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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

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:

Bi-State Primary Care Association (Bi-State) appreciates the opportunity to provide input on the Notice of Proposed Rulemaking.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 21 Federally Qualified Health Centers, one Look-Alike, one Rural Health Clinic, Planned Parenthood of Northern New England, Vermont Coalition of Clinics for the Uninsured, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in both Vermont and New Hampshire. All our provider members provide a wide range of services, including mental health and substance misuse services and have a high level of collaboration with other providers within their community.

Bi-State's members have served on the front lines of the COVID-19 pandemic providing not only comprehensive primary care services, but also testing for COVID-19 and vaccinating against the virus. In response to community need, our members have expanded mental health and substance misuse services and offered emergency dental when few practices were open. Notably, our members expanded nascent telehealth programs to ensure patients had access to services when in-person was not viable. Telehealth services, audio/visual and audio-only, enable our practices to provide equitable care to their patients. The patients we serve are universal in their appreciation of this modality of care delivery. We have also experienced success in patients accessing mental health services via telehealth where they previously were reticent to seek care. Telehealth services are now a necessary component in caring for our patients, especially in the rural parts of our two states.

Bi-State appreciates 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.
- Bi-State 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.
- Bi-State encourages CMS to provide maximum flexibility for health centers implementing in-person service requirements for patients receiving virtual mental health services.

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. Our members diverted available resources to provide vaccinations to Medicare patients before CMS even established a COVID-19 vaccine administration reimbursement. Working with our respective states, we reached into our communities to ensure vaccine distribution was efficient and effective. Bi-State 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. We are grateful for this guidance and urge CMS to continue oversight on FQHC lump-sum payments to streamline communication between health centers and their MACs.

While FQHCs appreciate the lump-sum payments, they are only a temporary solution. Bi-State 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/third 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 will 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. We request that CMS 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

[1] 85 Fed. Reg. at 71,147.

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

Bi-State appreciates the opportunity to provide feedback on the resource costs associated with administering COVID-19 vaccinations at mass events. Bi-State 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 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. We have been fortunate to partner with local hospitals, departments of health, and other community providers to meet the need in our communities. 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. Bi-State encourages CMS to increase COVID-19 vaccine administration reimbursement for mass vaccination events that occur outside of the health center to reach vulnerable and underserved communities more effectively.

One example of community partnership comes from a Vermont health center who partnered with their local community mental health agency, schools, and hospital. This partnership enabled both testing and vaccination in rural pockets of the state and among hard-to-reach, reticent populations. This partnership enabled numerous at-risk individuals to receive the COVID-19 vaccine.

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.

Our practices were forced to limit 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. Bi-State 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-only[2]. 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 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. We have patients for whom travel is nearly impossible due to weather events – telehealth has allowed these patients access to care when roads were impassable. Additionally, telehealth allows patients to avoid taking a full day off work or school reducing barriers to access that disproportionately impact our patients. Between 2019 to 2020, telehealth services for nutrition and dietary counseling increase 337% and 102% for substance use disorder services[4]. 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

Bi-State believes 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). However, we appreciate CMS' willingness to extend its statutory authority to increase access for health center patients.

Bi-State 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. Bi-State 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.

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[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.

[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.

Importantly, the same inequities, potential interruptions of care, and negative consequences exist for Medicare patients receiving remote medical services during the PHE. Bi-State strongly encourages CMS to revise the definition of a "medical visit" for FHQCs 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 increased 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.

Bi-State 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. Bi-State 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.
- 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. [6]

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. 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.

Bi-State's members greatly appreciate the availability of audio-only services. They have noted that this enables them to care for those with limited access to the internet, which is still a challenge throughout our two states. Additionally, our mental health clinicians have identified new opportunities to engage younger residents in services as those teens prefer to engage without video.

[6] Id.

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

Bi-State 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. Bi-State 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.

Thank you for your consideration of these comments. Should you have any questions about these comments, please feel free to contact Georgia Maheras at gmaheras@bistatepca.org or 802-229-0002 ext. 218.

Sincerely,

Tess Kuenning
Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer