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September 6, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted at <https://www.regulations.gov/document/CMS-2022-0113-1871/comment>

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements

Bi-State Primary Care Association (Bi-State) appreciates the opportunity to provide input on the Calendar Year (CY) 2023 Medicare Physician Fee Schedule Proposed Rule.

Established in 1986, Bi-State is a nonpartisan, nonprofit 51(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.

Our organization is funded by the federal Health Resources and Services Administration's (HRSA) to provide training and technical assistance to all the Federally Qualified Health Centers (FQHCs) in Vermont and New Hampshire. Our members are part of the national network of FQHCs, which together provide affordable, high quality, comprehensive primary care to 30 million medically underserved individuals, regardless of their insurance status or ability to pay for services.

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 two years, fighting the spread of the virus in hard-to-reach communities, including communities of color and among special populations such as the elderly, people experiencing homelessness, and agricultural workers. They have tested, vaccinated, diverted non-acute cases from overwhelmed hospitals, and connected affected patients to housing, food, and critical services. Through the HRSA programs in 2021, health centers in Vermont and New Hampshire delivered nearly 28,000 COVID-19 vaccinations and nearly 58,000 COVID-19 tests. These health centers have also leveraged their respective

state programs to test and vaccinate many thousands more and continue to do so. They are currently ramping up clinics that will deliver both the bivalent COVID-19 booster and the seasonal flu shot.

As CMS continues to explore new innovative models and expand services for Medicare beneficiaries, it is imperative the agency is intentional about including FQHCs and explicitly amending our reimbursement regulations. Bi-State is appreciative of the agency's commitment to health equity and value-based care. We request that CMS ensures FQHCs are not stifled by regulatory red tape that limits access to valuable services for the most underserved patients based on lack of health center resources. In 2021, health centers provided mental health services to nearly 2.7 million patients, which included 29 million virtual visits. Bi-State strongly encourages CMS to consider health centers' unique patient population and critical work with underserved communities when developing solutions to address the growing mental health crisis and health care workforce shortage.

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

- **CMS has regulatory authority to permit FQHCs to provide remote services by revising the definition of medical FQHC "visit" to include services furnished using interactive, real-time, audio and video telecommunications, or audio-only interactions under defined circumstances.**
- **Bi-State strongly encourages CMS to utilize its full regulatory authority to amend the FQHC "incident to" regulations and FQHC mental health visit to include an encounter performed by a LPC and LMFT to generate a billable visit in Medicare to better align with Medicaid.**
- **Bi-State appreciates CMS's interest in potential Medicare Part B payment for services involving Community Health Workers (CHWs) and supports reimbursement models that contribute to the sustainability and success of their workforce at FQHCs.**
- **Bi-State applauds CMS for recognizing the need to maximize its authority to cover "medically necessary" dental care in Medicare.**
- **Bi-State appreciates CMS's efforts to provide additional resources necessary for the unique components of chronic care management (CCM) services. We strongly urge CMS to create billing codes that reflect the complexities often present with FQHC patients and provide variable reimbursement rates that reflect the varying levels of care management services needed.**
- **Bi-State strongly recommends that CMS increase the AIPs to attract more safety net providers to the MSSP and provide adequate upfront payments to support required infrastructure investments.**
- **Bi-State supports policies that recognize that the rapid assumption of downside financial risk has prevented many practices and ACOs that serve vulnerable populations from transitioning to value-based payment.**

Telehealth and Remote Access to FQHC Services

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

For two years, both patients and health centers have benefitted immensely from Medicare's public health emergency (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

end of the PHE. Even as Americans start to transition back to their normal activities, the demand for telehealth services has continued to grow. In 2021, over 26 million patients benefitted from access to virtual FQHC services. Health centers' main priority is to provide uninterrupted comprehensive care for their Medicare patients. *Bi-State strongly urges CMS to revise the FQHC medical visit definition prior to the end of the PHE to avoid consequential gaps in care for some of the most vulnerable Medicare patients.*

Bi-State recognizes the agency's hesitation to amend FQHC medical visit regulations based on "temporary provisions" under the PHE. We urge CMS to consider the consequences if Medicare patients cannot receive virtual FQHC medical services due to lapse in coverage and reimbursement. Due to the cessation of regulatory flexibility 152 days after the PHE ends, Medicare patients that *choose* to utilize FQHC services will not have access to the same virtual services that Medicare beneficiaries currently enjoy. FQHC and providers should have the same flexible use of different care modalities as other providers under the PFS to provide clinically appropriate care in ways that best meet the needs of their 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.

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). As seen by the PFS CY 22, CMS does have the authority to amend the "visit" definition. *Bi-State encourages CMS to use its authority, vested by Congress, to broaden the FQHC visit definition to include virtual capabilities for medical visits.* In New Hampshire and Vermont, nearly a third of our patients are Medicare beneficiaries, receiving essential preventive and primary care services at their local health centers. The same patients who benefit from receiving mental health services through remote access often require that similar access to medical services. Previously, CMS has cited proven benefits of virtual care, 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 whether the remote access is for medical or mental health FQHC services.

Bi-State believes CMS has the regulatory authority to revise the regulation at § 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). 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.

Lastly, Bi-State urges CMS to permanently amend the definition of "direct supervision" to allow supervising professionals to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. It is critically important that CMS amend the FQHC definition of "direct supervision" to match the PFS definition. In 2022, like many health care facilities, nearly 68% of health centers reported losing 5-25% of their workforce in the last six months. However, health centers are experiencing unique workforce challenges related to competition with larger health care organizations. In a 2022 NACHC survey, more than 50% of health centers estimate that their employees who left for a financial opportunity at a competing health care organization were accepting 10-25% wage increases in competing offers. Amending the "direct supervision" definition to include virtual presence will allow health centers to utilize providers across multiple sites to meet growing patient demand.

Proposed Revisions to the “Incident to” Physicians’ Services Regulation for Behavioral Health Services

Bi-State strongly encourages CMS to utilize its full regulatory authority to amend the FQHC “incident to” regulations and FQHC mental health visit to include an encounter performed by a LPC and LMFT to generate a billable visit in Medicare to better align with Medicaid.

Health centers treat patients for a range of mental health conditions, including depression and mood disorders, anxiety and PTSD, ADHD, and more. Patients can also visit health centers for aid in recovering from substance use disorders (SUD), including for medication-assisted treatment. In 2021, health centers provided care to over 2.7 million patients with mental health care needs and nearly 285,000 patients with SUD. The number of mental health professionals at health centers has grown over 240% since 2010, reaching a total of 15,154 practitioners in 2021. Additionally, 32% of the health centers’ mental health workforce are licensed mental health providers that do not meet the current statutory list of Medicare billable providers.

Bi-State appreciates CMS’s commitment to supporting and strengthening the Medicaid and Medicare workforce. As the agency explores regulatory solutions, it is critical CMS intentionally reviews and amends FQHC regulations in concert with providers paid under the PFS. Health centers commonly employ licensed professional counselors (LPCs) and Licensed Marriage and Family Therapists (LMFT) to expand their behavioral health services. Currently, health centers are permitted to generate a FQHC Medicaid billable visit for LPCs in over 30 states and for LMFTs in about 25 states. *Bi-State strongly encourages CMS to utilize its full regulatory authority to amend the FQHC “incident to” regulations and FQHC mental health visit to include an encounter performed by a LPC and LMFT to generate a billable visit in Medicare to better align with Medicaid.*

Under the current regulations, a qualifying FQHC mental health “visit” must be comprised of face-to-face or virtual contact directly with a core provider to trigger a billable service. Auxiliary personnel services, like LPCs and LMFTs, are included in the health centers’ allowable service costs and would not generate a separate billable encounter for their time. The changes under this proposed rule would not create a financial benefit for FQHCs nor meaningfully contribute to reducing the mental health workforce shortage at health centers due to the lack of reimbursement. *Bi-State strongly urges CMS to amend the FQHC mental health “visit” definition, at 42 CFR 405.2463(b)(3), to include encounters (for HCPCS codes that qualify as mental health per the FQHC Specific Payment Codes) comprised of services performed by auxiliary personnel incident to the services of a physician, NP, PA, CNM, CP, or CSW. This amendment to the “visit” definition would recognize encounters that are carried out under the “incident to” authority as billable mental health “visits.”*

The FQHC PPS statute, (SSA Section 1834(o)), *does not* specify that the unit of payment for FQHC PPS be restricted to face-to-face or virtual interactions directly with a core provider. Bi-State believes CMS has the authority to recognize encounters that are carried out under the “incident to” authority as billable mental health “visits.” All the services carried out would still fall within the statutory FQHC benefit (comprising core practitioners’ services and services “incident to” those services, along with certain preventive services). Additionally, CMS should revise the FQHC “incident to” regulations 42 CFR 405.2413 (physician incident to services), 42 CFR 405.2415 (incident to services and direct supervision), and 42 CFR 405.2452 (services incident to clinical psychologist and clinical social worker services) to allow for general supervision for behavioral health services carried out by auxiliary personnel on an “incident to” basis. These revisions are necessary for the “incident to” standards in the FQHC regulation to remain in

alignment with the “incident to” standards under the PFS regulation, at 42 CFR 410.26. Accordingly, CMS should align the two sets of regulations in this instance, as well, by clarifying in the FQHC regulations that general supervision is permissible for “incident to” mental health services. The following regulations would need to be revised:

- 42 CFR 405.2413(a)(5) (because physicians may supervise auxiliary personnel in carrying out mental health services under the “incident to” framework).
- 42 CFR 405.2415(a)(5) (to change from general to direct supervision for NP, PA, CNM, CP, CSW “incident to” services).
- 42 CFR 405.2452(a)(5) (to provide that mental health “incident to” services may be carried out under the general supervision of a CP or CSW).

Bi-State strongly urges CMS to make the above recommendations to ensure consistency across the PFS and FQHC regulations. This will ensure health centers’ ability to provide comprehensive and accessible behavioral health services is optimized. This is particularly important for patients that are dually eligible for Medicare and Medicaid. As safety net providers, it is important health centers are not penalized for our separate reimbursement structure and can participate and benefit as CMS continues to innovate in the mental health space.

Request for Information: Medicare Part B Payment for Services Involving Community Health Workers

Bi-State appreciates CMS’s interest in potential Medicare Part B payment for services involving Community Health Workers (CHWs) and support reimbursement models that contribute to the sustainability and success of their workforce at FQHCs.

CHWs are often members of the communities in which they work, which makes them uniquely equipped to connect patients to community-based resources and help address barriers patients face in continually accessing the care they need. CHWs may be part of the FQHC multi-disciplinary care team, and their responsibilities can include:

- Determining resources available in the community and completing an action plan prior to the patient visit.
- Facilitating referrals to community resources based on patient needs.
- Case management and follow-up between patient visits.
- Health education and translation services.

In 2021, health centers employed nearly 1900 CHWs and identifying funding to support CHW positions is a constant challenge. CHW services are commonly supported by time limited grants from private foundations or governmental organizations that help develop and grow capacity at the health center, but do not deliver long term sustainability. A 2017 Kaiser Family Foundation survey of Medicaid managed care organizations found that 67% of plans used CHWs to address social determinants of health in the previous 12 months. CHWs in our communities are enabling family physicians to better address a patient’s identified social drivers of health (SDOH). CHWs provide key community connections and get at the root causes of challenges experienced by our patients. 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. In New Hampshire, the state is using American Rescue Plan Act funds to support CHWs in our communities. Similarly, in Vermont, the CHWs are funded by time limited sources. These are short-term solutions, however.

In the end, every patient, practice, and community is different. There is not a one-size-fits-all approach to addressing individuals' unique health-related social needs. Employing CHWs at the health center is one way to provide help and resources to patients. We look forward to working with CMS to explore ways in which Medicare Part B might better support inclusion of CHWs within primary care settings, including FQHCs. We also urge CMS to consider the ways in which it can support the development and use of community care hubs or other payer and provider agnostic centralized referral systems to ease the burden on all parties, including the community-based organizations best equipped to address patients' social needs. This model of utilizing a hub has been particularly valuable in Vermont for Patient-Centered Medical Home expansion.

Proposals and Requests for Information on Medicare Part A and B Payments for Dental Services

Bi-State applauds CMS for recognizing the need to maximize its authority to cover “medically necessary” dental care in Medicare.

Medicare's lack of dental coverage not only leaves oral health care unaffordable for millions of Americans, but it also exacerbates underlying racial, geographic, and disability-related health and wealth disparities; improved Medicare coverage for medically necessary dental care would help millions of people improve their health without having to make impossible financial tradeoffs and would mitigate some of these health inequities. Acting to maximize this authority as is being proposed and explored in this proposed rule would help people who need dental coverage the most. Overall, we strongly support the proposed clarification of CMS's authority on “medically necessary” dental coverage, and we will address several of the specific issues and questions that CMS has solicited input in the comments that follow.

Comment on Proposal to Clarify Interpretation of the Statutory Dental Exclusion

CMS proposes to clarify and codify the agency's interpretation that certain dental services may not be subject to the Medicare's payment exclusion for dental services under Section 1862 (a)(12) of the Act because they are “inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service.” This proposal is an important recognition and clarification of CMS's existing authority, which will help to ensure that Medicare beneficiaries can access and afford more of the dental care they need to advance their health. The Medicare statute does not bar payment for needed dental services in connection with the covered treatment of a medical condition. We agree with a wide array of stakeholders that CMS's existing interpretation of its authority in this area is unnecessarily restrictive and may contribute to inequitable access to dental services—and thus inequitable health outcomes—for Medicare beneficiaries. Moreover, this updated interpretation of authority would be consistent with coverage in other areas, such as the “medically necessary” exemption with respect to the statutory exclusion of payment for foot care.

We are pleased to see that CMS is considering dental coverage related to a variety of clinical scenarios, including certain surgical procedures, transplants, cancer treatments, diabetes and other chronic disease management, immunosuppression, heart disease treatments and other circumstances. There is strong legal consensus supporting the actions CMS has proposed, as well as adding coverage for additional medical scenarios that CMS is considering. Additionally, we know there is clinical consensus from many leading medical experts and professional associations about the importance of dental care in these and other medical treatments. We strongly support the proposed clarification and codification of existing authority, and, as discussed below, we encourage CMS to apply this authority in all settings and clinical circumstances where it is appropriate.

Clarifying and Codifying Payment Policies for Certain Dental Services

CMS proposes to clarify and codify existing examples of “medically necessary” dental coverage. Medicare’s dental policy already recognizes the following examples of dental services that are payable because they are integral to a covered medical service: the wiring of teeth when done in connection with an otherwise covered medical service, the reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, dental splints when used in conjunction with covered treatment of a medical condition, and an oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery. CMS also proposes to codify additional specific examples in which the proposed coverage standard applies, including dental examinations and necessary treatment performed as part of a comprehensive workup prior to organ transplant surgery, cardiac valve replacement or valvuloplasty procedures. *Bi-State supports CMS’s proposal to clarify and codify the existing examples of “medically necessary” dental coverage. We also support CMS’s proposal to recognize, as additional specific examples, dental examinations and necessary treatment performed as part of a comprehensive workup prior to organ transplant surgery, cardiac valve replacement, or valvuloplasty procedures.*

Care Management Services in RHC and FQHCs

Bi-State appreciates CMS’s efforts to provide additional resources necessary for the unique components of chronic care management (CCM) services. We strongly urge CMS to create billing codes that reflect the complexities often present in FQHC patients and provide variable reimbursement rates that reflect the different levels of care management services provided.

While health centers are required to capture the CPT code that represents the level of severity of the patient’s condition or time furnishing services and what level of provider furnished them, all CPT codes for the bulk of care management services (CCM, CCCM, PMC, BHI) are required to be billed by FQHCs under G0511. The rate for G0511 is set based upon the average FFS rate for a CMS defined list of services falling under G0511. This means that regardless of the severity of the patient’s condition, the amount of time spent treating them, and the level of provider education and training required for treatment, FQHCs will be compensated at the same rate for every patient across all existing care management services. Adding General BHI and Chronic Pain Management further dilutes the reimbursement to FQHCs under G0511 diminishing the fact that every patient is has unique needs with differing requirements in the time their care takes, and the skill level needed of their provider. It is critical that health centers can benefit from and participate in new FFS billing policies and alternative payment models as time progresses. *Bi-State urges CMS to evaluate current CCM codes and billing rates to ensure health centers are receiving adequate reimbursement to support their workforce and innovation.*

Additionally, *Bi-State encourages CMS to permit health centers to provide CCM and BHI to a patient in the same calendar month and receive separate reimbursement for each service.* As discussed in the proposed rule, CMS recognizes the value to patients by furnishing certain care management services during the same calendar month. However, G0511 is billable, by definition, once per calendar month. In 2021, CMS allowed CCM and BHI to be furnished and billed for in the same calendar month. The current proposal does not permit health centers to take advantage of the opportunity to allow General BHI to be furnished and billed during the same calendar month as CCM and for CPM to be furnished and billed for during the same calendar month as BHI/General BHI and CCM. Bi-State encourages CMS to intentionally consider FQHC billing codes and reimbursement when developing policies to increase access to mental health services.

Medicare Shared Savings Program

Bi-State applauds CMS for prioritizing health equity in the Medicare Shared Savings Program (MSSP) and creating resources to support safety net providers' transition into value-based care arrangements. Health centers are well positioned to be leaders in the value-based care space, and help CMS reach their goal to have all traditional Medicare beneficiaries participating in value-based care models by 2030. For decades, health centers 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. The transition to alternative payment models must work for diverse providers, serve to improve health equity, and be sustainable for participating providers. Safety net and small community providers face unique barriers to implementing new value-based payment models. Many of these models require significant up-front investments that safety net providers may be unable to make. It is important CMS understand the complexities related to health center patients, providing care in rural and medically underserved areas, and common barriers for safety net providers. Below are key considerations to support health centers growing into value based care arrangements and strengthening their ability to take on risk.

Optional Advance Investment Payments to Certain ACOs in Underserved Communities

Bi-State supports the concept of Advance Investment Payments (AIPs) but has concerns about the amount of funding and allowable uses under MSSP. Our experience with value based payment arrangements, both MSSP and Medicare Next Gen, indicates that there significant resources are needed to support the required infrastructure, workforce, and technical assistance health centers need to be successful. Bi-State is concerned the proposed \$250,000 is the same as the payment made to AIM model participants in 2016 and does not reflect the rising costs of providing health care and inflation. It is imperative that health centers participating in eligible low-revenue ACOs can directly benefit from AIPs, or other mechanisms, to ensure they have the necessary health IT infrastructure and workforce to meet the unique needs of their patients. *Bi-State strongly recommends that CMS increase the AIPs to attract more safety net providers to the MSSP and provide adequate upfront payments to support required infrastructure investments. Additionally, Bi-State urges CMS to consider expanding access to AIPs for ACOs that recently entered the MSSP or other Medicare value based care arrangements.*

Smoothing the Transition to Performance-Based Risk

Bi-State applauds CMS for recognizing the challenges safety net providers experience progressing through the MSSP as they transition to performance-based risk models. Alternative Payment Models should account for the higher costs associated with caring for underserved populations and must not penalize ACOs that spend more to invest in primary care, target historical and ongoing health inequities, and address social determinants of health. The rapid transition to downside risk accelerates the speed with which ACOs must develop and hone the skills and capabilities required to succeed in value-based payment arrangements. The result of this has caused ACOs to drop out of the program after the first three years, undermining the goals of value-based payment.

Health centers incur unique risks by providing care to all patients regardless of their ability to pay. They are also strategically placed in medically underserved areas to serve those patients. It is critical that CMS considers health centers' "risks" when evaluating how and when they transition into models that assume more downside risk. *Bi-State supports policies that recognize that the rapid assumption of downside financial risk has prevented many practices and ACOs that serve vulnerable populations from transitioning to value-based payment.* Providing practices with additional opportunities to participate in value-based payment arrangements, including non-ACO models, is an important step in advancing health equity.

Additionally, it is imperative CMS considers health center-specific challenges with maintaining required attribution rates for safety net providers.

Benchmarking Methodology Adjustments

Bi-State encourages CMS to create equity-motivated benchmark adjustments to support additional funding for ACOs that include safety net providers like CAHs, RHCs, FQHCs, and REHs. As noted by CMS, these adjustments would not only act to correct resource disparities but also establish incentives for ACOs to attract underserved groups with enhanced care.

Quality Measures

Bi-State appreciates CMS's incorporation of a health equity adjustment and is supportive of adding the low-income subsidy to its calculation. *We recommend that CMS apply the health equity adjustment to ACOs that report via the Web Interface. An ACO's population does not differ based on the reporting mechanism and restricting the adjustment to just ACOs that report via the APP does not align with the intent of the adjustment.* Ensuring all types of practices have opportunities to transition to a more sustainable payment model is critical to promoting a more equitable health system. Without viable opportunities, practices will be left in a payment system that does not provide adequate support and serve as a mechanism to perpetuate inequities.

Thank you for your consideration of these comments. If you have any questions, please contact Georgia Maheras, Senior Vice President of Policy and Strategy (gmaheras@bistatepca.org).

Sincerely,

Tess Kuenning

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