NATIONAL ASSOCIATION OF Community Health Centers

May 1, 2025

Chris Klomp
Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Information Collection Request (ICR) for the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912) [ICR: 202503-0938-001]

Submitted via Office of Information and Regulatory Affairs (OIRA) portal.

Dear Deputy Administrator Klomp:

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

Community Health Centers are the best, most innovative, and resilient part of our nation's health system. For nearly sixty years, health centers have provided high-quality, comprehensive, affordable primary and preventive care. In addition to medical services, CHCs provide dental, behavioral health, pharmacy, vision, and other essential health services in communities in urban, rural, suburban, frontier, and island communities. Today, health centers serve more than 32.5 million people at over 16,000 locations, ensuring patients receive the care they need and pay what they can based on a sliding fee scale.

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 and preventing chronic conditions. The collective mission and mandate of NACHC and the 1,496 health centers nationwide 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 the 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 reiterate our concerns around the burden of participating in the MTF, especially because the MTF Payment Module (PM) does not have mandatory participation, and guidance currently allows manufacturers leeway on how to furnish the MFP price to entities. Furthermore, we echo our concern that the mechanism for setting a fair professional dispensing fee (PDF) has not been described in statute, regulation, or guidance. Because the MFP is at the discretion of the Medicare plan payer, the PDF is an added cost that is exempted from the patient's cost-sharing copays. The average Medicare Part D dispensing fee was $0.65 in 20221, well below the $15-18 cost for a health center to dispense a prescription. We have significant concerns about the detrimental economic impact the failure to define the MFP professional dispensing fees will have on all independent pharmacies, particularly those within health centers.

NACHC respectfully requests that CMS pursue regulations setting fair professional dispensing fees, reflecting the cost of dispensing, or add to the Drug Price Negotiation Program Complaint and Dispute Intake Form a section allowing the dispensers to file grievances related to unfairly low PDFs. For over 30 years, the 340B program has been crucial to helping safety net providers like health centers purchase outpatient medications at significantly reduced costs, enabling them to provide affordable discounted or free medications to uninsured and underinsured patients.

By law and policy, health centers are required to invest every penny of 340B savings into activities that expand access to care for their patients. The 340B program generates savings that are reinvested in the health center to meet the unique needs of their communities, such as dental care, behavioral health, specialty care, translation services, food banks, housing support, and copay assistance programs. Health centers rely heavily on contract pharmacies to expand their community reach and provide patients with affordable, accessible medications.

Additionally, health centers operate on razor-thin margins and cannot afford to lose access to 340B-priced medications. NACHC and our health centers support the intent of the IRA as it lowers drug prices. We seek to provide constructive feedback on the effectuation of MTF to ensure health centers' opportunities for participation in the 340B program remain intact and do not unduly burden our pharmacies, particularly contract pharmacies.

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

[1] https://milligram-health.com/insights/2022-02-medicare-part-d-dispensing-fees

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 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 this approach. 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.[3] 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 recurring inventory issues, reduce waste, and identify differences between inventory and actual stock.[4] Additionally, health centers operate on razor-thin 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 than the U.S. population. Health center patients are also more than twice as likely to be uninsured as the U.S. population. Around 11% of patients at a health center have Medicare, with over 4% being

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

dually eligible for Medicaid as well.[5,6] 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 afford their medications. Another example is copay assistance programs, which lower patients' copay 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.[7] 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 respectfully suggests that CMS consider using voluntary claims identifiers for prospectively purchased MFP drugs, e.g. Submission Clarification Code (SSC) or Basis of Cost (BOC) Code. While we recognize that large chain pharmacies or health systems will not likely be interested in participating in this workflow, it is an option that would be desirable to CHCs and independent pharmacies. There are approximately 1,500 CHCs nationwide, with more than half having one or more pharmacies. Over 90% of those pharmacies operate with a physical inventory model and regularly submit the 340B-related submission clarification code 20 where state law requires. CHCs and independent pharmacies are two groups that anticipate having significant financial impacts from the economic changes expected under the MFP rebate structure.

This concern was emphasized in the Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes…, published in the Federal Register on December 10, 2024. "Under the current general PDE submission timeliness requirements, dispensing entities could wait up to approximately six weeks to receive access to the MFP (e.g., 30 calendar days for the Part D sponsor to submit PDE data to the DDPS, plus approximately one to three days for the PDE data to move from DDPS to the MTF to the Primary Manufacturer, plus up to an additional 14 days for the Primary Manufacturer to transmit an MFP refund payment). If the Primary Manufacturer does not prospectively make the MFP available to the dispensing entity, then the lag between when the dispensing entity receives payment from the Part D plan and when the dispensing entity receives the MFP refund payment from the Primary Manufacturer could impose a financial strain on dispensing entities given that anticipated MFP refunds could be a material percent of the dispensing entity's purchase price."[8] Even with the 30 calendar days for the Part D sponsor to submit PDE data to the DDPS being shortened to 7 days, it is still anticipated that the 3-4 weeks in being made whole to the initial purchase price, coupled with the loss of profit margin, and

[5] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf.
[6] https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=Full&year=2022.
[7] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf.
[8] https://www.federalregister.gov/documents/2024/12/10/2024-27939/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare#print

anticipated dispensing fee falling short of the cost of true expense will leave health centers in unintended financial hardships.

The 340B program has been prospectively priced for over 30 years. With the addition of IRA's MFPs, manufacturers are discussing the need for it to move to a rebate if the dispensations are not prospectively identified as 340B. Based on this, it is unlikely to see any manufacturers willing to offer a prospective Maximum Fair Price at the time of purchase if the dispensers did not have a mechanism to identify the claims as such in the MTF. Given that the pharmacies will be serving both Medicare and non-Medicare patients, if manufacturers opt to extend the MFP prospectively, the pharmacies will still be purchasing both inventories. So, it would not be appropriate to make assumptions about what was dispensed, especially considering the 14-day prompt payment expectation.

Large chain pharmacies and health systems have the scale to make the manual workflow of prospectively identifying the MFT claims unnecessary, and the financial reserves to sustain them with the delays in the rebate timing. Health centers and independent pharmacies do not. Smaller, more economically vulnerable dispensers would welcome the opportunity to purchase at MFP, and prospectively identifying the claims would be a welcome option. We fear that not creating the needed voluntary claims identifiers for prospectively purchased MFP drugs will disincentivize manufacturers from considering prospective MFP, especially to mitigate cashflow concerns for dispensing entities. NACHC respectfully asks that CMS consider the creation of an NCPDP clarification code that would allow for the prospective identification of medications purchased at the MFP.

NACHC supported CMS's changes at §423.505 in the CY2025 Physician Fee Schedule regarding Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements. The finalized proposal requires Part D sponsors' network contracts with pharmacies to enroll such pharmacies in the Medicare Drug Price Negotiation Program ("Negotiation Program") and Medicare Transaction Facilitator Data Module ("MTF DM"). However, we remain concerned about the MTF-DM collection of sensitive financial information. Instead of the MTF collecting banking information, as outlined in "Dispensing Entity Financial Information" (Section 3)[9], NACHC recommends that CMS revisit a suggestion on employing existing structures used to issue discounts and rebates. The rebates could be handled through the wholesaler rebate process, like chargeback or credit/rebills already in place with the 340B program. The wholesaler purchases the medication at the full wholesale acquisition cost (WAC) on the front end of the transaction. Depending on the inventory account where a purchase is made, the appropriate pricing is extended by the wholesaler prospectively (in this case, the MFP), and the manufacturer, through the chargeback process, credits the wholesaler the difference between the WAC and MFP. In the chargeback model, the dispensers can purchase prospectively at the MFP. They would not, as the smallest players in the system, bear the financial burden of sustaining the discounts for Medicare until they are made "whole" by a rebate. The credit/rebill process is also well established in the pharmacy industry, allowing a drug sold by a wholesaler on one account to be credited and reassigned to another account, for example, crediting a WAC purchase and reassigning (rebill) as an MFP purchase.

[9] Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form

Additionally, 340B covered entities are used to mass repayment models from manufacturers to covered entity purchasers facilitated by the 340B Prime Vendor. In this instance, the Health Resources and Services Administration (HRSA) requires manufacturers to refund covered entities on all drug overcharges and urges them to work in good faith with covered entities for repayments. HRSA expects repayment procedures to follow similar processes that align with standard business practice and be documented in the manufacturer's policies and procedures.[10] Facilitated by the 340B vendor, these rebates primarily take the form of credits to the wholesaler accounts where the purchases were made or checks sent directly to the entity, neither requiring the housing of entity banking information. On the other hand, a model exists to facilitate entity repayments directly to manufacturers within the 340B program for 340B over-purchases, also facilitated by Apexus.[11] In this, the covered entity's over-purchased amount is paid back to the drug manufacturer, facilitated by Apexus. CMS could consider these well-established processes for reconciling payments to run smoothly between covered entities and manufacturers while simultaneously protecting sensitive banking information from falling prey to bad cyber actors.

NACHC also encourages CMS to clarify and bolster the Negotiation Program Complaints and Disputes process described at 90.2.2 in the final guidance. We recommend implementing accountability measures for manufacturers if they do not pay their rebates to covered entities, like CHCs. Currently, as written, CMS states that manufacturers must pay the difference between MFP and 340B in a "timely manner" but offers no strict timelines or consequences if there is delinquent payment. We implore the agency to detail more clearly how disputes can be resolved and which governmental agency will be responsible for helping adjudicate any complaints related to the rebate process.

As the Administration continues to restructure the Department of Health and Human Services, we request specific guidance about which agency will have enforcement authority responsible for 340B claim verification. The 340B program and federal grantees that participate in the program have been under the oversight of HRSA since the 340B law was enacted in 1992. CMS has not previously had authority over the program. The final guidance states at 40.4.59 (page 231) that "CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim," meaning that the identification of the claims at the pharmacy to CMS is voluntary. The implication of voluntary claims identification is that individual manufacturers could create unique policies on how data is sent to them to differentiate claims. This could be administratively burdensome and confusing to health centers as they need to adhere to different manufacturer policies, and it could hinder the process of getting their rebate if eligible. It is essential that there is one clear, established set of rules as the future number of manufacturers and drugs covered under the IRA grows.

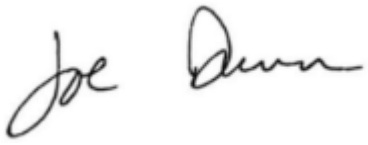
We have seen how varying manufacturer policies have been impacting 340B covered entities, as 37 manufacturers have restricted the distribution of 340B-priced medications to contract pharmacies (and in some recent cases, entity-owned pharmacies off-site), with some only unlocking 340B pricing when claims data are submitted and others not at all. Twenty-four of these restrictions currently impact health centers. Health centers that have chosen to submit data have stated that complying with various manufacturer policies is extremely burdensome and time-

[10] https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions.
[11] https://www.apexus.com/apexus-refund-services/covered-entity-refund-service.

consuming, creating limited success in restoring 340B pricing to contract pharmacies despite their adherence. Additionally, few enforcement mechanisms hold manufacturers accountable for ensuring rebates are given to health centers. For this reason, health centers have concerns about manufacturers appropriately extending both the statutorily required 340B and MFP discounts and rebates. With no agency as a clear arbiter for claims verification in the context of this guidance, this will continue to be difficult for covered entities to navigate. We request guidance from the department on which agency can oversee the 340B program and arbitrate enforcement of 340B claim verifications.

NACHC appreciates the opportunity to respond to this information collection request and looks forward to continuing to engage with CMS on this prominent 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