BY ELECTRONIC DELIVERY

September 13, 2021

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS-1751-P -- 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.

Dear Administrator Brooks-LaSure:

The undersigned organizations dedicated to health equity and mental health appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS') proposed rule updating Medicare payment and refining policies under the Physician Fee Schedule (PFS).

The undersigned organizations are aligned in their commitment to advancing health equity, especially in mental health and substance disorder where issues of equity are particularly pronounced. We believe that digital therapeutics (DTx), which "deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease," provide an important opportunity for promoting health equity by offering a critical option for individuals who otherwise would not be able to access effective mental health and substance use care.[1] We write to urge CMS to either (1) clarify that the payment mechanisms within the PFS, including the newly-created remote therapeutic monitoring codes, are sufficient to enable patient access to DTx that address mental health and substance use disorders; or (2) implement alternative payment and coding mechanisms that are sufficient. We similarly urge the Agency to permanently enable individuals with mental health care needs to access that care through audio-only telemedicine services.

CMS has recently recognized the tremendous toll the COVID-19 Public Health Emergency (PHE) has taken on the American public with respect to mental health and substance use disorder. Even before the COVID-19 PHE, approximately 44 million US adults suffered from mental health

[1] Digital Therapeutics Definition and Core Principles. Digital Therapeutics Alliance. Nov 2019. https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf

conditions with a steadily increasing prevalence.[1] The issues of health equity are particularly pronounced in mental health, where Black adults, and particularly Black women, are more likely than white adults to report emotional distress, such as sadness, hopelessness and feeling like everything is an effort. Despite the need for mental health care, fewer than 1 in 3 Black women receive it. In addition, Black women and girls are: less likely to receive guideline-consistent care, less frequently included in research, and more likely to use emergency rooms or primary care (rather than mental health specialists).

There is also a substantial relationship between mental health and substance use disorders, and many people are subject to both. The 2017 analysis of the National Epidemiological Survey on Alcohol and Related Conditions (NESARC) revealed that of adults reporting "alcohol dependence," 54% had experienced an anxiety disorder in their lifetime and 34% had experienced a personality disorder in their lifetime.[2] According to the 2016 Surgeon General's report on substance use disorders, "…of the 20.8 million people aged 12 or older who had a substance use disorder during the past year, about 2.7 million (13 percent) had both an alcohol use and an illicit drug use disorder, and 41.2 percent also had a mental illness. It is estimated that 30-60 percent of patients seeking treatment for alcohol use disorder meet criteria for PTSD and approximately one third of individuals who have experienced PTSD have also experienced alcohol dependence at some point in their lives."[3]

Workforce shortages keep mental health and substance use care out of reach for most Americans however, with the greatest impacts in communities of color:

- Primary care providers (PCPs) are responsible for 60% of mental healthcare, and prescribe 79% of antidepressants with ***little to no specialist services or support***.
- In 2018, 56.7% of the overall US population reported receiving ***no treatment*** for their mental health conditions.
- Treatment deficiencies for Black and Latinx adults are even more pronounced -- 69.4% (Black) and 67.1% (Latinx) report that they receive no treatment for their mental health conditions.
- Black and Latinx patients also frequently terminate treatment prematurely, and generally receive less culturally responsive care than white patients.

We know that meeting people where they are - whether with vaccines or mental health services - improves health. Digital therapeutics (DTx) can be an important option for extending access to mental health and substance use care and improving health equity, but only if effective DTx are utilized and paid for. We believe that digital therapeutics offer a modality of care that can be more accessible to Black women and girls and other communities that have been traditionally underserved. DTx can not only offer mobility and access to evidenced-based

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[2] Grant BF, Chou SP, Saha TD, et al. Prevalence of 12-Month Alcohol Use, High-Risk Drinking, and DSM-IV Alcohol Use Disorder in the United States, 2001-2002 to 2012-2013: Results From the National Epidemiologic Survey on Alcohol and Related Conditions. JAMA Psychiatry. 2017;74(9):911–923. doi:10.1001/jamapsychiatry.2017.2161

[3] Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (samhsa.gov)

solutions, but have potential for additional benefits of privacy (reducing the patient's concerns about stigma), consistency (reducing potential biases associated with a live therapist) and impartiality.

The Food and Drug Administration's (FDA's) April 2020 guidance recognized the potential crisis of increased patient care needs in mental health and substance use disorder meeting a health system without provider capacity to address those needs. That guidance permitted marketing of certain DTx used to address mental and behavioral health and substance use disorder during the PHE. Notwithstanding the FDA emergency action and demonstrable need for expanded access to every available treatment option, the integration of these devices into "mainstream" medical practice is generally limited. To the extent that communities of color and other underserved populations are aware of these tools, access is conditioned on patients having the financial means to absorb their costs or the time to research, identify, and navigate manufacturer access programs.

As coding and payment are essential elements toward availability of DTx, we appreciate CMS' thoughtful approach to considering implementation of, and payment for, remote therapeutic monitoring (RTM). Non-physicians, including nurses, may be more accessible to patients. RTM also appears to allow self-reported information and non-physiological data. Providers, including those within the primary care setting, should be compensated for their time discussing DTx with patients, evaluating the appropriateness of a particular tool, and monitoring patient adherence and response to treatment. **The undersigned organizations urge CMS to specify that RTM codes can be used to support the use of effective DTx, increasing equity in access to effective mental health care.**

In addition, meeting people where they are, especially for Black women, includes telephone-only services for mental health care. The increased accessibility for low-income and rural patients, and those who are otherwise on the wrong side of the digital divide is significant; audio-only also allows those with other reasons - including lack of privacy due to scheduling constraints, etc - to be able to get the care they need when they need it. Patients are in the best position to be able to determine if audio-only is appropriate; we believe that documentation of patient preference should satisfy CMS requirements. The **undersigned organizations urge CMS to ensure that audio-only mental health and substance use care does not face additional barriers than those ultimately put in place for telehealth.**

We also appreciate CMS's proposal to allow RHCs and FQHCs to report and receive payment for telehealth visits in the same manner as current in-person visits beyond the COVID-19 PHE. We thank CMS for including audio-only visits in the proposed language when the beneficiary is not capable of or does not consent to the use of video technology. These additional flexibilities beyond the PHE will likely increase convenience and access to mental health care for this under-served community.

In the same vein, CMS must be fiscally responsible and should only pay for DTx, remote therapeutic monitoring, and audio-only services when medically necessary. We believe that

these interventions should be evidence-based, implemented within a treatment plan, and actually used by the patient. **The undersigned organizations urge CMS to, in partnership with patients, develop a framework to support thoughtful coverage of effective DTx.**

Once again, the undersigned organizations appreciate the opportunity to comment on this CMS Proposed Rule, and we look forward to future discussions on how to address the care gaps and access inequities in mental health and substance use disorder.

Thank you for your attention and consideration of these comments.

Sincerely,

Black Women's Health Imperative
2020 Mom
American Foundation for Suicide Prevention
Center for Law and Social Policy
The Kennedy Forum
Maternal Mental Health Leadership Alliance
Mental Health America
National Alliance on Mental Illness