NATIONAL ASSOCIATION OF Community Health Centers

July 2, 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RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair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

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

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 stand ready to partner with the agency. NACHC, however, has some concerns 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.

For over 30 years, the 340B program has been crucial to help 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 co-pay assistance programs. Health centers heavily rely on contract pharmacies to expand their community reach in providing their patients 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 MFP, however, to ensure health centers' opportunities for participation in the 340B program remains intact and does not unduly burden our pharmacies, in particular contract pharmacies.

A summary of our comments is as follows:

- **NACHC is concerned about the impact of 340B claims identification requirements when an entity purchases MFP priced medications prospectively.**
- **NACHC recommends CMS create more flexibility to permit entities to identify 340B drugs through a retroactive process.**
- **NACHC recommends CMS clarify if Option 2 of the housing of banking information on the MTF would allow the use of well-established processes for the reconciliation of payments, including a credit/rebill model to make covered entities whole and a process like Apexus' "Covered Entity Refund Service" if covered entities are overpaid.**
- **NACHC recommends utilizing field 545-2F in the National Council for Prescription Drug Programs (NCPDP) Adjudication responses to help identify claims that were reimbursed MFP based on the patient's eligibility for Medicare.**
- **NACHC has 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.**
- **NACHC strongly urges that CMS does not permit any other payer besides Medicare to provide MFP pricing.**
- **It is critical for the success of this program that CMS retain and exercise all enforcement authority related to 340B claim verification.**

I. Comments around the Medicare Transaction Facilitator (MTF)

NACHC is concerned about the impact of 340B claims identification requirements when an entity purchases MFP-priced medications prospectively.

The current MTF transmittal seems to be based on the current prescription processing and flow logic, which is beneficial as it does not create an additional burden on the system. Claim information would be pulled from the switch and sent to the planned sponsor, which would then send the Prescription Drug Event data to the MTF to share with the manufacturer for reconciliation and rebate purposes. That said, the model shared does not illustrate the pathway for how it would handle a situation if an entity purchased the medication at the MFP price prospectively; further, it does not factor in the 340B process, which requires claims identifiers to be added on the front end. We request CMS clarify the following concerns:

1. How 340B claim identification would occur during the 14-day window through the MTF process if a health center purchased medications at the MFP price prospectively.

2. Whether there will be services to reconcile these payments or if health center pharmacies/contract pharmacies need to do this internally.

- Pharmacy Services Administrative Organizations (PSAOs) could serve as partners to help facilitate this because nearly every pharmacy will have a central payment, and the PSAO will deposit the money into the health center's bank account.

3. If the MTF will provide contract pharmacies with the rebate directly or if the contract pharmacies have an obligation to share that with the covered entity that they contract with.
    - If a contract pharmacy contracts with multiple covered entities, this could be difficult and confusing to operationalize, especially on smaller, independent pharmacies. Health centers rely heavily on contract pharmacies to expand their service area and enhance patient convenience. Eighty-six percent of health centers utilize contract pharmacies, allowing them to serve hundreds of zip codes.[1] A claim indicator requirement could severely impact a pharmacy's desire to contract with a health center, given the anticipated burden of working with a claims indicator.

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; however, we have concerns about the use of the 340B Claims Indicator. 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.[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 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. 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.

[1] https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf
[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

NACHC recommends CMS clarify if Option 2 of housing banking information on the MTF would allow the use of well-established processes for payment reconciliation, including a credit/rebill model to make covered entities whole and a process like Apexus' "Covered Entity Refund Service" if covered entities are overpaid.

It is essential CMS has a clear process in place for reconciliation payments as the number of drugs and manufacturers grow over time, if a rebate model must be used. While the manufacturer count is limited this year, more and more drugs will be added each year and be subject to negotiation; besides 10 this year, there will be 15 more in 2027, an additional 15 drugs in 2028, and 20 drugs in 2029, with a cumulative total of 60 drugs. While we do not believe a rebate model is in the best interest of health centers, given that health centers operate on financially thin margins, if CMS decides to utilize one of the options for housing banking information on the MTF, we recommend CMS use Option 2 but seek clarification on repayment methods.

Currently, there are already systems in place that health centers use to facilitate payments/rebates related to MFP and 340B pricing. However, current guidance on Option 2 is unclear whether when the MTF receives the aggregated refund amounts from participating primary manufacturers and passes through the refunds to participating dispensing entities, if this involves the collection and housing of new banking information from participating dispensing entities, or if the payments would go through already established payment channels, such as through Pharmacy Benefit Managers/PSAOs or through Apexus, as described in more detail below.

Instead of the MTF collecting banking information, NACHC recommends CMS employ existing structures used to issue discounts and rebates. The rebates could be handled through the wholesaler rebate process, similar to 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 are able to purchase prospectively at the MFP and would not, as the smallest players in the system, have to 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, credit a WAC purchase and reassigning (rebill) as an MFP purchase.

Additionally, 340B covered entities are also used to mass repayment models from manufacturers to covered entity purchasers facilitated by the 340B Prime Vendor, Apexus. In this instance, 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.[4] Facilitated by the 340B Prime 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, with 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.[5] 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 the reconciliation of payments to run smoothly between covered entities and manufacturers while simultaneously protecting sensitive banking information from falling prey to bad cyber actors.

[4] https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions

[5] https://www.apexus.com/apexus-refund-services/covered-entity-refund-service

We are particularly concerned with Option 1, where the MTF collects banking information from participating dispensing entities and provides that information to primary manufacturers electing to receive such information to issue payment to those accounts. We harbor concerns about cyber security and sharing this sensitive information across numerous manufacturers. In 2023 alone, 725 healthcare data breaches were reported to the Department of Health and Human Services (HHS) Office of Civil Rights, which resulted in more than 133 million records being exposed or impermissibly disclosed. This year, a massive cyberattack was launched against Change Healthcare/Optum, subsidiaries of United Health Group, which impacted around 1 in 3 Americans' sensitive health information.[6] This attack has had and continues to have significant repercussions for health centers and our patients; 77% of health centers report that they were negatively impacted by the cybersecurity breach. Over 60% of health centers have patients who were impacted by a delay in access to care due to the inability to obtain prior authorization, service interruption, or going without needed medications. Seventy-two percent of health centers report that access to discounted medication or health care services has been affected, and one in five health centers have had over half of their revenue impacted by the breach. An average of 75% of health center patients have been directly affected by the breach.[7] We are concerned about the MTF's ability to protect this highly sensitive financial information given the realities of cyberattacks against the healthcare sector. Furthermore, as the number of manufacturers participating increases each year, this means an increased number of manufacturers will be accessing this highly sensitive financial information.

NACHC recommends utilizing field 545-2F in the National Council for Prescription Drug Programs (NCPDP) Adjudication responses to help identify claims that were reimbursed MFP based on the patient being an eligible Medicare patient.

The NCPDP develops and promotes healthcare industry standards and business solutions in the drug supply chain through a multi-stakeholder forum that improves patient safety and health outcomes.[8] There is a field in Segment 25, 545-2F, of this NCPDP payer sheet that work in conjunction with the pharmacy software that can tell the dispensing pharmacy who is actually paying the claim and what contract the reimbursement is based on.[9] There would be numerous positives if this or a similar process could be implemented for the MTF:

1. This would allow health center pharmacies to know which claims may need to have a payment rebate from the manufacturer to reduce the actual acquisition cost to the MFP.
2. The pharmacy could then track these claims or have a third party track them to ensure they received the proper retrospective payments.
3. This would also allow contract pharmacies to identify claims for CEs to capture (if 340B price is below MFP) without the contract pharmacy having to share payer information (BIN/GRP/PCN), which could be a massively cumbersome process.

If this was possible with Medicare, a similar setup could help identify Medicaid / Managed Care Organization (MCO) claims as well. If every claim had a response that identified it as being paid by Fee-For-Service/MCO, we could ensure no duplicate discounts occur due to unclear adjudications. If there was something in the NCPDP Response from the payor (Segment 25), the payor could be identified as a Medicaid MCO and then adhere to the proper requirements. This could be done in tandem if a patient modifier, such as N1, could be used. This could help with retrospective claim identification. However, in 2019, NCPDP convened a report that stated there was not a necessity for 340B batch processing.[10] NACHC

[6] https://energycommerce.house.gov/posts/what-we-learned-change-healthcare-cyber-attack
[7] https://www.nachc.org/wp-content/uploads/2024/04/NACHC-Change-Healthcare-Cybersecurity-Breach.pdf
[8] https://www.ncpdp.org/Who-We-Are.aspx
[9] See Appendix 1 and 2 for more details at the end of this comment letter.
[10] https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf

suggests CMS ask NCPDP to create a 340B batch processing opportunity where covered entities, like health centers, could voluntarily retrospectively identify these claims.

II. Access to the MFP

NACHC has 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.[11] 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 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.[12, 13]

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.[14] 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 is also concerned about promptness of payment if health centers are paid retrospectively, which gives manufacturers 14 days to pay after a dispense is verified. Realistically, it will take much longer than 14 days for the health center pharmacy to receive any type of payment. When adding in the 30-day window

[11] https://dclcorp.com/blog/inventory/physical-inventory-count/#:~:text=Physical%20inventory%20counts%20can%20help,help%20to%20improve%20customer%20satisfaction.
[12] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf
[13] https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=Full&year=2022
[14] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf

for plan sponsor claim submission, it could be a total of 44 days before the pharmacy gets that rebate payment. As previously mentioned, it would be extremely difficult for pharmacies, both entity-owned and contracted, to continue to keep operations afloat, given the tight financial margins they operate within. We recommend CMS decrease the 30-day window for plan sponsors to submit claims to ensure safety net providers like health centers are not negatively impacted by delayed payments.

We encourage CMS to permit entity-owned pharmacies to have the option to buy drugs at MFP price prospectively from all manufacturers subject to negotiated prices. Health center pharmacies currently operate with physical inventory models for the 340B Program. Additionally, if a health center has a closed-door entity-owned pharmacy, then nearly all the drugs dispensed are 340B-eligible. Having the option to purchase at the MFP price in advance of dispensing and then being able to pass the cost directly along to Medicare, instead of purchasing at a higher price and operating at a loss until if and when a rebate is received, would be more financially viable for health centers serving our nation's most vulnerable populations. This model would also help alleviate the administrative burden on the health center from needing to track the receipt of MFP rebates from multiple manufacturers on what could become a daily basis.

NACHC strongly urges that CMS does not permit any other payer besides Medicare to provide MFP pricing.

Referencing language on page 37, Section 40.4,[15] NACHC is concerned about what this language construes because the manufacturers are only obligated to provide the MFP when the individual claim is eligible under specific Medicare plans and payment structures, as defined in the guidance. Pharmacies and health systems do not have a mechanism to compel manufacturers to provide the MFP pricing when they are filling prescriptions for commercial payers or Medicaid. However, the guidance could be interpreted as that they may be able to dispense medications at these rates to non-Medicare patients. The scope of the IRA is intended for Medicare patients; however, if CMS believes the MFP can extend beyond the Medicare patient population, the health centers should be able to use MFP drugs for their non-Medicare patients as well. We request CMS clarify which payers, if any, can provide MFP pricing.

III. CMS is Not Responsible for 340B

It is critical for the success of this program that CMS retain and exercise all enforcement authority related to 340B claim verification.

This guidance states at 40.4.2 (page 49) 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 now voluntary. This statement is further bolstered by the voluntary claims indicator section. 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 extremely administratively burdensome and confusing to health centers to adhere to different manufacturer policies, and overall 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.

[15] "CMS reiterates that section 1193(a)(1)(A) of the Act places the obligation on the Primary Manufacturer to ensure that the MFP is made available to pharmacies, mail order services, and other dispensing entities that dispense the selected drug to MFP-eligible individuals. The Primary Manufacturer is also obligated to ensure that the MFP is available for units of the selected drug that are marketed and sold by a Secondary Manufacturer(s). Commercial and other payers continue to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies."

We have seen how varying manufacturer policies have been impacting 340B covered entities, as 36 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. Sixteen of these restrictions currently impact health centers. Numerous health centers that have chosen to submit data relay that having to comply with manufacturers' various policies, it is extremely burdensome, and time consuming, creating limited success in restoring 340B-pricing to contract pharmacies, despite their adherence. Additionally, there seems to be little enforcement mechanisms holding manufacturers accountable for ensuring rebates are given to health centers. It is for this reason that health centers have concerns about manufacturers appropriately extending both the statutorily required 340B and MFP discounts/rebates. With no agency as a clear arbiter for claims verification in the context of this guidance, this will be difficult for covered entities to navigate.

As CMS looks to clarify and bolster the Negotiation Program Complaints and Disputes process described at 90.2.2 in the guidance, we recommend the implementation of accountability measures for manufacturers if they do not pay covered entities, like health centers, their rebate. Currently as written, CMS states that manufacturers have to pay difference between MFP and 340B in a "timely manner" but offers no strict timelines or any consequences if there is delinquent payment. We understand that CMS is still looking at any limits on to what extent the agency can help facilitate private transactional disputes between manufacturers and covered entities; however, 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.

NACHC appreciates the opportunity to comment on this draft guidance 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 Vacheria Keys, Associate Vice President of Policy & Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

Joe Dunn
Senior Vice President of Public Policy and Advocacy

Appendix 1: NCPDP Payer Sheet

	Response Insurance Segment Segment Identification (111-AM) = "25"			**Claim Billing/Claim Rebill Accepted/Rejected**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
301-C1	GROUP ID			*Imp Guide:* Required if needed to identify the actual cardholder or employer group, to identify appropriate group number, when available. Required to identify the actual group that was used when multiple group coverages exist. *Payer Requirement:* (any unique payer requirement(s))
524-FO	PLAN ID			*Imp Guide:* Required if needed to identify the actual plan parameters, benefit or coverage criteria, when available. Required to identify the actual plan ID that was used when multiple group coverages exist. Required if needed to contain the actual plan ID if unknown to the receiver. *Payer Requirement:* (any unique payer requirement(s))
545-2F	NETWORK REIMBURSEMENT ID			*Imp Guide:* Required if needed to identify the network for the covered member. Required if needed to identify the actual Network Reimbursement ID, when applicable and/or available. Required to identify the actual Network Reimbursement ID that was used when multiple Network Reimbursement IDs exist. *Payer Requirement:* (any unique payer requirement(s))
568-J7	PAYER ID QUALIFIER			*Imp Guide:* Required if Payer ID (569-J8) is used. *Payer Requirement:* (any unique payer requirement(s))
569-J8	PAYER ID			*Imp Guide:* Required to identify the ID of the payer responding. *Payer Requirement:* (any unique payer requirement(s))

Appendix 2: Pharmacy Software Response