale to help lower the cost they pay for services based on family size and income. Furthermore, health center entity-owned and contract pharmacies offer prescription assistance programs to help patients with lower incomes be able to afford their medications. Another example is copay assistance programs, which lower the copay patients see when acquiring their prescriptions at the pharmacy. Health centers put their patients first, stretching their scarce federal resources as far as possible while discounting services to ensure healthcare remains affordable and accessible to all their patients. More than half of community health centers operate with margins below 5%, and 11 million patients were served by health centers operating with negative margins in 2022.[6] These facts show that forcing a rebate model would not be economically or financially feasible for health center pharmacies. All pharmacies, but especially the safety-net 340B covered entities, should have the opportunity to purchase MFP drugs prospectively at their discretion, not at the individual manufacturer's discretion.

NACHC appreciates the opportunity to respond to this information collection request and looks forward to continuing to engage with CMS on this important issue. Health centers are eager to work in concert with CMS to implement provisions of the IRA and provide affordable medications to Medicare patients. If you have any questions, please contact Elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elinderbaum@nachc.org.

Sincerely,

Joe Dunn
Chief Policy Officer

[4] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf
[5] https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=Full&year=2022
[6] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf