

June 16, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, SW
Washington, D.C. 20201

Re: Employing Digital Therapeutics to Help Address Mental Health & Substance Use Crises

Dear Secretary Becerra and Administrator Brooks-LaSure:

The undersigned organizations urge the Centers for Medicare & Medicaid Services (CMS) to build on President Biden's unprecedented support for behavioral health care in the American Rescue Plan by ensuring access to digital therapeutics for Americans with mental health and substance use disorders.

Preliminary reports from the Center for Disease Control & Prevention (CDC) indicate that more than 87,000 Americans died of drug overdoses over the 12-month period that ended in September, eclipsing the toll from any year since the epidemic began in the 1990s. Similarly, the incidence rate for suicide among Black Americans and people of color has increased markedly since the start of the COVID-19 pandemic and the total nationwide percentage of hospital emergency department visits linked to behavioral health crises has also escalated.

Digital therapeutics (DTx) have emerged as an innovative modality for expanding treatment options for patients facing any number of health conditions, with particular emphasis on mental health and substance use. Recognizing the potential crisis of increased patient care needs meeting a health system without provider capacity to address those needs, the Food and Drug Administration (FDA) released a guidance in April 2020 giving some of these devices permission to be marketed immediately during the Covid Public Health Emergency (PHE).

Notwithstanding the FDA emergency action and demonstrable need for expanded access to every available treatment option, the uptake of these devices into medical practice is generally limited because payment codes either do not exist or have not been appropriately clarified for clinicians to know whether and under what circumstances they can be used. Specifically, the lack of new coding for DTx or guidance on use of existing coding mechanisms has stymied clinicians in dispensing, ordering, or recommending DTx to their patients thereby severely reducing the intended effect of the April 2020 FDA enforcement policy changes.

We need your help to expedite an urgently needed set of pragmatic codes that do not place significant time and resource burdens on physicians to work through with payers, especially Medicaid. It is critical to recognize that codes that make caring for our patients as turnkey as possible for clinicians is the only way to meet the urgent need. These therapeutics are simply a new modality for delivering care that is covered when utilized in conjunction with clinician-provided care or under the auspices of a credentialed clinician. **We ask CMS to use all expedited processes at their disposal to quickly issue codes that are**

immediately and easily recognized and used by Medicare, Medicaid, and commercial payers for DTx utilized “incident to” a clinician’s service. We have also sent a similar request to the American Medical Association (AMA), recognizing their important role in the coding process, to CDC to advocate for use of all expedited coding processes, and to Congressional offices working on legislation that, we believe, must include all DTx interventions that are dispensed ordered, or otherwise used under the direction of a clinician within a plan of care. We emphasize that any language defining the set of DTx eligible for billing codes must focus on how they are used and integrated into patient treatment, and not turn on whether a manufacturer has sought and received FDA labeling that specifies “prescription use only.” When a clinician incorporates a DTx into their care plan for a particular patient, provides a product “key,” and instructs the patient on DTx use, there is no distinction between those that are and are not “prescribed.”

Finally, beyond the discrete issues discussed above, it is clear that CMS, the FDA and CDC need to engage in an interagency effort to chart a path forward. **We ask CMS to convene federal agencies, payers, providers, and consumers in a collaborative process to chart a path forward for DTx coverage that can promote mental health and substance use equity and address the growing crisis in America.**

Thank you for your attention to this important matter.

Sincerely,

American Association for Psychoanalysis in Clinical Social Work
American Association for the Treatment of Opioid Dependence
American Foundation for Suicide Prevention
Anxiety and Depression Association of America
Association for Ambulatory Behavioral Healthcare
Association for Behavioral Health & Wellness
C4 Recovery
Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)
Clinical Social Work Association
Depression and Bipolar Support Alliance
Global Alliance for Behavioral Health and Social Justice
Illinois Association for Behavioral Health
Inner Wisdom Public Policy Committee
International Society for Psychiatric Mental Health Nurses
Maternal Mental Health Leadership Alliance
Mental Health America
National Alliance on Mental Illness
National Association for Behavioral Healthcare
National Association for Children's Behavioral Health
National Association of County Behavioral Health and Developmental Disabilities Directors
National Association of Rural Mental Health
National Association of Social Workers
National Association of State Mental Health Program Directors
Reilly Group, Inc.
RI International, Inc.
Schizophrenia and Psychosis Action Alliance of America
2020 Mom

CC: Director Rochelle Walensky, Centers for Disease Control and Prevention
Acting Assistant Secretary for Mental Health and Substance Use Tom Coderre, Substance Abuse
and Mental Health Services Administration
Acting Director Regina LaBelle, Office of National Drug Control Policy