ABHW
Advancing Health Care Policy for
Mental Health & Substance Use Disorders

September 9, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2439-P
PO 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; CMS–1807–P.

Dear Administrator Brooks-LaSure:

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM or proposed rule) for the Medicare and Medicaid Programs: Calendar Year 2025 Payment Policies Under the Physician Fee Schedule (CY25 PFS or PFS) and Other Changes to Part B Payment and Coverage Policies.

ABHW is the national voice for payers managing behavioral health insurance benefits. Our member companies provide coverage to approximately 200 million people in both the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness. We aim to increase access to timely, quality, and appropriate care, drive integration, support prevention, advance health equity, raise awareness and reduce stigma, and foster evidence-based treatment and innovation. Across the nation, the opioid crisis has been exacerbated by the COVID-19 pandemic, and the barriers to access to Medication for Opioid Use Disorder (MOUD) treatment have further come to the forefront. We believe that enhancing access to MOUD is more critical than ever.

I. Telehealth

ABHW supports the expansion of coverage for evidence-based telehealth services and removing unnecessary barriers to telehealth care delivery. We understand that CMS has limited authority and must defer to Congress to make telehealth flexibilities more permanent. However, some current Medicare laws and regulations unnecessarily limit access to and coverage of telehealth services and should be permanently changed. In particular, ABHW continues to advocate for Congress to remove the in-person requirement for MH services via telehealth. Requiring in-person visits can be a barrier to accessing necessary care, especially for individuals with MH conditions. This mandate will exacerbate

healthcare disparities and impede access for rural populations, older adults, and low-income residents. A blanket requirement for in-person sessions may hinder access for those unable to travel for in-person care or those concerned about the stigma of receiving MH services.

CMS made some noteworthy proposals in the CY25 PFS, which we have highlighted below:

1. Direct Supervision Through Audio- Visual

CMS is proposing to continue to:

- Define direct supervision to permit the supervising practitioner's presence and "immediate availability" through real-time audio and visual interactive telecommunications through December 31, 2025.
- Extend its current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually (for example, a three-way telehealth visit, with the patient, resident, and teaching physician all parties in separate locations) through December 31, 2025.
- Allow a subset of services required to be furnished under the direct supervision of a physician or other supervising practitioner, permanently adopt a definition of direct supervision that allows the physician or supervising practitioner to provide such supervision through real-time audio and visual interactive telecommunications.

ABHW supports these advancements but reinforces our commitment to permanently adopting virtual supervision through real-time audio-visual technologies. There is no evidence that patient safety is compromised by virtual direct supervision for behavioral health services. Additionally, virtual direct supervision has helped alleviate the burden on the already limited and strained provider workforce. The US does not have enough MH professionals to meet the demands of the current MH crisis and must adopt measures that increase the utility of and reduce the burdens on the existing workforce. According to the Health Resources and Services Administration (HRSA), as of March 2023, 163 million Americans live in MH professional shortage areas (HPSAs), with over 8,000 more professionals needed to ensure an adequate supply. For example, while nearly one-third of the US population is Black or Hispanic, only about a tenth of practicing psychiatrists come from these communities.[1] Adopting virtual supervision permanently will help maintain the critical availability of services for Medicare beneficiaries.

2. Permanent Expansion of Audio-only Telehealth

CMS proposes to permanently expand the allowable forms of telehealth "interactive telecommunications systems" to include audio-only communication technology if the patient is incapable of, or does not consent to, using video technology. The new definition

[1] https://data.hrsa.gov/topics/health-workforce/shortage-areas

permits the use of audio-only equipment for all telehealth services (not just MH services) furnished to established patients in their homes if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of or does not consent to, the use of video technology.

ABHW is grateful that CMS already reimburses audio-only telehealth services for diagnosing, evaluating, or treating MH disorders furnished to established patients when the originating site is a patient's home. This was made permanent in the Consolidated Appropriations Act of 2021 (CAA 2021) and included in the 2022 PFS. **We support expanding coverage for appropriate audio-only telehealth services. However, ABHW advocates that audio-only services be evaluated, as there is insufficient evidence to support the appropriateness of audio-only for applied behavioral analyses, psychological testing, and group therapy. CMS should also assess quality standards and protections against fraud, waste, and abuse.**

Please see below regarding our support for CMS's proposal for audio-only telehealth technology at Outpatient Treatment Programs (OTPs).

II. Outpatient Treatment Programs (OTP):

ABHW applauds CMS for the provisions in this proposed rule that seek to streamline access and delivery of MOUDs. **We strongly support allowing OTPs to utilize telehealth services.**

1. Audio Only

CMS proposes to extend the use of audio-only for periodic assessments by OTPs to the extent permitted by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) and only if video is unavailable. **ABHW fully supports this proposal and urges CMS to make this provision permanent.**

2. Extended for Methadone Treatment

CMS proposes permanently extending current telehealth flexibilities for periodic assessments and the initiation of methadone treatment. **ABHW supports the change to allow methadone treatment via an audio-visual telehealth visit. We agree with the distinction between audio-visual and audio-only visits, as Methadone's risk for sedation in patients makes this distinction appropriate while enabling increased access to needed care.**

3. Opioid Agonist and Antagonist Medications

CMS proposes to establish payment for new opioid agonist and antagonist medications that the Food and Drug Administration (FDA) approved recently. Specifically, the rule would create a new add-on code to the bundled payment to reflect take-home supplies for nalmefene hydrochloride (nalmefene) nasal spray (Opvee®) and for a new extended-release injectable buprenorphine product (Brixadi®).

ABHW supports expanding access to opioid treatment medication for generic nalmefene hydrochloride and extended-release buprenorphine products. However, we advise CMS not to directly identify specific pharmaceutical brands to reimburse in the final PFS rule.

III. Advancing Access to Behavioral Health

1. Digital Mental Health Therapies

CMS proposes Medicare payment for billing practitioners for digital therapeutics that:

- Treat MH conditions;
- Are cleared by the FDA;
- Are furnished incident to or are integral to professional behavioral health services; and
- Are used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care.

ABHW believes digital therapeutics are beneficial and can positively impact treating MH and SUDs. Digital Mental Health Therapies (DMHTs) are a tool to eliminate gaps in behavioral health care by increasing efficiency and accessibility, addressing stigma, and helping support behavioral health provider shortages. Many ABHW members currently contract with DMHTs as they can help providers make more informed treatment decisions and improve patients' lives by offering better ways to manage their MH and SUD conditions.

However, some available digital solutions have limited evidence to support their effectiveness and medical necessity. This could be due to shorter or smaller scale studies, not having control groups, or having control groups that show comparable improvement. Studies may also be subject to selection bias, as those participants have circumstances that enabled their access to digital therapeutics that contribute to the marked improvements.

There cannot be a one-size-fits-all approach to regulating the safety and efficacy of digital therapeutics – a wide range of digital applications support numerous MH and SUD treatment functions. As a result, there are instances in which a non-FDA-approved therapy may be effective and should be considered for coverage. **ABHW supports coverage for digital therapeutics and appreciates the need for guardrails around what should be covered. This includes some solutions evaluated and approved by the FDA as safe**

and efficacious for the conditions or symptoms they are proven to address. However, classification as a prescription digital therapeutic by the FDA shouldn't be the only means of approval for a DMHT. Additionally, work should be done to identify that digital therapeutics have evidence of medical appropriateness and will be medically beneficial to ensure that they are cost-effective and can be implemented effectively.

2. Safety Planning Interventions (SPI) and Post Post-Discharge Telephonic Follow-Up Contacts

ABHW supports suicide prevention through evidence-based screening and safety planning templates. Additionally, our members feel that there needs to be an evidence-based continuum of crisis care and stabilization services for individuals experiencing a behavioral health crisis. Ensuring crisis response and sustaining effective crisis care is vital nationwide and critical to advancing equity.

CMS has proposed a new payment for safety planning interventions (SPI) and post-discharge follow-up contact (FCI) for patients with elevated suicide or overdose risk. ABHW generally believes that designated billing codes for SPI and FCI and associated insurance payments should help expand the use of these evidence-based suicide prevention practices. It will create a standard system to document whether these interventions are furnished when indicated, allowing for quality improvements. However, the current proposals should be improved in order to be more easily operationalized.

It would be helpful to clearly define where and how SPI and FCI fall on the behavioral health crisis continuum. Behavioral Health "crisis " and "emergency" services are not perfectly synonymous. There are crisis situations where the crisis services are not emergency services.

A) SPI – Evidence Based

ABHW supports enabling evidence-based SPI. Many emergency departments (EDs) report furnishing some SPI-related services, but only a small fraction report furnishing all the components of evidence-based SPI. These components must be listed as required service elements for billing SPI, as in CMS' current proposal, because this incentivizes providers to furnish—and document—these elements.

The current proposal requires that for patients receiving care in an ED, safety planning must be conducted by the same practitioner, i.e., the emergency physician, or that the patient also receives a psychotherapy visit with the emergency department. Neither of these options reflects typical ED practice nor how safety planning has been staffed in research-based or real-world safety planning intervention programs. **ABHW supports permitting safety planning to be furnished not only by the licensed provider who furnishes the visit when an elevated suicide risk is identified but also when ordered by a licensed provider. Moreover, safety planning should also be able to be furnished by an appropriate member of the practice's staff or emergency department licensed**

practitioner, such as a nurse with safety planning training, under the supervision of the licensed provider.

CMS' current proposal should be modified in several ways:

- Permit additional types of staffing for SPI, including:
    - By a licensed practitioner (i.e., a type of practitioner who is permitted to bill Medicare, such as physicians, advanced practice nurses, PAs, clinical psychologists, LCSWs)
    - By appropriate types of clinical staff, under the supervision of a licensed practitioner (i.e., the licensed practitioner would order and supervise SPI, while a practice or hospital clinical staff member would furnish the SPI).

- Support more than 20 minutes of SPI, e.g., by permitting a 20-minute SPI code to be billed multiple times based on the actual duration of the SPI service.

B) Follow Up Contacts

CMS's current proposal for FCI is constructive and consistent with research-based and real-world FCI programs. CMS invites input on the number of months for FCI to be supported. **ABHW members feel that, based on available evidence, including from the ED-SAFE trial, three months of follow-up contacts would be appropriate.**

3. Interprofessional Consultation Billed by Practitioners Authorized to Treat Behavioral Health Conditions

CMS is proposing six new interprofessional consultation codes that can be billed by providers who cannot independently bill Medicare for Evaluation/Management (E/M) visits (e.g., clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors). Providers would need to obtain patient consent before providing these services. The new codes would facilitate interprofessional consultations between treating/requesting practitioners and consultant practitioners. **ABHW supports extending E/M payment to allow those listed providers to conduct interprofessional consultations with psychiatrists and other physicians.**

CMS intends to integrate these six new G codes to enhance behavioral health specialty treatment integration into primary care and other settings. ABHW fully supports the Collaborative Care Model; however, it is unclear whether this proposal advances its adoption. **Specifically, ABHW requests clarity on how this would be distinct from or whether there would be interplay with the Collaborative Care Model.**

IV. Intensive Outpatient Program (IOP) Request for Information (RFI)

ABHW members have witnessed fraud in some SUD treatment facilities regarding licensure, accreditation, administrative and billing practices, quality, and enrollment. As a

result, as CMS considers outlining how freestanding SUD facilities could bill Medicare under the PFS, we request that CMS issue the following:

- Develop a clear operational definition of recovery homes that accurately delineates recovery home services from IOP services.
- Ensure all facilities are licensed and fully accredited to provide SUD services.
- Identify, disseminate, and adopt quality standards, best practices, and model policies to ensure appropriate patient care and treatment.
- Examine fraudulent administrative and billing practices of these facilities.

Additionally, we recommend that CMS align its approach to IOP with the American Society of Addiction Medicine (ASAM) Criteria 4th Edition, released in December 2023.[2]

Thank you for the opportunity to comment on the behavioral health provisions in the CY25 PFS. ABHW is committed to working with CMS and other partners to improve access to behavioral health treatment for all Americans. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,

Pamela Greenberg, MPP
President and CEO

[2] https://www.asam.org/asam-criteria