



September 13, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1751-P

P.O. Box 8016

Baltimore, MD 21244-8016

Main Office
7501 Wisconsin Ave.
Suite 1100W
Bethesda, MD 20814
301.347.0400 Tel
301.347.0459 Fax

Division of Federal, State
and Public Affairs
211 N. Union Street
Suite 200
Alexandria, VA 22314
202.296.3800 Tel
202.296.3526 FAX

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 28 million people, including 1 in 5 Medicaid beneficiaries and 1 in 3 people living in poverty nationwide. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other “enabling” or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

In the fight against COVID-19, the community health center mission of advancing equity in the nation’s pandemic response is now more critical than ever. Health centers have been on the ground in force for over a year, fighting the spread of the virus in hard-to-reach communities, including communities of color and among special populations such as the elderly, homeless, and agricultural workers. They have tested, vaccinated, diverted non-acute cases from overwhelmed hospitals, and connected affected patients with housing, food, and critical services. To date, health centers have delivered over 8 million COVID-19 vaccinations and over 12 million COVID-19 tests.

Both patients and health centers have benefitted immensely from the increased telehealth flexibilities, which have allowed health center providers to reach more vulnerable patients and improve the delivery of care. Health center patients deserve to have the same access as other Medicare beneficiaries, which requires CMS to amend the definition of a FQHC visit to include remote access through, audio and video telecommunications technology or audio-only interactions.

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

- CMS should amend the FQHC cost report and instructions to ensure FQHCs receive Medicare reimbursement at 100% of the reasonable costs for the COVID-19 vaccine and its administration, Monoclonal antibodies infusion, and Medicare Advantage enrollees' vaccine administration.
- NACHC encourages CMS to increase COVID-19 vaccine administration reimbursement for mass vaccination events that occur outside of the health center, to effectively reach vulnerable and underserved communities.
- CMS should use its regulatory authority to permit FQHCs to provide remote services by revising the definition of medical and mental health FQHC visits to include services furnished using interactive, real-time, audio and video telecommunications, or audio-only interactions under defined circumstances.
- NACHC encourages CMS to provide maximum flexibility for health centers implementing in-person service requirements for patients receiving virtual mental health services.
- CMS should use its authority to align FQHC patient choice with other Medicare beneficiaries by permitting patients to change their attending FQHC provider after they have made their initial election to receive hospice benefits.

Vaccine Administration

CMS should amend the FQHC cost report and instructions to ensure FQHCs receive Medicare reimbursement at 100% of the reasonable costs for the COVID-19 vaccine and its administration, Monoclonal antibodies infusion, and Medicare Advantage enrollees' vaccine administration.

As soon as the COVID-19 vaccine was approved, health centers were on the front lines ready to reach the nation's most vulnerable and highly marginalized communities. Health centers immediately diverted all available resources to provide vaccinations to Medicare patients before CMS even established FQHC COVID-19 vaccine administration reimbursement. NACHC submitted comments on the COVID-19 Public Health Emergency 4th Interim Final Rule with Comment (IFC) in December 2020, urging CMS to issue interim payments for vaccine administration and establish FQHC Medicare reimbursement at 100% of the reasonable costs for the COVID-19 vaccine and its administration. We greatly appreciated Medicare's rapid response and willingness to meet with the National Association of Community Health Center's staff to understand FQHC COVID-19 vaccine reimbursement challenges. In early April 2021, CMS issued guidance permitting FQHCs to request lump-sum payments from their Medicare Administrative Contractors (MACs) for administering the COVID-19 vaccine in advance of cost report settlement. As this was a step in the right direction, we urge CMS to continue oversight on FQHC lump-sum payments to streamline communication between health centers and their MACs. Health centers have experienced challenges with burdensome reporting requirements, data collection, and slow distribution.

While health centers appreciate the lump-sum payments, they are only a temporary solution that fails to create permanent reimbursement for vaccine administration. NACHC strongly encourages CMS to amend the FQHC cost report template and instructions to reflect accurate cost reimbursement for the COVID-19 vaccine. Health centers are beginning to incorporate vaccinations into routine primary care visits, and within the next few weeks will begin providing COVID-19 booster shots to Medicare patients. It is imperative that CMS amends the cost report establishing a permanent reimbursement mechanism for COVID-19 vaccine and treatments as health centers continue to provide these services for the foreseeable future. Amending 42 C.F.R. §405.2466(b)(1)(iv) and its cost reporting instructions will ensure health centers will be adequately reimbursed for serving the Medicare population throughout the pandemic and for as long the COVID-19 vaccine is required.

CMS stated in its COVID-19 IFC that it intended to treat Medicare payment to FQHCs for the COVID-19 vaccine the same as payment for the flu and pneumococcal vaccines since the COVID-19 was added to the same subparagraph of the Medicare statute.¹ However, COVID-19 vaccine administration requires more resources, logistical planning, and patient education than flu and pneumococcal vaccines. CMS should amend 42 C.F.R. §405.2466(b)(1)(iv) and its cost reporting instructions with the recommendations below:

- Add COVID-19 vaccine to the cost report and permit health centers to account for the total amount of staff time and clinical costs incurred.
- Add Medicare Advantage to the cost report to ensure health centers receive adequate reimbursement.
- Add Monoclonal Antibodies Infusion to the cost report permit health centers to account for the total amount of staff time and clinical costs incurred.

The current CMS cost report instructions use assumptions that limit reimbursement for the flu and pneumococcal vaccines. For example, it is assumed that the vaccine administration consumes no more than five minutes of clinical time. CMS should amend the cost report template to account for the range of factors associated with administering the COVID-19 vaccine to Medicare patients. At least 30 minutes of clinical time per administration should be assumed, and additional time for an infusion of monoclonal antibodies, which is a more intensive procedure. CMS will also need to provide program instructions on the reconciliation of lump-sum payments to the costs reflected on the cost report vaccine payment worksheet.

Mass Immunizer Reimbursement

NACHC appreciates the opportunity to provide feedback on the resource costs associated with administering COVID-19 vaccinations at mass events. NACHC encourages CMS to increase the reimbursement rate for vaccinations administered at mass sites from \$40 to at least \$120 to reflect the reasonable costs that providers like FQHCs incur. Mass COVID-19 vaccination clinics take more people and resources to operate than health centers often have available. The workforce shortage for health centers has been exacerbated by the pandemic and many centers relied on contract workers, volunteers, and community partners to fill the gaps. Health centers

¹ 85 Fed. Reg. at 71,147.

have found that logistical and operations planning and execution of mass COVID-19 vaccination clinics often require an “all hands on deck from multiple departments” approach. This additional work is needed to ensure these offsite vaccination clinics are organized and operate efficiently and effectively in administering the vaccines. However, this approach diverted clinical time and staff resources away from health center patients that needed essential primary and preventive care services. For a typical mass vaccination event, health centers would incur thousands of dollars in upfront costs to cover: staff overtime and mileage, contract workers, EMT services, and security. CMS should take into consideration the reasonable costs associated with providers operating outside of their medical offices and going into the community to administer the vaccine.

While mass COVID-19 vaccination sites continue and vaccinations are being incorporated into routine or other clinic visits, health centers are reaching deep and wide into their communities to ensure they are equitably distributing vaccines. Health centers staff are going door to door vaccinating shut-ins, hosting “pop-up clinics” at churches and back to school events and partnering with senior living facilities. NACHC encourages CMS to increase COVID-19 vaccine administration reimbursement for mass vaccination events that occur outside of the health center to more effectively reach vulnerable and underserved communities.

Telehealth and Remote Access to Services

CMS has regulatory authority to permit FQHCs to provide remote services by revising the definition of medical and mental health FQHC visits to include services furnished using interactive, real-time, audio and video telecommunications, or audio-only interactions under defined circumstances.

Health centers were forced to shutter many of their in-person operations during the COVID-19 Public Health Emergency (PHE) and continued to provide essential health care services to over 28 million patients through increased usage of telehealth. NACHC applauds CMS for recognizing the significant impact increasing access to telehealth services has on patients across the country. Health centers have been highly effective in using telehealth during the PHE to provide vital primary and preventive care to patients and communities disproportionately impacted by COVID-19 who may have otherwise not had access to these services. Both patients and health centers have benefitted immensely from Medicare’s PHE flexibilities, which have allowed health center providers to care for more vulnerable patients and improve their existing patient relationships. However, patients without reliable transportation, internet, or the necessary technology will still face difficulties accessing services after the pandemic.

Before the PHE, only 43% of health centers used telehealth, and just 40% used audio-only². Their utilization increased dramatically with the onset of the PHE, with 98%³ using telehealth overall. Almost all health centers used both virtual and audio telehealth for behavioral health and

² 2019 Uniform Data System, Bureau of Primary Health Care, HRSA, DHHS. Federally funded health centers only; see methodology section for audio-only rates.

³ Bureau of Primary Health Care, Health Resources and Services Administration, Health Center COVID-19 Survey collected April 2, 2020 - June 25, 2021. 58-82% of federally-funded health centers responded. Survey data are preliminary and do not reflect all health centers. For more information, please visit <https://bphc.hrsa.gov/emergency-response/coronavirus-healthcenter-data>.

medical services. Urban health centers and those with significant low-income populations had slightly higher rates of providing services via both modes as well as treating patients with chronic conditions, behavioral health, or substance use disorder needs compared to the general health center population. According to the Bureau of Primary Health Care's 2020 Uniform Data System, telehealth utilization increased 6,000% from 2019 to 2020.

After over a year on the front lines of the COVID-19 pandemic, health centers' main concern is to ensure they continue to provide the best comprehensive care for their Medicare patients. Between 2019 to 2020, telehealth services for nutrition and dietary counseling increase 337% and 102% for substance use disorder services⁴. We support the Agency's effort to create more consistency among providers by aligning FQHC related policies with services covered under the Physician Fee Schedule, like increasing remote access for health center patients. Health centers cannot continue to carry out their critical role as primary care safety-net providers unless Medicare recognizes patients receiving health center services through remote access.

Medical and Mental Health Visits

For years, NACHC argued that CMS has authority to amend the FQHC visit definition to include virtual interactions, irrespective of the definition of or limitations on "telehealth services" under Section 1834(m) of the Social Security Act. In the past, CMS has stated it lacks statutory discretion to amend the "visit" definition in this manner because FQHCs are not included as "distant site providers" for the purposes of telehealth services in Section 1834(m). NACHC encourages CMS to use its authority, vested by congress, to broaden the FQHC visit definition to include virtual capabilities for both mental health and medical visits.

NACHC supports CMS's proposal to revise the regulation at §405.2463(b)(3) to define a mental health FQHC visit as a face-to-face encounter or an 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 a mental health disorder. Since 2020, health centers have seen a 25% increase in behavior health telehealth utilization.⁵ The UDS data provides global insight into health centers' commitment to expanding and maintaining access to virtual care. Health centers welcome the opportunity to develop Medicare utilization data to demonstrate the positive impact remote access has on their patients. We strongly believe FQHC Medicare claims data will indicate that the use of interactive communication technology, and audio-only communication, for mental health care will continue to be in broad use beyond the circumstances of the pandemic NACHC appreciates CMS acknowledging the potential inequities in access to modes of care, problematic interruptions to care, and negative consequences of fragmented care for health center patients who could lose remote access to mental health services provided by FQHC practitioners.

Importantly, the same inequities, potential interruptions of care, and negative consequences exist for Medicare patients receiving remote medical services during the PHE. NACHC strongly

⁴ 2019-2020 Uniform Data System, Bureau of Primary Health Care, HRSA, DHHS. Federally funded health centers only; see methodology section for audio-only rates.

⁵ Id.



encourages CMS to revise the definition of a “medical visit” for FQHCs to permit patients to access FQHC services virtually and allow FQHC providers to collect utilization data to support continuation beyond the PHE. Over 10% of health center patients are Medicare beneficiaries, receiving essential preventive and primary care services at their local health centers. The same patients that benefit from receiving mental health services through remote access deserve the same access to medical services. The proposed rule cites proven benefits including, improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increase access to specialists outside of a local area. Health center patients deserve the same benefits, regardless of if remote access is for medical or mental health FQHC services.

Health centers across the country have created innovative solutions during the pandemic to address chronic diseases and diabetes management, that many Medicare patients struggle with daily. For instance, health centers were able to overcome broadband challenges in rural areas by providing glucose monitoring meters that stored data even when patients were out of range. The combination of access to technology that addresses existing access challenges and PHE telehealth flexibilities at health centers enabled FQHC providers to adequately assess patients and provide comprehensive nutritional education to diabetic patients.⁶

NACHC strongly encourages CMS to revise the regulation at § 405.2463, to revise 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).

Additionally, CMS should amend cost reporting instructions to ensure the costs associated with services under (b)(2) and (b)(3) are included as “FQHC services” on the cost report. NACHC welcomes the opportunity to work with CMS to develop requirements including the 95 modifier for telehealth and additional specific HCPCS codes, to indicate what service is being provided within an FQHC visit. This will provide the opportunity for FQHCs to collect more robust data on the impact of virtual care on our patient population.

Audio-only

Health centers greatly benefited from the improved flexibilities surrounding audio-only telehealth. This mode of care reduced patient no-show rates, improved provider relationships with their patients, and allowed health centers to reach more vulnerable populations. Health centers are now well-positioned to further implement integrated telephone-based health care activities for chronic disease management, preventive care services, and expand access to behavioral health and social needs through the work done around the pandemic.

Health centers reported several important benefits from the use of audio-only telehealth.

- Nearly all health centers (92%) reported audio-only telehealth improved patient access.

⁶ <https://cdn1.digitellinc.com/uploads/nachc/articles/ce8243e9a656eb810810fb1c99712f4c.pdf>



- 85% said that audio-only care increased the ability to reach vulnerable populations, which is vital in making health care more equitable.
- 7 in 10 health centers stated that audio-only telehealth helped treat more patients with behavioral health and substance use needs.⁷

Video-assisted telehealth visits require both video-capable devices and adequate bandwidth to communicate, which many rural and low-income patients lack access to reliable broadband coverage. Patients in medically underserved communities who may have a smartphone or other device may have difficulties connecting or have limited technical knowledge. In these cases, a telephone may be their only connection to a provider, like a rotary phone. For patients with chronic conditions, audio-only check-ins can be done more frequently to better address challenges like poorly controlled diabetes or hypertension. Thus, removing the option of phone-only visits is likely to exacerbate existing health disparities.

To ensure health centers can continue to provide audio-only interactions, we encourage CMS to revise § 405.2469, FQHC supplemental payments. In particular, we would recommend revising paragraph (d) by adding that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of services defined under (b)(2) and (b)(3) or occurs between a MA enrollee and a practitioner as outlined in § 405.2463.

In-Person Service Requirement

NACHC appreciates the opportunity to provide feedback on a 6-month in-person service requirement for FQHC mental health services. It is important to note that on its face, CAA 2021 Section 123 does not have any impact on FQHC visits because it applies to only Part B “telehealth.” Furthermore, the in-person visit requirement in Section 123 was intended as a precondition for waiver of the originating site requirements for telehealth.

Health centers should have the flexibility to determine if an in-person service requirement for mental health services furnished by FQHCs via telecommunications is necessary for their patient population. There are over 1,400 health centers nationwide, that serve patients in rural and medically underserved communities. NACHC believes there is no “one size fits all” approach to in-person service requirements due to workforce shortages and competition with virtual medical practices. For instance, some states with rural populations establish in-person service requirements to protect FQHCs from competition with virtual care only providers. In contrast, some rural areas benefit from no in-person service requirements to accommodate the lack of public transportation and provider availability. If CMS ultimately implements an in-person requirement, it should be longer than 6 months to create maximum flexibility for health centers.

⁷ Id.



FQHC Hospice Services

Health centers value building life-long relationships with their patients and having the opportunity to deliver compassionate care by providing medical and emotional support for patients with terminal diseases and may include hospice care. NACHC appreciates CMS codifying the statutory provisions in Section 132 of the CAA 2021 in 42 CFR 405, to reflect that hospice attending physician services are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient at the time of hospice election as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished. However, NACHC encourages CMS to align FQHC policies with other Medicare providers and permit patients to change their attending provider after they have made their initial election to receive hospice benefits. CMS has the authority to provide more flexibility for health center patients to ensure they have the provider of their choice during every step of hospice care.

Thank you for your consideration of these comments. If you have any questions, please contact Vacheria Tutson, Director of Regulatory Affairs at vtutson@nachc.org.

Respectfully,

Joe Dunn
Senior Vice President
Public Policy & Research