Topic 1: Streamline Regulatory Requirements

1A. Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined without compromising patient safety or the integrity of the Medicare program? (10,000 character limit)

Community Health Centers (CHCs) are the best, most innovative, and resilient part of our nation's health system. Health centers have provided high-quality, comprehensive, affordable primary and preventive care for nearly sixty years. In addition to medical services, CHCs provide dental, behavioral health, pharmacy, vision, and other essential health services to America's most vulnerable, medically underserved 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.

Over the past decade, the number of health center Medicare patients has increased significantly, from 1.5 million in 2010 to over 3.3 million in 2023. Medicaid patients currently comprise 11% of the patient's health centers serve.[1] Health centers play an integral role in helping lower out-of-pocket costs for Medicare patients. Costs for health center Medicare patients ($2,370) are 10% lower than physician office patients ($2,667) and 30% lower than outpatient clinics.[2] This could be attributed to the health center model of care that strives to provide Medicare patients with affordable and high-quality care.

Telehealth: CHCs serve as the primary care home for 10 million rural patients at 6,500 locations in rural and frontier communities. Since 2020, telehealth has played a crucial role in maintaining access to care, allowing health center patients to receive timely medical services remotely, reducing barriers and improving healthcare access for rural populations. NACHC urges CMS to make general supervision via telehealth services permanent for CHCs. Continuing to allow virtual supervision for "incident to" services will help health centers better optimize staff, enhance communication, and reduce provider burden, which in turn will benefit patient care.

In a NACHC survey, data revealed that health centers are facing a severe workforce crisis, with nearly two-thirds experiencing staff turnover rates of 5-25% in 2022.[3] Making virtual supervision permanent for "incident to" services will offer needed relief to providers while also helping enhance healthcare access, especially in medically underserved, rural areas where many health centers are located. NACHC strongly supports these advancements, which enable health centers to expand access to care for the over 32.5 million patients they currently serve and address critical workforce challenges.[4]

NACHC supports CMS revising the regulatory requirement that a CHC medical visit must be a face-to-face encounter between a beneficiary and a CHC practitioner, also to include encounters furnished through interactive, real-time, audio, and video telecommunications technology. Amending the definition of a "medical visit" will eliminate confusion and billing complexities for CHCs and be an easy regulatory lift for CMS. Amending the definition of a "medical visit" creates parity with the revised definition of mental health visits, updated at § 405.2463 b(3) in the CY2023 PFS Final Rule. We also support ensuring the definition of a medical visit allows for audio-only capabilities and suggest CMS use the below definition for § 405.2463, paragraph (b)(1) to define a medical visit:

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[1] https://data.hrsa.gov/tools/data-reporting/program-data/national
[2] https://data.hrsa.gov/tools/data-reporting/program-data/national
[3] https://www.nachc.org/wp-content/uploads/2022/03/NACHC-2022-Workforce-Survey-Full-Report-1.pdf
[4]https://data.hrsa.gov/tools/data-reporting/program-data/national

> "as a face-to-face encounter or encounter where services are furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of or do not consent to, the use of devices that permit a two-way audio/video interaction for the purposes of diagnosis, evaluation or treatment of services under (b)(2)."

CHCs receive approximately $96 for telehealth medical services that generate the same costs related to workforce and technology. In 2023, 98.3% of health centers reported using telehealth or telemedicine to deliver comprehensive primary care (96%), mental health (92%), chronic conditions management (61%), substance use disorder (58%), and nutrition and dietary counseling services (35%).[5] Being able to bill PPS for telehealth medical visits will bolster financial stability, improve cash flow, and ensure fairer compensation for these essential services. By simplifying the billing process, health centers can expand telehealth access to underserved populations. NACHC strongly supports amending the definition of a medical visit, which would help provide more congruent payment for telehealth visits, whether medical or behavioral health visits.

Finally, NACHC recommends that CMS adopt the new AMA CPT codes for office-based E/M services furnished via telehealth, replacing in-person E/M codes (99202–99215) with modifiers. Many Medicare Advantage, Medicaid, and commercial payers inconsistently adopt different office visit telehealth code sets, leading to billing confusion and frequent denials. Adopting the AMA codes would ensure a unified national code set, reduce administrative waste, and simplify education, coding, and claims processing across payer types. A standardized national code set would improve claims accuracy, auditability, and the ability to monitor service utilization consistently across systems, reducing the risk of fraud and abuse.

1B. Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers? (10,000 character limit)

Updating the CHC PPS: Health centers consistently operate on razor-thin financial margins while serving some of the most vulnerable, low-income populations. CHC patients are four times more likely to have incomes 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 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 dually eligible for Medicaid. Health centers provide healthcare services to all patients, regardless of their ability to pay, and evaluate uninsured and underinsured patients on a sliding fee scale to help lower the cost they pay for services based on family size and income.

NACHC urges the Administration to ensure that patients at health centers have the same access to services as other Medicare patients. Under Section 10501 of the Affordable Care Act, Medicare payments to health centers were changed to use a Prospective Payment System (PPS). This system created an alternative to the Physician Fee Schedule (PFS) and created a single, bundled rate to cover the costs of all the services and supplies in a single visit. The FQHC PPS rate was created to be a consistent and predictable reimbursement so that CHCs can appropriately fill gaps with Section 330 grant funds. However, health centers face several challenges, such as a limited set of billing codes, underpayment for certain services, and regulatory hurdles that make it difficult to get reimbursed for critical care within Medicare. Given that health centers serve as comprehensive, affordable care and health homes for Medicare patients, we urge CMS to ensure that CHCs are adequately reimbursed for the quality care they deliver.

[5] 2023 Uniform Data System, Bureau of Primary Healthcare, HRSA, DHHS.

In accordance with Section 1834(o)(1)(A) and 1834(o)(2)(C) of the Social Security Act, CMS established specific payment codes that CHCs must use when submitting a claim for CHC services for payment under the CHC PPS. CHCs must also report detailed HCPCS coding for all services provided during an encounter. They must identify the qualifying visit (typically a face-to-face encounter with a core provider type) and include line-item charges for all services rendered. This documentation supports the encounter-based payment system under the CHC PPS. This requirement does add administrative complexity for CHC providers and staff, who must ensure proper coding and compliance with Medicare billing practices. Unfortunately, the current manual has not been updated since December 2017, meaning many of the payment codes and qualifying visit lists are outdated and no longer reflect the full extent of services provided by CHCs to their Medicare patients.[6]

NACHC has consistently advocated for CHCs to be eligible for new codes and reimbursement opportunities, including those introduced in the annual Physician Fee Schedule (PFS) updates. Historically, some new codes and services, like certain telehealth or behavioral health services, have not automatically included CHCs, creating a financial burden on health centers that are not properly reimbursed for these essential health services. Health centers already have a sliding fee scale that helps make patient services more affordable. Health center patients deserve access to affordable services available at a sliding fee discount. We encourage CMS to align CHC billing codes with PFS to ensure health centers are reimbursed for the same services without incurring additional costs to serve their patients.

Specifically, NACHC recommends CMS update the PPS "qualifying visit list" (G0466 and G0467) for new and established patients, respectively, to avoid unnecessarily complex billing, loss of reimbursement, and provider confusion that can lead to unintentional errors. As it has remained unchanged since 2017, newer services that CMS has approved in the broader Physician Fee Schedule should be included. Certain behavioral health, telehealth, and procedure-only visits, especially when these services are clinically appropriate and independently billable in other settings, should be included in the qualifying visit list. This would solve the billing complexity for CHCs that do not exist for other providers. In addition, this update would provide appropriate reimbursement opportunities for services already being provided by CHCs. For example, Transitional Care Management (TCM), personalized and supportive services provided to patients who are being discharged from an inpatient hospital setting to a community setting, should be billable for both new patients and existing patients. However, there is only a billable code for existing patients and not new patients, leading to confusion on how CHCs should bill Medicare for TCM for new patients when it should be reimbursable.

Community health centers expend valuable resources to ensure compliance with all documentation and reporting requirements, including those for Medicare. Resources are sometimes spent to ensure compliance with complex or redundant requirements that do not improve patient outcomes or cost savings. Health centers should use their capacity and resources to meet patient demand and ensure the delivery of timely and quality services. We urge CMS to review duplicate requirements that, unfortunately, redirect limited CHC resources away from patient care.

Additionally, NACHC encourages CMS to consider the burdens CHCs face in meeting the behavioral health needs of Medicare patients. Health centers provided care to over 3.2 million patients with behavioral healthcare needs in 2023. While CHCs are not required to provide behavioral health services under the HRSA Health Center program, 98% of health centers provide some form of that service. Health centers may offer comprehensive individual or group counseling, intensive outpatient services, addiction and recovery services, Medication-Assisted Treatment (MAT), school-based therapy, or crisis services. Behavioral health providers work to integrate these services with the CHC care team to ensure patients can

[6] https://www.cms.gov/medicare/medicare-fee-for-service-payment/fqhcpps/downloads/fqhc-pps-specific-payment-codes.pdf

access both behavioral health and primary care in a comprehensive one-stop shop. The number of CHC behavioral health providers continues to rise, from 17,930 FTEs in 2021 to 21,179 FTEs in 2023.[7] Unfortunately, health centers face several barriers to creating integrated behavioral healthcare teams, including workforce shortages, low and inflexible reimbursement structures, a lack of telehealth flexibility, and the administrative burden and barriers associated with training staff.

NACHC has continuously advocated for policies to support health centers' ability to fully integrate behavioral health services within the primary care setting. We continue to encourage CMS to amend the definition of a medical visit at § 405.2463(b)(1), which would help provide more congruent payment for telehealth visits, whether medical or behavioral health visits. Medicare currently reimburses CHCs for telehealth services at less than half the in-person rate for most visits. By aligning these services with the PFS, CHCs will be able to bill PPS for these visits, bolstering financial stability, improving cash flow, and ensuring fairer compensation for integrated care services. By simplifying the billing process and increasing revenue, health centers can expand behavioral health access to underserved populations.

By updating the health center PPS, aligning it with the Medicare Physician Fee Schedule, and improving the qualifying visit list, CHCs can be fully reimbursed for the low-cost, high-quality care they provide to Medicare beneficiaries. CMS should continue supporting CHCs as positive and responsible actors in the system and adequately reimburse them for their services.

Payments by Medicare Administrative Contractors (MACs): NACHC urges CMS to streamline guidance for providers and Medicare Administrative Contractors (MACs) to ensure health centers receive timely wrap-around payments. This would reduce the administrative burden, claims processing delays, and fraud and abuse concerns within the Medicare program. Per 42 CFR 422.316, health centers must be made "whole" by Medicare through supplemental payments to cover the difference, if any, between the payment received by the CHC for treating Medicare Advantage (MA) enrollees and the payment to which the health center is entitled.[8] The intent behind the statute involving wrap-around payments for CHCs is to ensure that they are paid for services that MA patients are entitled to receive. However, we have heard several concerns about MACs processing health center payments. CHCs have reported having to submit separate claims to MACs for medical and behavioral health services, which they would typically put on a single claim for the payment to be processed.

Additionally, many MACs are not transparent about their preferred process for wrap payments, and there is no uniform guidance for health centers and MACs to rely on. These complications surrounding timely wrap-around payments further increase existing financial challenges faced by CHCs, as well as burdening their staff with additional administrative work. Therefore, we encourage CMS to address these issues affecting CHCs by ensuring timely wrap-around payments by MACs.

1C. Are there specific Medicare administrative processes, quality, or data reporting requirements, that could be automated or simplified to reduce the administrative burden on facilities and other providers? (10,000 character limit)

Cost reporting: NACHC recommends CMS streamline the Medicare cost reporting process for health centers by simplifying the CMS-224-14 form and eliminating redundant data fields. While cost reports are essential for ensuring accurate Medicare reimbursement, the process places a significant administrative burden on health centers. Form CMS-224-14 for CHCs requires extensive documentation of allowable costs, visit counts, allocation methods, and compliance with various regulations. Preparing this report demands significant time, expertise, and attention to detail, often necessitating dedicated finance staff or external

[7] https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/state-of-the-behavioral-health-workforce-report-2024.pdf
[8] 42 U.S.C. §1395w-23(a)(4)(A)

consultants. Compiling and reconciling financial, clinical, and operational data across departments to complete the cost report is also a time-intensive, administratively burdensome process.

Additionally, the interpretation of cost reporting rules can vary between Medicare Administrative Contractors (MACs), leading to inconsistent audits, delays in settlement, or disputes that take time to resolve. Health centers already operate on razor-thin financial margins. Any errors in cost reports can lead to delays in reimbursement, audits, or financial penalties, which can delay payments and ultimately disrupt cash flow and service delivery. We would support an alternative process, such as full cost reporting every 5 years and allowing CHCs to perform a more skeletal cost reporting in between. Simplifying the cost reporting process would allow health centers to focus on delivering high-quality, cost-effective while streamlining Medicare cost reporting practices to ensure compliance and enhance efficiency.

Topic 2: Opportunities to Reduce Burden of Reporting and Documentation

2A. What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity? (10,000 character limit)

For decades, CHCs have been the leading example of good stewards of federal grant funding. Serving over 3.4 million Medicare patients a year, health centers are committed to working closely with Medicare to ensure every dollar is used to increase access to quality services. This includes compliance with the Medicare reporting and documentation requirements. Community health centers use their limited resources to hire staff and deploy software and data systems to remain in compliance. While NACHC supports these standards to ensure program integrity, we also believe there is room to simplify some of the requirements.

NACHC urges CMS to ensure the Medicare PPS bundle includes and reimburses all appropriate services. This will improve efficiency and streamline Medicare reimbursement for CHCs without reducing the quality of care or risking program integrity. For example, billing G-codes outside of the Medicare PPS rate has become more widely used and complicated, as the Medicare PPS bundle definition does not have any provisions for scope changes. CHCs are billing for telehealth and care management services when they could be included under the Medicare PPS bundle, increasing the administrative burden in the reimbursement process. Additionally, the auditing required for unbundled services is complicated. We request CMS clarify what is included in the bundle versus what should be billed separately.

2B. Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers? (10,000 character limit)

NACHC recommends that CMS evaluate the administrative burden of provider enrollment requirements. Health centers have shared concerns that Medicare provider enrollment can be cumbersome and add complexity to already burdened providers in an already resource-constrained environment. Small hurdles like having the same address on the Medicare provider enrollment form and HRSA forms can suddenly act as a roadblock for providers in getting paid for their services. The 2025 Medicare provider enrollment fee of $730 can be expensive for health centers already working on thin margins. Depending on the state, health centers may need to receive Medicaid site approval before they are able to receive Medicare provider status. CMS should streamline Medicare provider enrollment requirements to ensure the process is robust yet accessible for providers.

2C. Are there documentation or reporting requirements within the Medicare program that are overly complex or redundant? If so, which ones? Please provide the specific Office of Management and Budget (OMB) Control Number or CMS form number. (Note: The OMB Control Number consists of two groups of four digits joined by a hyphen and it generally appears on the top right of the first page of a Medicare form and the CMS form number generally appears on the bottom left of the page of a Medicare form.) (10,000 character limit)

N/A

Topic 3: Identification of Duplicative Requirements

3A. Which specific Medicare requirements or processes do you consider duplicative, either within the program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)? (10,000 character limit)

Duals: Health centers are key partners in supporting dually eligible Medicare and Medicaid individuals. However, the lack of alignment between Medicare and Medicaid often penalizes health centers and undermines a patient's access to cost-effective and comprehensive patient-centered care and services. In 2017, health centers served 1.03 million dually eligible patients, growing to 1.35 million in 2023.[9] As health centers adapt to meet the needs of the populations they serve, they are uniquely positioned to offer targeted programs and services that help prevent costly conditions such as End-Stage Renal Disease, heart disease, diabetes, and obesity. Given that the dual eligible population includes intense users of health services that can be more costly than other populations, efforts to integrate care must focus on innovative clinical models and streamline administrative processes to reduce service fragmentation.

CHCs have experience coordinating between public and privately funded care management and care coordination services for this population. Health centers provide each patient with an individual assessment to determine their eligibility for health insurance, striving to connect medically complex and underserved patients with the most affordable and comprehensive coverage they qualify for. One member ID card for a patient enrolled in a Medicare and a Medicaid managed care plan would reduce the administrative burden on health centers when checking coverage and potential out-of-pocket costs. This upfront clarity supports health centers in managing their care plans for these patients, will help improve patient outcomes, and could reduce overall healthcare spending.

With the growing shift towards keeping individuals in their homes and communities as they age and receive care, health centers are critical healthcare providers to meet the growing demand to serve more dually eligible patients. All efforts to address the inconsistencies between both programs for dually eligible beneficiaries will help ensure the timeliness of care, ultimately improving health outcomes and reducing administrative costs.

Requirements for CHC Participation in ACOs: Health centers use a standardized reporting system known as the HRSA Uniform Data System (UDS) that captures a core set of data that includes patient characteristics, services provided, clinical processes and health outcomes, patients' use of services, staffing, costs, and revenues. This data set does not always align with quality metrics often used by CMS' value-based payment models. The promotion of interoperability between HRSA and CMS reporting processes would greatly improve health center participation by decreasing the data reporting burden and ensuring that patient outcomes are correctly attributed to the health center where these patients get their primary care services.

While the number of Medicare patients in health centers is rapidly growing, they currently represent a smaller portion of the overall Medicare population. This ultimately creates a barrier to meeting the minimum Medicare participation requirements in many value-based models, resulting in health centers often being unable to participate in CMS' alternative payment models.[10] Health centers need transparent, continuous, and accurate attribution numbers and a simple methodology to enter value-based care

[9] https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=4&year=2023

[10] e F et al. If Medicare builds it, can CHCs come? Medical Care. American Public Health Association. 2023. https://www.themedicalcareblog.com/CHCs-medicare-primary-care-model/.

arrangements. CMS and payers need to share this information, which should include how patients are transferred into and out of a provider's attributed population.

Alignment of Attribution Models: NACHC urges CMS to align patient attribution requirements and processes among the same payer and work with other agencies, such as CMMI, to see where patient attribution strategies can be better streamlined across payers. Patient attribution helps identify the healthcare relationship between the patient and provider. Successful patient attribution is a key component to helping achieve success in value-based care (VBC) arrangements.[11] CMS has strongly encouraged healthcare providers, including CHCs, to increase their participation in these arrangements. In partnership with their state PCAs and Health Center Controlled Networks (HCCNs), health centers across the country have already been actively engaged in Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program (MSSP). In 2021, 15 states had CHCs that led ACOs.[12] Some health centers participating in these VBC arrangements have reported issues with the patient attribution system. If not correctly attributed, this places an undue administrative burden on providers who cannot access crucial data for their patients, such as prior authorization data, ultimately hurting the patient's access to care. Furthermore, incorrect attribution can hurt overall care coordination efforts and the health center's ability to maintain VBC arrangements.

We have heard from health centers that it is challenging to track patients, given the existing limitations of accessing updated Medicare Advantage (MA) patient attribution panels. Furthermore, many patients are automatically attributed to a specific CHC when their primary care provider is at another facility. This auto attribution has a negative impact because the CHC is responsible for a patient they are not providing care to, and the system provides the CHC with limited options to remove that patient from their panel. Incorrect attribution does not accurately reflect the patient's care, which impacts the CHC's financial success when participating in VBC arrangements.

Additionally, incorrect attribution can make it difficult for CHC to successfully target patients to schedule their Annual Wellness Visits (AWVs). AWVs are a vital opportunity for patients and their providers to discuss preventive strategies collaboratively and for the provider to recommend clinical preventive services, leading to the identification of diagnoses.[13] These can help improve patient health as well as establish and develop a deeper, trusted relationship with their provider. Health centers have stressed the need for a timelier way to accurately identify eligible patients on their rosters for AWVs. While they are switching to newer technologies in many elements of their practices, health centers currently rely on outdated payor reporting. We request that CMS require Medicare plans to allow providers, like health centers, access to updated patient attribution lists via the plan's portal. Access to a Medicare portal would allow them to verify the eligibility of the entire attribution list, which would help improve their efforts in identifying and reaching out to patients to schedule their AWV, a crucial component of overall care. The linkage between patient attribution and provider care creates better alignment between providers and plans, reduces the administrative burden on both entities, streamlines payer-provider coordination, and improves patient outcomes.

Consolidation of Overlapping Medicare Value-Based Care Models: Currently, CHCs are responsible for submitting overlapping quality data to multiple payers, and often reporting the same data in different formats, through different portals, and on different timelines. CMS should conduct a comprehensive review of its current portfolio of value-based care (VBC) initiatives—including ACOs, PCMHs, MIPS Value Pathways, Innovation Center models, bundled payment programs, and advanced primary care models. Many of these models pursue similar goals (cost control and improved quality) and focus on the same

[11] https://www.soa.org/493462/globalassets/assets/files/resources/research-report/2018/patient-attribution.pdf
[12] NACHC 2021 PCA Policy Survey Assessment
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8455445/.

beneficiaries and conditions, yet they differ in design, reporting, and payment mechanics. This proliferation creates unnecessary complexity, particularly for safety-net providers like CHCs, who must assess eligibility, track participation, and report performance across multiple, partially redundant initiatives. CMS should explore opportunities to consolidate, align, or sunset overlapping programs and standardize core value-based care components (e.g., risk adjustment, attribution, quality measures) to create a unified national framework. By streamlining the value-based care landscape, CMS can improve program transparency and ensure that fraud prevention and oversight resources are concentrated on meaningful system reform.

3B. How can cross-agency collaboration be enhanced to reduce duplicative efforts in auditing, reporting, or compliance monitoring? (10,000 character limit)

NACHC urges CMS to collaborate with HRSA to simplify the Medicare site registration process for health centers under § 424.510, as part of the new Administration for a Healthy America. The current process is overly complex, with inconsistent requirements across states and Medicare Administrative Contractors (MACs), creating significant administrative and financial burdens for health centers. To open a new Medicare site, health centers must navigate both CMS and HRSA requirements and fulfill specific state and MAC requirements. As responsible stewards of the Medicare program, NACHC supports a streamlined application and registration process to help health centers expand access to high-quality, affordable care for Medicare beneficiaries.

3C. How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems? (10,000 character limit)

Duals: NACHC requests CMS clarify regulatory language requiring integrated care plans to include CHCs in their provider network. As the population ages, health centers care for more seniors and dual-eligible patients. Over the past five years, the number of health center Medicare patients has increased by 21%, and the number of dual-eligible patients has increased by 20%. In 2023, dual eligibles accounted for about 4.2% of the entire health center patient population, up from 3.77% in 2019.[14] Health centers' unique model of integrated primary care has a successful track record of managing chronic conditions for vulnerable populations, improving patient outcomes, and saving taxpayer money. Health centers' model of providing integrated care and wrap-around services makes them uniquely effective at serving vulnerable populations. Allowing states to carve out CHCs from the integrated plan's network could disrupt the continuity of care for current duals and limit access to care in underserved communities as the dual eligible population ages.

Additionally, we urge CMS to include language clarifying that the new integrated care plan should not pay less than the FQHC Prospective Payment System (PPS). Congress created the PPS in Medicare and Medicaid in recognition of the critical role health centers play in caring for underserved communities and the value they deliver to these federal insurance programs. The PPS is essential to ensure predictability and stability for health centers while protecting the value of other federal investments.

Topic 4: Additional Recommendations

4A. We welcome any other suggestions or recommendations for deregulating or reducing the administrative burden on healthcare providers and suppliers that participate in the Medicare program. (10,000 character limit)

Medicare Drug Price Negotiations: NACHC continues to voice our concerns about how health centers will access 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. Health

[14] HRSA, UDS Data, 2023.

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. 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 remain concerned about the administrative and financial burden to CHCs as guidance currently allows manufacturers leeway on how to furnish the MFP price to entities.

Additionally, NACHC respectfully requests that CMS pursue regulations setting fair professional dispensing fees (PDFs), reflecting the cost of dispensing, or adding to the Drug Price Negotiation Program Complaint and Dispute Intake Form a section allowing the dispensers to file grievances related to unfairly low PDFs. 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 2022, well below the $15-18 cost for a health center to dispense a prescription. We have significant concerns about the detrimental economic impact of the failure to define the MFP professional dispensing fees on all independent pharmacies, particularly those within health centers.

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. Health centers operate on razor-thin margins and cannot afford to lose access to 340B-priced medications.

NACHC requests that 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 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.

NACHC also requests that CMS create regulatory guidance that allows 340B entities the opportunity to purchase MFP drugs prospectively at their discretion, not at the individual manufacturer's discretion. 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 of the final guidance, 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 final guidance), or
2. Retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (section 40.4.3 final 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.[15] Additionally, health centers operate on razor-thin financial margins while serving many.[16] Health centers provide healthcare services to all patients, regardless of their ability to pay, and evaluate uninsured and underinsured patients 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 contracted pharmacies offer prescription assistance programs to help patients with lower incomes afford their medications. Another example of how health centers seek to keep services and prescriptions affordable is copay assistance programs, which lower patients' copay 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.[17] 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.

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-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 are concerned about manufacturers appropriately extending 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 how CMS will arbitrate the enforcement of 340B claim verifications, given the movement of 340B under the agency.

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