

September 9, 2024

Centers for Medicare & Medicaid Services Department of Health and Human Services **Attention: (CMS-1807-P)** P.O. Box 8016 Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

To Whom It May Concern:

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 10 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, FQHCs 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 1,496 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.

The number of health center Medicare patients has increased significantly over the past ten years, from 1.5 million in 2010 to over 3.3 million in 2023, currently making up 11% of the patients health centers serve¹. The number of health center Medicare patients has increased significantly over the past ten years, from 1.5 million in 2010 to over 3.3 million in 2023, currently making up 11% of the patients health centers serve. 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.

¹ National Health Center Program Uniform Data System (UDS) Awardee Data (hrsa.gov)

² National Health Center Program Uniform Data System (UDS) Awardee Data (hrsa.gov)

NACHC supports CMS' proposals to expand coverage and billing of Medicare services to better serve our patients. We greatly appreciate CMS' efforts to expand access to care with a health equity lens and the agency's intentional approach to proactively include health centers in their innovative proposals to address ongoing challenges for safety-net providers and underserved patients.

NACHC welcomes the opportunity to provide comments on the proposed NPRM. In brief, we appreciate CMS considering the following proposals below:

- NACHC supports the unbundling of the G0511 code and urges CMS to establish adequate reimbursement rates to ensure health centers' continued financial viability.
- NACHC requests that CMS provide additional resources and support to help health centers transition to the new billing method and meet the increased documentation requirements when billing for individual general care management codes previously included in G0511
- As CMS calculates the reimbursement rates for all these different general care management services, we implore CMS to ensure payment rates accurately reflect the cost of these services.
- NACHC generally supports the proposed Advanced Primary Care Management Services code bundle, but health centers may be unable to bill APCM services due to the performance measurement requirements for providers.
- NACHC seeks clarification on whether participation in the ACO Primary Care Flex Model could meet the performance measurement requirement to bill for APCM.
- NACHC is concerned about the proposed reimbursement for GPCM1, GPCM2, and GPMC3, which is \$10, \$50, and \$110, respectively.
- While NACHC supports obtaining patient consent for APCM services, we are concerned about the burden a monthly cost-sharing responsibility will have on health center patients.
- NACHC recommends CMS allow a co-insurance waiver for health center patients who consent to using APCM services.
- NACHC applauds CMS' proposal to amend regulations § 405.2415 and § 405.2452 to continue allowing direct supervision through either physical presence or continuous real-time virtual interaction until December 31, 2025.
- NACHC supports CMS revising the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face encounter between a beneficiary and an RHC or FQHC practitioner also to include encounters furnished through interactive, real-time, audio and video telecommunications technology.
- NACHC supports delaying the in-person mental health visit requirement for telehealth mental health services furnished to Medicare beneficiaries via telehealth by RHCs and FQHCs until January 1, 2026.
- NACHC supports CMS' proposal to add a payment rate for FQHCs and RHCs for days with four or more services and appreciates CMS restructuring regulatory language at § 405.2410(c) to ensure correct policy application for beneficiary coinsurance.
- NACHC supports the proposal to allow health centers to bill for the vaccine and administration of Part B preventive vaccines at the time of service, for dates of service beginning on or after July 1, 2025.
- We recommend CMS keep in mind when releasing cost reporting instructions on this process that interim payments received at the time of service be reconciled to the health centers' reasonable costs during the Cost Reporting process.
- NACHC recommends that health centers should be permitted to bill for vaccine counseling under the Physician Fee Schedule (PFS). Health centers have reported investing time to educating patients about the importance of vaccines, which takes additional time with the Medicare population.
- We also recommend CMS allow for "immunization only visits" with nurses/pharmacists outside the Prospective Payment System (PPS).

- NACHC supports CMS' proposal to rebase and revise the FQHC market basket from a 2017 base year to a 2022 base year.
- NACHC supports CMS allowing FQHCs to receive PPS payments for dental services furnished in physician offices when such services are integral to other covered services.
- NACHC supports allowing FQHCs to bill for a patient's medical and dental visits on the same day.
- NACHC urges CMS to review and amend as necessary the proposed revised regulatory language at §491.9(a), that FQHCs and RHCs 'must provide primary care services,' does not unintentionally prohibit the existence of behavioral health-only FQHC sites in Medicare.
- While NACHC supports the spirit of CMS' proposal at §410.152, we are concerned about the impact of changing coverage for pre-exposure prophylaxis (PrEP) from Part D to Part B on health center pharmacies and patients.
- NACHC recommends that CMS' estimation methodology only use HRSA's Prime Vendor Program (PVP) retail pharmacy data within the numerator to ensure accuracy in estimating the 340B percentage.
- NACHC supports CMS' proposal to require covered entities to enroll in a repository and submit specific data elements from 340B-identified claims for all covered Part D drugs billed to Medicare.
- NACHC recommends adding the National Drug Code (NDC) as another field for covered entities to submit to the Medicare Part D claims data repository claims for covered Part D drugs purchased under the 340B program and dispensed to Part D beneficiaries.
- NACHC appreciates CMS' efforts to gather feedback on the newly implemented codes for Community Health Integration (CHI), Principal Illness Navigation (PIN), and Social Determinants of Health (SDOH) Risk Assessment services.
- As CHWs continue to be essential to the health center care team, NACHC strongly urges CMS to make CHWs a billable Medicare Part B provider.
- NACHC recommends CMS allow health centers to bill for SDOH Risk assessments not connected to an Annual Wellness Visit.
- NACHC strongly encourages CMS to adopt more flexible policies that reimburse health centers for follow-up visits after patients have a positive screen for SDOH needs. Additionally, it's important the health center has the discretion to determine how often a patient should be screened.
- NACHC is encouraged to see proposed changes to increase behavioral health access in Medicare but strongly recommends CMS include FQHCs in their ability to utilize the proposed new codes for safety planning interventions and post-discharge telephonic follow-up, digital mental health treatment, and interprofessional consultation billing by practitioners.
- NACHC advises CMS to allow health centers to be able to bill for the proposed new stand-alone G-code, HCPCS code GCDRA, and Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors.
- NACHC supports CMS in permanently expanding the list of services that can be furnished under the primary care exception, including all levels of E/M services and additional preventive services.

Proposed Payment Policy for General Care Management Services (G0511)

NACHC supports the unbundling of the G0511 code and urges CMS to establish adequate reimbursement rates to ensure health centers' continued financial viability.

Health centers currently use G0511 to bill for general care management services, including Chronic Care Management (CCM) and Behavioral Health Integration (BHI) when at least 20 minutes of service are provided within a calendar month. NACHC appreciates CMS' proposal to discontinue the use of the single bundled code G0511 for FQHCs and instead require the use of individual codes that comprise the general care management services. This change aims to promote transparency and more accurately identify the services furnished.

Proper billing and reimbursement practices are vital for health centers to ensure financial stability and enhance the quality of care provided to patients.³ Providers implement standardized documentation protocols and ensure that all patient interactions, services provided, and time spent are meticulously recorded.⁴ This proposal would expand on this by providing greater clarity, accuracy, and insight into the specific services health centers provide to their patients. We have heard from health centers that billing multiple Care Management Services within the same code can make it challenging to track performance, identify delivered services, and confirm them against documentation. Although health centers will need to adjust their billing practices to report individual HCPCS codes instead of the single G0511 code, this would help reduce add-on units and modifiers, the need to combine encounters/claims, and the likelihood of denials for same-day care or "duplicate" management services.

If implemented, the new billing method would require more detailed documentation to support the individual codes billed. This includes tracking time and ensuring compliance with the specific requirements of each service code. NACHC requests that CMS provide additional resources and support to help FQHCs transition to the new billing method and meet the increased documentation requirements when billing for individual general care management codes previously included in G0511, including:

- Updated cost reporting instructions to help FQHCs understand the specific requirements for each service code and ensure accurate documentation.
- Comprehensive training guides, such as FAQs, to educate FQHC staff on the detailed documentation requirements, time tracking, and compliance with each service code.
- Access to technical assistance and support to help FQHCs implement new billing systems and processes
 effectively.

As CMS calculates the reimbursement rates for all these different general care management services, we implore CMS to ensure payment rates accurately reflect the cost of providing these services. For instance, reimbursement rates for remote patient monitoring (RPM) have been flagged as potentially generating lower reimbursement rates. This could result in health centers struggling to provide this crucial service to their patients, especially smaller ones with limited budgets.

Both health centers and their patients continue to report positive experiences with RPM. It has helped increase patient self-sufficiency and allowed patients to gain confidence using these self-measurement tools. Many health centers have shifted to incorporating this model and using remote monitoring technology in general to streamline communication and access for patients.

Furthermore, health centers have been able to reimagine preventive care and chronic disease management with at-home care utilizing remote patient monitoring. With many U.S. adults delaying preventive care and 6 in 10 having at least one chronic condition, including heart disease and diabetes,⁵ regular health management can be a matter of life and death. Health centers serve a large population of high-risk patients who are more likely to suffer from a disproportionate array of chronic conditions. To promote financial stability for health centers, we ask CMS to ensure sufficient reimbursement for all services previously under the G0511 code.

³ https://drkumo.com/g0511-cpt-code-explained-step-by-step-billing-and-reimbursement-process-for-fqhcs-and-rhcs/#:~:text=Ensuring%20Accurate%20and%20Timely%20Documentation,help%20maintain%20consistency%20and%20accuracy.

⁴ https://drkumo.com/g0511-cpt-code-explained-step-by-step-billing-and-reimbursement-process-for-fqhcs-and-rhcs/#:~:text=Ensuring%20Accurate%20and%20Timely%20Documentation,help%20maintain%20consistency%20and%20accuracy.

⁵ https://www.cdc.gov/chronic-disease/living-with/index.html#:~:text=Chronic%20conditions%20like%20high%20blood,feel%20well%20and%20avoid%20complications.

Advanced Primary Care Management (APCM) Services (HCPCS codes GPCM1, GPCM2, and GPCM3) NACHC generally supports the proposed Advanced Primary Care Management Services code bundle, but health centers may be unable to bill APCM services due to the performance measurement requirements for providers.

NACHC appreciates the creation of the APCM services code as it encompasses several of the services that are fundamental to the health center model. Health center patients are more likely to have been diagnosed with diabetes mellitus, asthma, high cholesterol, or hypertension as compared to the U.S. population. Furthermore, one in three health center patients report their overall health as being fair or poor (32%), as compared to 18% of the overall population. These patients would benefit from the set of care management services described in these three G-codes. However, given some of the requirements to bill these G-codes, we are unsure how many health centers will be able to take advantage of APCM. For example, the ways a provider can meet the performance measurement require being either:

- 1) a MIPS-eligible clinician,
- 2) a practitioner in a Shared Savings Program ACO, or
- 3) a practitioner participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary or Primary Care First.

Health centers are supportive of moving towards more value-based care arrangements and appreciate CMS creating opportunities specifically with health center needs in mind, like the Marking Care Primary model. Unfortunately, many health centers still lack the financial and operational resources to meaningfully and successfully engage in these arrangements. For decades, health centers have provided comprehensive primary care by screening for social determinants of health and used this information to build patient-centric models of care. However, challenges related to restrictive reimbursement models have stifled health centers' ability to employ the right workforce and provide the unique services their patient populations need.

To participate, health centers need significant financial resources to purchase the proper technological infrastructure to comply with requirements. This could mean the health center has to switch Electronic Health Record (EHR) vendors or enhance the capabilities of their existing EHRs, all costing more money. Furthermore, the health center must invest in the training and workforce to oversee quality metrics and the type of coordination of care the model requires. The health center also needs to accept downside risk to participate in some models, yet many health centers lack the financial stability to do so.⁶ We have also heard that some health centers with smaller Medicare populations cannot justify the financial investment involved in embarking on value-based pay arrangements, which APCM is on the path towards. We urge CMS to consider entry paths that empower health centers to invest in infrastructure while being able to participate in APCM.

NACHC seeks clarification that eventual participation in the ACO Primary Care Flex Model could meet the performance measurement requirement to bill for APCM. In early May, CMS announced the release of this voluntary model to promote primary care delivery in MSSP.⁷ As the deadline for applications just passed, we have heard from health centers that applied wonder if this model would satisfy the performance measurement requirement to bill for APCM if they are chosen to participate. Because this is a new model, we want to ensure that health centers and their practitioners taking up this opportunity could bill for APCM.

NACHC is concerned about the proposed reimbursement for GPCM1, GPCM2, and GPMC3, which is \$10, \$50, and \$110, respectively. We appreciate that health centers will be eligible for reimbursement for these services at the FFS national non-facility physician fee schedule rate, and the Prospective Payment

https://www.cms.gov/priorities/innovation/innovation-models/aco-primary-care-flex-model

⁶ https://www.agilonhealth.com/news/blog/value-based-care-barriers/

System (PPS) rate, the bundled rate that health centers receive to reimburse a visit. In comparison to general care management services, APCM services are more intensive and include more specific documentation requirements. We are concerned that the low reimbursement rate does not reflect the complexity of care nor the administrative burden placed on health centers. However, these services are even more advanced than some of the general care management services health centers already provide; along with the heightened requirements associated with APCM, the reimbursement across the three codes is lower than most of the other general care management services. Furthermore, there are many care management services that cannot be billed concurrently alongside APCM, which coupled with the coding billing requirements, APCM may be quite complicated for health centers to understand and implement. To better account for patient care costs, NACHC recommends CMS consider raising the payment rate for the APCM bundle. Furthermore, NACHC recommends CMS develop additional technical assistance, beyond cost reporting instructions, to help health centers understand how to take up this new APCM bundled payment option for advanced primary care.

While NACHC supports obtaining patient consent for APCM services, we are concerned about the burden a monthly cost-sharing responsibility will have on health center patients. Health centers are well-accustomed to obtaining patient consent before furnishing certain high-touch services. For instance, this already exists prior to beginning Chronic Care Management (CCM) services as well as Community Health Integration (CHI) services. In the proposed rule, CMS states that providers can bill for this service monthly, and not all elements included in the code descriptors for APCM services must be furnished during any given calendar month for which the service is billed. Like other care management services, patients have cost-sharing obligations for this Part B service, generally around 20%.

NACHC recommends CMS allow a co-insurance waiver for health center patients who consent to using APCM services. Many health center patients are financially vulnerable. Two out of three health center patients are at or below 100% of the Federal Poverty level (FPL), and 90% of health center patients live at or below 200% of the FPL. While health centers can place this co-insurance obligation on the sliding fee scale, patients have historically been wary of monthly payment requirements for general care management services. Health centers have had problems with patients disenrolling or otherwise interrupting care when they receive a monthly bill for general care management services - and these are for services furnished in person on a monthly basis. Waiving co-insurance costs of APCM for health center patients alleviates potential financial barriers to care and will help maintain patient enrollment in receiving these vital services.

Telecommunication Services

NACHC applauds CMS' proposal to amend regulations § 405.2415 and § 405.2452 to continue to allow for direct supervision through either physical presence or continuous real-time virtual interaction until December 31, 2025.

Continuing to allow virtual supervision of certain assistants 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. In Maintaining allowance of virtual supervision 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. Health centers provide care to 13.3 million rural residents, who make up 2 in 5 health center

⁸ https://www.nachc.org/wp-content/uploads/2023/07/Action-Guide Payment.pdf

⁹ https://www.medicare.gov/basics/costs/medicare-costs

⁹ 2023 National Report (hrsa.gov)

¹¹ https://www.nachc.org/wp-content/uploads/2022/03/NACHC-2022-Workforce-Survey-Full-Report-1.pdf

patients.¹² 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.¹³ NACHC supports CMS revising the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face encounter between a beneficiary and an RHC or FQHC practitioner also to include encounters furnished through interactive, real-time, audio and video telecommunications technology.

Amending the definition of a "medical visit" creates parity with the revised definition of mental health visits, defined at § 405.2463 b(3). 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:

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).

CMS needs to amend the definition of an FQHC medical visit to ensure health centers are receiving their full PPS rate. Currently, health centers are receiving around \$96 for services that generate the same costs related to workforce and technology. Being able to bill PPS for medical visits will bolster financial stability, improve cash flow, and ensure fairer compensation for telehealth services. By simplifying the billing process and increasing revenue, 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, no matter if they are medical or behavioral health visits.

Telehealth has been crucial in bridging gaps in care for health center patients. In 2023, 99% of health centers nationwide offered telehealth services compared to just 43% in 2019. Fifty-four percent of telehealth visits were for medical services, 34% for behavioral health services, 9% for enabling services, and 3% for other services. By offering telehealth services for medical and mental health care, health centers can expand access to comprehensive care and better serve Medicare beneficiaries facing socioeconomic challenges. Telehealth is also popular among health center patients. Results from a NACHC survey show that almost 90% of patients surveyed agreed that telehealth addressed their needs, was suitable for interaction with their clinician, and they were generally comfortable and satisfied with care via telehealth. A quarter of the patients surveyed had a visit for behavioral health – 52.55% via audio-only and 65.7% via video (and some were both). This adds to the growing body of research about the strength of telehealth in providing clinically equivalent care¹⁶ besides eliciting strong satisfaction from patients. Further expansion of telehealth continues to connect more providers to patients and break down social drivers of health barriers for patients.

Changing the definition of a medical visit to include virtual encounters allows the health center to provide patients services through the modality of their choice and to best address their medical needs. Health centers strive to meet patients where they are and enhance access to care; telehealth helps health centers fulfill their purpose of providing high-quality, affordable, and accessible care to all their patients.

¹² https://bphc.hrsa.gov/about-health-center-program/impact-health-center-program

¹³ https://data.hrsa.gov/tools/data-reporting/program-data/national

^{14 2023} National Report (hrsa.gov)

¹⁵ https://www.nachc.org/resource/assessing-patient-satisfaction-with-telehealth-at-community-health-centers-a-policy-brief/

¹⁶ https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796668

NACHC supports delaying the in-person mental health visit requirement for telehealth mental health services furnished to Medicare beneficiaries via telehealth by RHCs and FQHCs until January 1, 2026.

Telehealth has become essential to mental health care delivery at health centers. By postponing in-person visit requirements for telehealth mental health visits until January 1, 2026, health centers can continue providing essential mental health care to patients in rural and underserved areas, ensuring continuity of care and preventing disruptions in treatment for vulnerable populations.

Health centers are a critical access point for mental health and substance use disorder care. In 2022, health centers provided care to over 3 million patients with behavioral health needs, including depression, anxiety, Post-Traumatic Stress Disorder (PTSD), Attention-Deficit / Hyperactivity Disorder (ADHD), and substance use disorders. Additionally, more than 300,000 patients received medication-assisted treatment services. Health centers' dedicated behavioral health professionals conducted over 8 million in-person and virtual mental health visits, serving 3 million patients.¹⁷

Extending the flexibility for telehealth mental health services is essential for addressing the unique needs of health center patients. This approach helps mitigate the impact of social drivers of health, including poverty and limited access to transportation, which can significantly hinder individuals from seeking necessary mental health support and make it difficult to meet the in-person requirement. To meet patients where they are and not disrupt access to crucial mental health services, delaying the in-person visit requirement continues to help the vulnerable populations health centers serve.

Intensive Outpatient Program Services (IOP) in RHCs and FQHCs

NACHC supports CMS' proposal to add a payment rate for FQHCs and RHCs for days with four or more services and appreciates CMS restructuring regulatory language at § 405.2410(c) to ensure correct policy application for beneficiary coinsurance.

As previously mentioned, health centers have long served patients with complex behavioral health needs by providing services to support substance use disorders (SUD), such as medication-assisted treatment (MAT). The number of health center Medicare patients has also risen significantly over the past ten years, from 1.5 million in 2010 to 3.4 million in 2023, representing 11% of patients served. According to the Commonwealth Fund, around one in four Medicare beneficiaries have a mental health condition, such as depression, anxiety, schizophrenia, or bipolar disorder. Yet only 40 percent to 50 percent receive treatment. 18 Health centers' 18,800 behavioral health staff continue to stand ready to help address their patients' behavioral health needs through furnishing IOP services.

NACHC appreciates CMS' proposal to add a payment rate for FQHCs and RHCs for days with 4 or more services. This will provide parity and site-neutral payments for IOP services across different settings. Initially, Medicare payments for IOP services in FQHCs and RHCs were only based on a 3-service per-day payment rate. 19 This rate was determined because it was initially believed that patients visiting FQHCs or RHCs typically would only receive three or fewer services on one day.

Health center patients already experience more complex conditions than other populations, which intersect with other chronic conditions. Furthermore, there are significant links between mental health impacting physical health, and vice versa. For instance, data shows high comorbidity rates with SUDs and anxiety

¹⁷ 2023 National Report (hrsa.gov)

¹⁸ https://www.commonwealthfund.org/publications/explainer/2023/mar/medicare-mental-health-coverage-included-changedgaps-remain

19 https://www.cms.gov/newsroom/fact-sheets/cy-2025-medicare-hospital-outpatient-prospective-payment-system-and-

ambulatory-surgical-center

disorders. SUDs oftentimes also co-occur with mental disorders, such as depression and bipolar disorder, ADHD, psychotic illness, borderline personality disorder, and antisocial personality disorder. Additionally, patients diagnosed with schizophrenia are more likely to have alcohol, tobacco, and drug use disorders than the general population. For health centers to allocate so many resources and the volume of staff time to one patient through IOP services, health centers must be adequately compensated for all costs associated with providing this intensive level of care. We appreciate and support CMS' proposal to align payment rates with those of hospitals and community mental health centers, which promotes fairness and consistency in reimbursement for IOP services, regardless of the setting.

Additionally, NACHC appreciates CMS restructuring regulatory language at § 405.2410(c) to ensure correct policy application for beneficiary coinsurance. These corrections identified specific errors that did not accurately reflect the policy for beneficiary coinsurance for patients receiving IOP services in RHCs and FQHCs. Under CMS' proposal, health center patients will be responsible for a coinsurance amount of 20 percent of the lesser of the health centers' actual charge for the service or the IOP rate. We appreciate the clarification because this means that health center beneficiaries do not have to meet a deductible before Medicare begins to cover their services. Simplifying this structure ensures that health center patients can receive necessary behavioral health services without the barrier of high upfront costs, making it easier for them to seek timely care. Additionally, this change enhances affordability and predictability of the coinsurance amount and provides financial relief and certainty for beneficiaries, further promoting health equity and access to essential services.

Payment for Preventive Vaccine Costs in RHCs and FQHCs

NACHC supports the proposal to allow FQHCs to bill for the vaccine and administration of Part B preventive vaccines at the time of service, for dates of service beginning on or after July 1, 2025.

We appreciate that this extends to all the Part B preventive vaccines: pneumococcal, influenza, hepatitis B, and COVID-19. Health centers serve as a community hub where patients can get their routine vaccinations. However, some high-cost vaccines like shingles – around \$200 per dose²¹ – have made it difficult for health centers to proactively stock and administer some vaccines and have been limited to keeping them in their pharmacy. Ensuring more timely payment for both the vaccine and administration will significantly help health centers, which operate on financially thin margins.

Timelier payments for vaccines and their administration will also allow health centers to stock vaccines in other sites around the health center besides their pharmacy. One health center in Massachusetts began a Pharmacist-Led Vaccination Program in 2020, where all pharmacists are certified immunizers, per their state's guidelines. Being able to stock and then administer vaccines in places outside of the pharmacy allowed them the flexibility to immunize patients based on their preferences. Whether they are placed in the pharmacy or clinically integrated, pharmacists can help increase the number of vaccines administered.

We recommend CMS keep in mind when releasing cost reporting instructions on this process that interim payments received at the time of service be reconciled to the FQHCs' reasonable costs during the Cost Reporting process. Ensuring reconciliation of FQHCs' reasonable costs will make FQHCs "whole" for any costs that exceed the fee schedule reimbursement. Health centers operate on slim financial margins; more than half of community health centers operate with margins below 5%. ²² Inadequate payment could be devastating for their financial stability. Therefore, it is crucial that health centers get reimbursed for any costs above the fee schedule reimbursement at the time of reconciliation.

²⁰ https://www.ncbi.nlm.nih.gov/books/NBK571451/

²¹ https://www.goodrx.com/conditions/shingles/shingles-vaccine-cost-shingrix

²² 2023 National Report (hrsa.gov)

NACHC recommends that health centers should be permitted to bill for vaccine counseling under the PFS. Health centers have reported investing time in educating patients about the importance of vaccines, which takes additional time with the Medicare population. Vaccine administration often requires providers to spend time upfront counseling patients before receiving a vaccine. However, current coding and reimbursement policies are not designed to support adult vaccine counseling. Adult providers must use multiple codes depending on the services performed during the patient visit. This complexity is amplified for pharmacists, who are often unable to bill for medical visits, as well as for health centers, which are unable to separately bill for adult vaccine counseling due to their bundled payment methodology.

In 2022, CMS mandated that states cover stand-alone vaccine counseling for all vaccines covered under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit for children with Medicaid or Medicaid-expansion CHIP coverage. Even if the patient does not end up getting the vaccine, every state must cover counseling to a parent and/or caregiver for a vaccine for a child eligible for EPSDT.²³ This was a huge step forward, as we have seen childhood vaccination decline as well as lags in adult vaccination²⁴, and general vaccine hesitancy has increased.²⁵ While health centers have already been engaged in vaccine counseling, it is now more important than ever for CMS to allow for separate payment for vaccine counseling to try to increase vaccination rates. CMS has moved the needle forward in billing at the time of service for vaccine administration; we urge the agency to take another step forward and consider compensating FQHCs for time spent counseling, especially when counseling is given but a vaccine is not administered.

We also recommend CMS allow for "immunization only visits" with nurses/pharmacists outside the Prospective Payment System (PPS). This would help improve immunization rates among underserved individuals who seek care at FQHCs. Currently, "immunization-only" does not qualify for payment as an FQHC "visit." Furthermore, FQHCs do not have authorization to bill separately for the service under Part B. There could be a multitude of reasons why a patient does not get their routine vaccines at the time of a regular visit and decides they need to come back. Perhaps they were hesitant about getting the vaccine and after doing their own research, they come back and get the vaccine. Another reason could be the patient realizes they are behind on their vaccines and decides to stop at the health center pharmacy to get a vaccine. Whatever the reason, health center nurses or pharmacists should be able to bill for an immunization only visit, which will more accurately reflect all the services the health center offers as well as adequately financially reimburse them for services furnished.

Proposed Rebasing and Revising of the FQHC Market Basket

NACHC supports CMS' proposal to rebase and revise the FQHC market basket from a 2017 base year to a 2022 base year.

Even before the COVID-19 pandemic, health centers have historically operated on thin margins due to their federal requirement to serve all patients, regardless of their ability to pay. At roughly two out of every five health centers, Medicare patients make up at least 15 percent of total patients. ²⁶ This market basket update is crucial to ensuring that Medicare payments to FQHCs accurately reflect the costs incurred in delivering high-quality care to underserved populations. This is especially important because, after Medicaid

10

²³ https://www.medicaid.gov/federal-policy-guidance/downloads/sho22002.pdf

²⁴ https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2021.html

²⁵ https://www.annenbergpublicpolicycenter.org/vaccine-confidence-falls-as-belief-in-health-misinformation-grows/

²⁶ https://www.nachc.org/policy-advocacy/health-insurance-reimbursement/medicare/

redeterminations and rising inflation costs, health centers are experiencing unprecedented financial constraints.

NACHC appreciates CMS recognizing these financial challenges and using the 2022 cost report data to support the FQHC market basket. We also appreciate that the proposed 2022-based market basket uses a fixed-weight, Laspeyres-type price index, which will provide a reliable measure of price changes over time.²⁷ This method, along with reliable data sources, ensures that the market basket accurately reflects the cost trends that FQHCs experience. As Medicare patients are the fastest growing population for health centers, it is critical they are reimbursed to cover all the costs associated with delivering care.

Furthermore, we strongly support the inclusion of telehealth services in the 2022-based market basket, as it reflects the critical regulatory changes and the expansion of telehealth services that took place in 2022. Given the requirement for health centers to provide comprehensive services in high-need areas, telehealth has become essential in overcoming geographic, economic, transportation, and linguistic barriers to healthcare access. During the COVID-19 pandemic, health centers rapidly expanded their telehealth services, with nearly 95 percent offering virtual visits.²⁸ The inclusion of telehealth services in the market basket underscores its vital role in maintaining and expanding access to care, particularly in underserved communities. This update is a crucial step in ensuring that FQHCs continue to meet the evolving needs of their patients.

Clarification for Dental Services Furnished in FQHCs

NACHC supports CMS allowing FQHCs to receive PPS payments for dental services furnished in physician offices when such services are integral to other covered services.

With 82% offering dental services and serving over 6 million patients annually, FQHCs are a cornerstone of dental care delivery for underserved communities. In 2023, health centers provided over 15 million inperson dental visits, demonstrating their significant contribution to oral health care.²⁹ We applaud CMS for ensuring health centers can bill for the dental policies in CY23 and CY24 final rules, and updating the FQHC qualifying visit list as appropriate.

This decision to allow the furnishing of services to qualify as a visit is critical to ensure equitable access to care for all Medicare beneficiaries. Health centers serve as a safety net for millions of low-income and uninsured individuals, many of whom have complex dental needs. The expanded Medicare coverage of dental services aligns with other Medicare providers and helps alleviate the financial burden on health centers, allowing health centers to continue to provide whole-person, comprehensive care. Health centers already have a sliding fee scale that helps make services for patients more affordable, but allowing FQHCs to bill for these dental services under PPS is a positive step forward in reimbursing for care delivered to patients by health centers. By aligning FQHC billing codes with the PFS and ensuring health centers get reimbursed PPS for these dental services, CMS can ensure FQHCs can efficiently deliver essential dental services and maximize their positive impact on patient health.

Medical and Dental Visits Furnished on the Same Day

NACHC supports allowing FQHCs to bill for a patient's medical and dental visits on the same day.

Allowing health centers to bill for multiple, necessary visits for a patient per day enhances healthcare accessibility and equity for their patients. Health center patients oftentimes face many barriers to accessing

11

-

²⁷ https://corporatefinanceinstitute.com/resources/economics/laspeyres-price-index/#:~:text=Advantages%20and%20Disadvantages%20of%20the,to%20the%20changes%20in%20price

²⁸ https://www.nachc.org/topic/telehealth/

²⁹ 2023 National Report (hrsa.gov)

care. Being able to have both a medical and dental visit on the same day would minimize patient burden, particularly for those in underserved areas, by reducing travel time and logistical challenges. It also could serve patients well if, for example, a health center provider discovers a dental issue during a routine medical visit. Depending on the availability of the dentists on-site and the patient's schedule, the medical provider could direct the patient to see the dentist who could address the dental issue. The ability to have same-day billing for medical and dental visits would further bolster the care coordination services health centers are already providing.

Same-day billing for medical and dental visits is an example of how the health center model is built to be a one-stop shop for patients. Same-day billing barriers interfere with the health center's ability to maximize a patient's time without increasing uncompensated care costs. There are clear links between oral health and overall health. For instance, endocarditis, diabetes, and cardiovascular disease, chronic conditions that health center patients disproportionately experience compared to the general population, can contribute to oral health complications.³⁰ By allowing for separate billing of each unique patient encounter, health centers can help treat patients' health holistically and fully.

Given the narrow operating margins of health centers, this policy change would significantly bolster their financial stability by allowing each visit to be billed under the current FQHC PPS methodology. In addition, allowing same-day billing ensures accurate reimbursement for the services they provide, reflecting the actual time and resources invested in each patient encounter. This would also align with the current exceptions that exist to allow for same day billing for behavioral health and a medical need.³¹ NACHC strongly supports the policy of allowing health centers to bill separately for same-day medical and dental visits and hopes CMS will adopt this as another exception to the same-day visit limitation.

Rural Health Clinics and Federally Qualified Health Centers Conditions for Coverage

NACHC urges CMS to review, and amend as necessary, the proposed revised regulatory language at §491.9(a), that FQHCs and RHCs 'must provide primary care services,' does not unintentionally prohibit the existence of behavioral health-only FQHC sites in Medicare.

We understand CMS' main prerogative in amending § 491.9(a)(2) is to allow RHCs to offer more specialty services without being restricted to needing to be "primarily engaged in furnishing primary care services." However, given that the Conditions for Coverage requirements apply to health centers as well, NACHC has concerns that this revised language will unintentionally preclude Medicare-enrolled behavioral health-only sites for health centers, as these services and sites are a critical part of the comprehensive care they provide, especially in underserved areas.

Moreover, the proposed changes include specific language for RHCs, stating that they cannot be rehabilitation agencies or facilities primarily for the care and treatment of mental diseases, language directly from the Social Security Act.³² However, under the statute, this restriction does not apply to FQHCs, and therefore, making an implicit extension to FQHCs through these regulatory changes problematic. Since CMS lacks explicit statutory authority to impose such conditions on FQHCs, this change would have significant negative consequences, particularly for health center sites focused solely on behavioral health

_

³⁰ https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/dental/art-20047475

³¹ Medicare Claims Processing Manual, Chapter 9 - Rural Health Clinics/Federally Qualified Health Centers (https://www.cms.gov/regulations-and-guidance/guidance/guidance/manuals/downloads/clm104c09.pdf)

³² Social Security Act 1861(aa)(2)(A)

services. This would hinder access to essential behavioral health care, especially in areas where there are already significant barriers to healthcare access.

As previously mentioned, health centers provided care to over 3 million patients with behavioral health care needs and nearly 300,000 patients with SUD in 2023. Health center sites that focus solely on behavioral health services are a direct response to community needs and play a crucial role in addressing the SUD crisis, and often serve patients who may not have access to other healthcare settings. In fact, in 2022, health centers employed over 18,000 full-time behavioral health staff, with psychiatrists and licensed clinical psychologists making up 10% of that workforce at 5% each.³³ CMS' proposed change in language is concerning because the statutory requirements for FQHCs do not impose the same restrictions as those for RHCs. Health centers are designed to offer a broad range of services, including behavioral health, without a statutory mandate that each site provide medical services.

While the proposed changes are intended to clarify and improve the regulatory framework for RHCs, they may inadvertently prevent Medicare-enrolled, behavioral health-only FQHC sites. Therefore, we urge CMS to review the proposed revisions and make any changes to ensure that health centers can continue to meet the full spectrum of healthcare needs in their communities, including through behavioral health-only sites.

Payment for Drugs Covered as Additional Preventive Services (DCAPS) (§410.152)

While NACHC supports the spirit of CMS' proposal at §410.152, we are concerned about the impact of changing coverage for pre-exposure prophylaxis (PrEP) from Part D to Part B on health center pharmacies and patients.

Health centers across the country provide high-quality care to many patients with chronic conditions, including HIV. In 2022, health centers provided care to over 199,000 HIV-positive patients, tested over 8.1 million patients for HIV, and provided PrEP management services to nearly 85,000 patients.³⁴ Out of all the patients who benefit from PrEP, around 10% have Medicare coverage.³⁵ We appreciate that health centers would receive 100% of the Medicare payment amount for DCAPS drugs and any administration and supply fees. Because health centers have previously not been able to receive a separate payment for physician-administered drugs, we see this as a positive step forward in helping enhance financial stability for centers that provide physician-administered injectable PrEP medications.

However, we remain concerned about the impact that changing PrEP coverage from Part D to Part B will inadvertently have on health center pharmacies. We understand that CMS is disseminating information to prepare for the coverage transition anticipated in September 2024. While our health center pharmacies are doing everything they can to prepare for this change, the core issue is that many health center pharmacies face significant barriers to signing up for Part B due to the expense, administrative burden, and delay of reimbursement. Just the enrollment application fee to enroll in Part B is \$704.³⁶ Furthermore, many retail pharmacies cannot bill a medical plan for Medicare medical prescriptions (Part B drugs) or medical equipment.³⁷ Even if a health center pharmacy does sign up, it takes significantly more work to bill for Part B. We have heard from our health center members that often, there is lower reimbursement in Part B, and it takes longer to receive reimbursement, with many Part B claim submissions receiving payment denials.

³³ 2023 National Report (hrsa.gov)

 $[\]frac{34}{\text{https://bphc.hrsa.gov/technical-assistance/clinical-quality-improvement/hiv-hepatitis-health-centers}$

³⁵ https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id310.pdf

³⁶ https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-

MLN/MLNProducts/EnrollmentResources/provider-resources/provider-enrollment/Med-Prov-Enroll-

 $[\]underline{MLN9658742.html\#:\sim:text=The\%202024\%20enrollment\%20application\%20fee\%20is\%20\$709.\&text=Whether\%20you\%20apply\%20for\%20Medicare,to\%20submit\%20the\%20application\%20fee$

³⁷ https://www.cigna.com/knowledge-center/part-b-part-d-coverage-differences

Health centers' existing practices align with CMS' goal to minimize out-of-pocket costs for PrEP. Health centers 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. Health centers help patients enroll in specific manufacturer assistance programs, like Gilead's Patient Assistance Program to help lower the cost of medications like PrEP. While we commend CMS' intention behind this coverage change because it will achieve zero out-of-pocket costs, the most underserved Medicare patients are at risk of a lack of access to affordable PrEP if health centers must switch to Part B billing. Due to the existing challenges, a number of health centers will have to forgo this service.

NACHC is excited about this expansion of DCAPS and appreciative that CMS recognizes the significant limitation—lack of flexibility—stemming from the inclusion of all medication costs within the FQHC PPS rate. By creating mechanisms allowing for the billing of DCAPs physician-administered drugs and critical vaccines within office visits (outside of the cost report), CMS is supporting health centers in their work to provide access to high-quality care for those they serve in a financially sustainable manner. Historically, health centers have expressed feedback on the significant burden of bearing the expense of vaccines and supplies purchased until cost report payments were received. We also appreciate CMS' clarification that DCAPS and any accompanying administration and supplying fees are not subject to cost-sharing in FQHCs.

In conclusion, we ask CMS to provide clarity around a couple of points around DCAPS:

- Is there a specific ways health centers will be able to access these medications?
- Besides PEP and PrEP, what other drugs are going to be included under this designation? And if there are other drugs, will CMS publish a list?

<u>Medicare Prescription Drug Inflation Rebate Program - Exclusion of 340B Acquired Units from Part D</u> <u>Rebatable Drug Requirements</u>

NACHC recommends that CMS' estimation methodology only use HRSA's Prime Vendor Program (PVP) retail pharmacy data within the numerator to ensure accuracy in estimating the 340B percentage.

NACHC agrees that the PVP has sufficient data to help the agency calculate the estimated total number of units purchased under the 340B program for an NDC-9. NACHC is concerned about using a broad data set from the PVP that includes hospitals and other covered entity (CE) outpatient purchases, such as clinic-administered drugs (CAD). We recommend CMS only include retail pharmacy data to avoid any overestimates that would cause an incorrect calculation of the manufacturer's rebate (costs). Adjusting the data set from the PVP to include only 340B purchases made within the retail and specialty pharmacy settings will better comport with the data CMS proposes to pull to identify the denominator of the estimation percentage, existing manufacturer reporting under the Medicaid Drug Rebate Program (MDRP) of unit sales.

Comment Solicitation on a Medicare Part D Claims Data Repository

NACHC supports CMS' proposal to require covered entities to enroll in a repository and submit specific data elements from 340B-identified claims for all covered Part D drugs billed to Medicare.

_

³⁸ https://www.gileadadvancingaccess.com/patient

The data repository, in theory, will allow for both prospective and retrospective claim identification to accommodate all types of pharmacy models, which is 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. Similar to a clearinghouse, this data repository 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. This data repository will also help address duplicate discounts in a way that is least administratively burdensome and ensure the most pertinent data is collected to support providers and support CMS' overall goals in this space. Besides including the Date of Service, Prescription or Service Reference Number, Fill Number, and Dispensing Pharmacy NPI in the data elements, the NDC could be another data field included in the data repository.

NACHC recommends adding the National Drug Code (NDC) as another field for covered entities to submit to the Medicare Part D claims data repository claims for covered Part D drugs purchased under the 340B program and dispensed to Part D beneficiaries. The NDC comprises a unique 10- or 11-digit number that is already required for pharmaceuticals dispensed from pharmacies.⁴⁰ This field can easily be provided by covered entities into the repository. Adding this to data will help CMS more readily crosswalk between data submitted by the covered entity and the Prescription Drug Event (PDE) records for each Part D rebatable drug dispensed during the applicable period.

NACHC also supports the following ideas related to the repository:

- NACHC supports the two proposed ways a covered entity can revise previously submitted data in the Medicare Part D claims repository. Having the ability to easily correct data for selected data fields through a resubmission or submitting new data for claims that were later identified as purchased under the 340B program will decrease administrative burden for pharmacies and give them the flexibility to ensure correct claims data is within the repository. NACHC requests that covered entities have an opportunity to submit revisions within a defined timeframe before each of the two defined Reconciliation Preliminary Rebate Report Periods.
- NACHC believes that the proposed initial data submission timeframe, requiring completion within 3 months of the end of a given calendar quarter, will be sufficient for health centers. The three-month time frame will also allow pharmacies adequate time to compile required data and review submissions for accuracy prior to uploading to the repository to ensure that only 340B records are present in the repository.
- NACHC supports and appreciates CMS's decision not to require a 340B claims identifier on Medicare Part D drugs. While we understand this policy could be pursued in the future, NACHC greatly appreciates not requiring a 340B identifier given the lack of feasibility for health centers and existing technology to identify a 340B drug at the point of sale. The proposed Medicare Part D claims repository data elements will quickly and accurately provide CMS with the information they need to remove 340B units from Medicare Part D rebatable drugs. Given that 340B eligibility is most often determined retrospectively in a replenishment model, most pharmacies that health centers contract with

-

 $[\]frac{39}{\text{https://www.oregon.gov/oha/HSD/OHP/Tools/340B\%20State\%20Policy.doc}}$

 $[\]frac{\text{https://health.maryland.gov/pophealth/Documents/Local}\%20Health\%20Department\%20Billing\%20Manual/PDF\%20Manual/Section\%20II/National\%20Drug\%20Code\%20(NDC)\%20Info\%20and\%20Guide.pdf}$

do not know at the point of sale if the drug they are dispensing will ultimately qualify as a 340B drug. 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.

In conclusion, NACHC thanks CMS for considering our previous comments into consideration when crafting these proposals, particularly regarding the data repository, the modifier, and operational concerns health centers have related to implementing components of the Inflation Reduction Act (IRA). The proposals in this Medicare PFS will be helpful for implementing other provisions of the IRA, specifically effectuation of the Maximum Fair Price as well.

CHI, PIN, SDOH Risk Assessment Request for Information

NACHC appreciates CMS' efforts to gather feedback on the newly implemented codes for Community Health Integration (CHI), Principal Illness Navigation (PIN), and Social Determinants of Health (SDOH) Risk Assessment services.

The CHI, PIN, and SDOH Risk Assessment codes are promising tools for addressing the complex needs of FQHC patient populations. Health centers often serve communities with significant social and economic challenges, making these codes particularly relevant. Based on 2022 federal data from 1,338 health centers across the country, 21.7 million patients reported positive screening rates; 27.6% for financial strain, 16.3% for food insecurity, 15.4% for housing insecurity, and 14.1% for lack of transportation. Health centers use various tools to screen for SDOH, including PRAPARE. By enabling health centers to offer structured, reimbursable services through trained auxiliary personnel, the codes can facilitate more comprehensive and continuous care, especially for patients managing chronic illnesses or navigating social determinants of health.

One of the primary barriers health centers face in implementing these codes is the challenge of recruiting, training, and certifying auxiliary personnel. While the codes recognize the importance of community health workers and other auxiliary personnel, there may be significant hurdles in terms of the resources and time required for training. This is especially true for smaller or resource-limited health centers, which may struggle to meet these requirements without additional support. Additionally, reimbursement rates must be set at a level that fully accounts for the costs associated with training, certification, and the provision of these services. Without adequate funding, health centers may find it difficult to sustain these programs, particularly in rural and underserved areas where financial constraints are already a significant concern.

Furthermore, the roles of auxiliary personnel, such as Community Health Workers and certified peer specialists, are crucial for the continued success of utilizing these codes. For instance, some health centers that screen for SDOH outside of the AWV are first implemented by the Medical Assistant but then fully administered by the Community Health Worker. The current billing system does not allow CHWs to bill for the SDOH Risk Assessment either connected to or outside of an AWV; it must be billed by the supervising practitioners. Health centers pride themselves on employing comprehensive care teams to enhance care coordination, and it is a barrier for health centers to only allow the supervising practitioner to bill for these crucial services.

As CHWs continue to be essential to health center care team, NACHC strongly urges CMS to make CHWs a billable Medicare Part B provider. Over the last few years, more health centers have entered contractual agreements with managed care plans that provide reimbursement based on patient size or outcomes. A 2017 Kaiser Family Foundation survey of Medicaid managed care organizations found that

⁴¹ https://www.brown.edu/news/2024-06-20/fqhcs-social-risk-factors

67% of plans used CHWs to address social determinants of health in the previous 12 months. 42 While CHWs have traditionally not been reimbursed by public and private insurers, a growing number of states are using funding mechanisms such as Medicaid State Plan Amendments, Section 1115 Demonstration Waivers, and legislative statutes to reimburse for CHW services.

We are excited that Medicare Part B will cover CHI services, including CHW services. Reimbursement for responding to SDOH needs is crucial as more FQHCs seek to transition to alternative payment models (APMs), such as participating in the recently announced Making Care Primary model and Medicare Shared Savings Program.⁴³ Health centers need payment models that will provide adequate financial support and flexibility to deliver the kind of whole-person care their patients deserve in new and innovative ways. In the end, every patient, practice, and community is different. There is no one-size-fits-all approach to addressing individuals' unique health-related social needs. Employing CHWs at health centers is one way to provide help and resources to patients and reimbursement for CHI services. Coverage of CHWs as a billable Medicare provider will support health centers and CHWs long term.

NACHC recommends CMS allow health centers to bill for SDOH Risk assessments not connected to an Annual Wellness Visit. Screening for SDOH is embedded in the health center's mission and model of care. Screening for SDOH can happen during a variety of times. Health centers complete an initial risk assessment for new patients and then incorporate routine check-ins every 6-12 months. The risk assessment inclusion in the AWV naturally fits within the typical health center visit. However, other instances necessitate reimbursing a health center to administer this risk assessment. Once a health center can make an intervention based on the results of the patient's risk assessment, a follow-up within six months to see if meaningful change has occurred using this same risk assessment would be helpful in continuing to create a care plan for that patient.

NACHC strongly encourages CMS to adopt more flexible policies that reimburse health centers for follow-up visits after patients have a positive screen for SDOH needs. Additionally, it's important the health center has the discretion to determine how often a patient should be screened. The development of billing codes that reflect the time and effort health center care team members invest when assessing patients and connecting those patients to essential services is critical. One health center in Washington State offers an SDOH screen form to patients at every visit. This tool is offered in English and Spanish, and they offer corresponding services or partner with community-based organizations depicted via icons. Pictures and a caption underneath are especially helpful for patients whose second language is English or patients with lower health literacy. NACHC also recommends CMS create billing codes that support care coordination efforts aimed at addressing SDOH. This could include reimbursement for activities like connecting patients with community resources, coordinating with social workers, and monitoring SDOHrelated interventions.

Advancing Access to Behavioral Health Services

NACHC is encouraged to see proposed changes to increase behavioral health access in Medicare but strongly recommends that CMS include FQHCs in their ability to utilize the proposed new codes for safety planning interventions, and post-discharge telephonic follow-up, digital mental health treatment, and interprofessional consultation billing by practitioners.

Health centers have long been at the forefront of treating mental and behavioral health in America because they are accessible, community-based, and comprehensive. NACHC has continuously advocated for policies to support health centers' ability to fully integrate behavioral health services with primary care

⁴² https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-inpromoting-health-and-health-equity/
43 https://innovation.cms.gov/innovation-models/making-care-primary

settings. Since 2010, the number of patients receiving behavioral health services at health centers has grown by almost 63%. In 2023, health centers provided more than 26 million mental health visits to patients, 3.2 million more visits than in 2020.⁴⁴

The mental health services provided by health centers can vary based on the needs of the community where facility sites reside. Health centers offer a wide range of integrated mental and behavioral health services for children and adults, such as comprehensive individual or group counseling, intensive outpatient services, addiction and recovery services, Medication-Assisted Treatment (MAT), school-based therapy, and crisis services. These services are patient-centered and often delivered while working in harmony with community partners (hospitals, counselors, pharmacies, and others) to support the full range of health needs of patients. Health centers utilizing interdisciplinary teams coordinate care and case management to diagnose, treat, and care for individuals with trauma, sleep disorders, abuse, depression, anxiety, or alcohol or drug use, among other mental health conditions.

Health centers are uniquely positioned to provide integrated mental health and primary health care services directly in a community-based setting. They are known for their emphasis on cultural competence and because they provide services regardless of a clinic user's ability to pay. Any recommendations related to integrating care that prioritizes mental health need to take into consideration the ability of the largest primary care network for health centers to improve the quality and availability of care.

Safety Planning Interventions and Post-Discharge Telephonic Follow-up Contacts

NACHC supports the addition of safety planning interventions and post-discharge telephonic follow-up and strongly recommends CMS amend these sections to include RHCs and FQHCs as eligible providers to utilize these codes. As of January 1, 2022, a health center mental health visit is defined as a face-to-face encounter or an encounter furnished using interactive, real-time audio and video telecommunications technology or, in certain cases, audio-only technology. However, under Medicare, a health center FQHC mental health visits are narrowly defined to include only a limited range of services, and Medicare regulations recognize only a narrow group of behavioral health clinicians. While practitioner groups may use a wider range of workforce as "auxiliary personnel" who are paid for on an "incident to" basis under the Physician Fee Schedule, FQHCs do not benefit from that flexibility since health center visits must include direct involvement by the billable FQHC clinician.

Suicide is one of the leading causes of death in the United States, and rates are increasing, especially for people aged 65 and over. Compared to 2021, suicide deaths rose 8.1% among people aged 65 and over. Suicide is higher in older adults for several reasons, including depression, grief over the passing of loved ones, or chronic illness. In 2023, 72% of health center patients over 12 years old were screened for depression and received a follow-up plan. Research has shown that primary care is the most likely point of contact for suicidal patients in the healthcare system. Alarmingly, 77% of patients who die by suicide visited primary care in the year prior, and 45% visited a primary care office within the month before death. Health centers are trusted providers in their communities and respond to their patient's needs, but to have the far-reaching impact of this suicide and risk prevention strategy, they must be included.

While these codes are focused on the risk of suicide and other crisis care needs, NACHC requests guidance on how these codes would integrate with reimbursement for transitional care management services. Suicide risk is also increased for individuals with opioid use disorders and chronic pain.⁴⁹ Last year, 975

⁴⁴ https://bphc.hrsa.gov/about-health-center-program/impact-health-center-program/four-years-top-ten-achievements

⁴⁵ https://www.cdc.gov/suicide/suicide-data-statistics.html

⁴⁶ https://www.ncoa.org/article/suicide-and-older-adults-what-you-should-know

⁴⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9196265/#B6

⁴⁸ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5072576/

⁴⁹ https://heal.nih.gov/news/stories/suicide-prevention-primary-care

health centers provided access to Medication for Opioid Use Disorder (MOUD) services to 208,000 patients. Over 12,000 health center providers are eligible to distribute medication to treat opioid use disorders. Additionally, many health center patients have experienced some form of trauma from their lived experiences, which can increase the risk for chronic pain, SUD, and or poor mental health. While trauma can manifest and exhibit different mental and medical conditions for patients, last year, in health centers, over 3.4 million patients were diagnosed with anxiety disorders, including post-traumatic stress disorder (PTSD). Lastly, a few of the approximately 200 crisis centers of the nation's 988 network are also FQHCs.

Health centers do not turn away patients based on their inability to pay. Health centers serve all patients and operate on a sliding fee scale for patients as needed. Safety planning interventions and post-discharge telephonic follow-ups for crisis care are meeting the needs of patients when they are most vulnerable to prevent deliberate self-harm. Given the sensitive nature of these services, payment arrangements with cost-sharing may inadvertently create a devastating barrier to extremely necessary care and support. NACHC urges CMS to find an alternative payment methodology for these crisis code services that offer flexible payments that ensure patients are not disincentivized to seek help. We recommend considering a set number of calls per month or other specified duration before beneficiary cost-sharing kicks in.

NACHC recommends CMS change the time for the code safety-planning code, GSPI1, from 20 minutes to 20-60 minutes, with an additional add-on code option. We heard from one health center that provides moderate to advanced crisis care services express that they need at least 45-60 minutes for the initial safety planning with a patient after a recent crisis encounter. For the follow-up, the health center has determined that the appropriate duration is 15-30 minutes, so the proposed bundled service of four calls in a month, each lasting between 10-20 minutes, would be sufficient. Another health center, Hill Country Community Clinic in California, provides crisis care, follow-up support, and care coordination, in addition to mobile crisis services. In their experience, 20 minutes is insufficient to complete safety plans when someone is experiencing suicidal risk. An appropriate telephone follow-up after hospitalization is 30 to 60 minutes, which allows for engagement, review, and update of safety planning and identification of any unmet psychosocial needs. Health & Wellness Center, Inc., the largest rural health center in Oklahoma, has trained staff in the evidence-based suicide-specific intervention Collaborative Assessment and Management of Suicidality (CAMS). Their licensed clinicians typically bill for counseling or crisis when this intervention is utilized and agree that 30 – 45 minutes would be a more realistic minimum time to complete an evidence-based suicide intervention.

Care coordination is essential to follow up to support patients with stabilization and prevention of future crises. In-person follow-up is more appropriate for patients who may experience housing instability and other barriers to phone follow-up. Licensed mental health professionals, trained crisis workers, and peer support specialists work together to provide follow-up services. We ask CMS to revisit the time for the safety-planning code to better reflect the actual time health centers spend in helping patients in distress. **Digital Mental Health Treatment (DMHT)**

NACHC supports CMS's proposal to include digital therapeutics for behavioral health services as this can provide a foundation for future innovations in care delivery. We would encourage CMS to prioritize clarity and avoid adding administrative burden when determining how to cover these services. While CMS intends to model DMHT codes on remote therapeutic monitoring (RTM) the billing requirements differ. The proposed language restricts billing to "DMHT devices that have been cleared by the FDA," whereas RTM codes only require devices to meet the FDA's definition of a device, not necessarily FDA clearance. This wording could inadvertently exclude DMHT devices approved through

⁵⁰ https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/2023-uds-trends-data-brief.pdf

⁵¹ https://www.nachc.org/resource/increasing-equity-in-pain-management-substance-use-disorder-treatment-and-linkages-to-care/

alternative FDA pathways. CMS should ensure the FDA language between DMHT and RTM devices is aligned.

Additionally, CMS should consider whether separate codes for DMHT and RTM are necessary. CMS modeled the proposed DMHT codes (GMBT1, GMBT2, GMBT3) directly on existing RTM codes (98978, 98980, 98981), reflecting similar structures and functions. While RTM focuses on monitoring, and DMHT emphasizes treatment, both code sets involve non-physiologic data reporting. Consolidating these codes or providing clearer distinctions would reduce provider confusion, streamline billing processes, and enhance the overall efficiency of care delivery.

Interprofessional Consultation Billed by Practitioners Authorized by Statute to Treat

Integrated care for health centers means that patients can access and receive care seamlessly. Health centers have been leaders in integrating medical care, behavioral health, dental care, pharmacy, and other services under one roof. Integrated care is the foundation for care coordination. Health centers have used this strategy to manage and control high-risk patients through the full range of their care needs, which leads to better health outcomes. This can include tracking referrals, working with the pharmacy to manage a patient's medication use, and aligning treatment plans for patients who have multiple health issues. It is a way to build better care plans, prevent care gaps, and prevent emergency department visits.

NACHC supports CMS' proposal to allow interprofessional consultation to be billed by practitioners authorized by statute for the diagnosis and treatment of mental illness. If implemented, CMS would need to add these G codes to an FQHC-qualifying visit⁵² and the specific providers to the core providers list. Nationwide behavioral health staff in health centers grew by eight percent to make up 11% of the overall care team in 2022.⁵³ These providers include licensed clinical psychologists, psychiatrists, licensed clinical social workers, substance use disorder staff, and other mental and licensed mental health providers. These interprofessional consultant codes also align with CMS' efforts in the Medicaid space. In January 2023, a State Health Official (SHO) 23-001 letter⁵⁴ explained how interprofessional consultative providers in Medicaid can be directly paid, superseding the previous policy where the treating practitioner (for example, a health center) was paid an increased rate for a covered Medicaid service. Previously, the treating practitioner paid the consulting practitioner out of that payment rate through a separate arrangement between the two providers. NACHC supports these G codes and their availability to both the treating/requesting practitioner and the consulting provider. The time increments offer greater flexibility for the providers and are appropriate for varying care and consulting needs. Health centers will appreciate policies that support innovative practices to make interprofessional consultations more efficient and enhance care coordination efforts. Furthermore, consultation is a crucial component of assessment, treatment, and ongoing care. Mental health professionals spend time in consultation to better understand their patient's needs. Additionally, NACHC seeks guidance on how providers can utilize these new G codes in relation to the Psychiatric Collaborative Care Model (CoCM). As a reminder, the current Medicare regulatory structure does not permit health centers to take advantage of these new G code opportunities like other providers.

NACHC requests clarity on whether the treating/requesting practitioner and the consulting provider must be in the same organization to bill these new G codes. Per the requirements of their Section 330 of the Public Health Service Act grant, health centers must be in or serve patients in geographic areas designated by the Health Resources and Services Administration as Health Professional Shortage Areas (HPSA) and Medically Underserved Areas/Populations (MUA). As of December 2023, over half of the U.S. population lives in a mental health HPSA. Rural counties are more likely to have a maldistribution of

 $^{^{52}\}underline{https://www.cms.gov/medicare/medicare-fee-for-service-payment/fqhcpps/downloads/fqhc-pps-specific-payment-codes.pdf}$

https://www.nachc.org/wp-content/uploads/2024/07/2024-2022-UDS-DATA-Community-Health-Center-Chartbook.pdf

⁵⁴ https://www.medicaid.gov/sites/default/files/2023-01/sho23001 0.pdf

psychiatric mental health nurse practitioners, psychologists, social workers, and counselors.⁵⁵ Allowing more behavioral health specialists to share their expertise through interprofessional consultation will help achieve better healthcare outcomes, especially for rural patients. Interprofessional consultation could be useful for Medicare health center patients, such as when a health center practitioner consults with a psychiatrist on medication management when a patient is unable or willing to seek care directly from the specialist. Additionally, interprofessional consultations can enhance timely access to mental and behavioral care services, lessen the need for an in-person referral or visit, allow for shorter wait times, and support team-based care.⁵⁶ Utilizing interprofessional consultation is a step towards stronger behavioral health integration (BHI) services.

While FQHCs and RHCs are authorized to participate in the Medicare monthly care management programs, including those focusing on behavioral health (BHI and the psychiatric collaborative care model), payment is not on par with Part B physician groups. NACHC recommends that the advancing access to behavioral health services proposed changes in the CY 2025 PFS should be amended for effective inclusion of FQHCs and RHCs to improve the sustainability of and expand mental health integration in primary care and for safety net providers.

Comment Solicitation on Payment for Services Furnished in Additional Settings, including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs) - Intensive Outpatient Program Services (IOP)

NACHC recommends CMS, as they consider a Medicare payment methodology for CCBHCs, it should be as consistent as possible with the methodology used in the Medicare FQHC PPS as many of these services and workflows are intertwined and support the integration of behavioral health and primary care across the nation. The National Council for Mental Wellbeing 2024 CCBHC Impact Report⁵⁷ found that health centers are the most common primary care partners for CCBHCs to meet the primary care screening and monitoring requirements. This can be accomplished by co-locating FQHC services on-site at the CCBHC, designating an FQHC as a designated collaborating organization to the CCBHC, or having a care coordination or referral relationship with an FQHC. Health centers have experience connecting the dots between public and privately funded care management and care coordination services for mental and behavioral health. As FQHCs are required to adapt and tend to the needs of the population they serve, health centers can provide targeted service and program offerings that can avoid more costly care and emergency department visits.

Health centers providing a broad range of behavioral health services are well-positioned to become dually certified as CCBHCs in their State. Like FQHCs, CCBHCs are safety-net providers that provide services to patients regardless of their ability to pay, offer services in a defined service area, and have consumer majority boards and data reporting requirements, among other similarities. Both providers have Medicaid PPS rates; however, the methodology is different, with CCBHCs having a daily or monthly rate and an established three-year timeframe to rebase clinic-specific PPS rates. As of August 2023, 60 health centers are also CCBHCs. Inadequate payment is a threat to the viability of health centers. Careful consideration and review are needed to make sure that neither PPS rate is made weaker or less robust, as a lack of alignment could penalize safety net providers and undermine a patient's access to comprehensive patient-centered care and services.

58 https://www.nachc.org/wp-content/uploads/2023/07/NACHC-FQHC-and-CCBHC-Program-Crosswalk.pdf

⁵⁵ https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Behavioral-Health-Workforce-Brief-2023.pdf

⁵⁶ https://www.apaservices.org/practice/reimbursement/health-codes/interprofessional-record-health-consultations#:~:text=Interprofessional%20consultation%20services%20offer%20several,team-based%20approach%20to%20care

⁵⁷ https://www.thenationalcouncil.org/resources/2024-ccbhc-impact-report/

Cardiovascular Risk Assessment and Risk Management

NACHC advises CMS to allow health centers to be able to bill for the proposed new stand-alone G-code, HCPCS code GCDRA, and Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors.

Health center patients are more likely to have been diagnosed with diabetes mellitus, asthma, high cholesterol, or hypertension as compared to the U.S. population.⁵⁹ All of these common diagnoses for health center patients, cited in the proposed rule as conditions that could necessitate an ASCVD Risk Assessment, show the importance of including health centers in administering and billing for this risk assessment when conducting an evaluation/management visit. Health centers are uniquely involved in this space due to their patient population, and NACHC has also been directly involved in the Million Hearts initiative.

NACHC has led national learning communities, implementation, and evaluation efforts with community health centers, primary care associations (PCAs), and health center-controlled networks (HCCNs) since 2014 in support of the CDC's Million Hearts® initiative with demonstrated success. Focus areas have included addressing undiagnosed hypertension, accelerating blood pressure control, implementing self-measured blood pressure monitoring (SMBP) using clinical-community care models, improving blood pressure control for African Americans, and improving the use of statin therapy for people at high risk of cardiovascular events. NACHC has been helping our members in this area for years, and this risk assessment would help positively impact health outcomes for our patients, as it will support health centers' efforts to try and prevent further adverse health events.

<u>Request for Information for Teaching Physician Services Furnished under the Primary Care</u> Exception

NACHC supports CMS in permanently expanding the list of services that can be furnished under the primary care exception, including all levels of E/M services and additional preventive services.

Currently, valuable primary care and preventive services are outside the scope of the primary care exception, which does not allow their integration into primary care residency training settings. This can negatively impact physician training and patient access to these crucial services. Additionally, enhancing the levels of E/M services under the primary care exception could bolster primary care workforce development while improving patient continuity of care and maintaining patient safety.

While NACHC supports the inclusion of these codes, unfortunately, these regulations do not expressly address payment for FQHC services rendered in a teaching setting and do not define "teaching setting" in a way that encompasses health center-run residency programs that are funded through the Teaching Health Center (THC) grant program. Under the Primary Care Exception, §415.174 (a)(1), the regulation states that "The services must be furnished in a center that is located in an outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining intermediary payments to a hospital under §§413.75 through 413.83.

The intermediary payments refer to Medicare GME payments. Given that payments made under the Teaching Health Center Graduate Medical Education (THCGME) program for training residents are reimbursed under Section 340H of the Public Health Service Act, THC resident training does not fit the requirements of the primary care exception. While the primary care exception does not apply to THCs, this expansion could benefit health centers that are a rotation site, as part of a physician in training's residency program.

⁵⁹ 2023 National Report (hrsa.gov)

Thank you for considering these comments on the health center portion of the CY25 Medicare Physician Fee Schedule and areas in which we hope FQHCs can participate. If you have any questions, please contact Elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elizabeth Linderbaum, Deputy Director of Regulatory Affairs (elizabeth Linderbaum, Deputy Director of Regulatory Affairs (elizabeth Linderbaum, Deputy Director of Regulatory Affairs (elizabeth Linderbaum, Deputy Director of Regulatory (elizabeth Linderbaum, Deputy Director of Regulatory (elizabeth Linderbaum, Deputy (elizabeth Linderbaum, Deputy (elizabeth Linderbaum, Deputy (elizabeth Linderbaum, Deputy (<a hr

Sincerely,

Joe Dunn

Chief Policy Officer