

February 28, 2022

Director Eric Lander
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Re: Strengthening Community Health Through Technology

Dear Mr. Lander:

I am writing on behalf of the American Psychological Association (APA). As requested by the Office of Science and Technology Policy (OSTP), APA is providing comments on the Request for Information (RFI) on Strengthening Community Health Through Technology. APA is the largest scientific and professional organization representing psychology in the United States. APA's membership includes over 133,000 researchers, educators, clinicians, consultants, and students. APA seeks to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

We appreciate OSTP soliciting information from a variety of interested stakeholders on how digital technologies can be used to improve, transform, and innovate community health. At no time in our history as a nation has this been more critical than now. The coronavirus pandemic has taken a toll on U.S. population's mental health and thus has expanded the need for mental health care. In April 2020, the average reported stress level for U.S. adults was 5.4 out of 10, compared with 4.9 of overall average stress level in the previous year ([APA, 2020a](#)). Six months into the pandemic, about three in ten psychologists (29%) reported seeing more patients, nearly three quarters (74%) reported increased demand for treating anxiety disorders, and 60% reported increased demand for treating depressive disorders ([APA, 2021b](#)).

Telehealth

The COVID-19 public health emergency (PHE) forced mental and behavioral health providers to find new ways to meet the needs of their patients as leaving home put patients and those with co-morbid conditions at risk of being exposed to the virus. In September 2020, about 96% of psychologists provided some or all services via telehealth and 33% worked with patients who lived in a different state than where they were licensed ([APA, 2021b](#)).

Without the waivers expanding the use of telehealth in Medicare, beneficiaries would have lost access to mental and behavioral health services at a time when their health, both physical and mental, was extremely vulnerable. APA thanks CMS for the flexibility extended under the waivers, such as making the home an originating site, adding more services to telehealth, and

allowing patients to use audio-only devices. APA believes the next step is to ensure that flexibility remains available to Medicare beneficiaries after the PHE comes to an end. CMS should continue its efforts to close gaps in access to mental and behavioral health services by continuing to allow patients from underserved communities—such as rural areas and communities of color—to access these services, often for the first time. For many patients seeking mental and behavioral health services, the availability of telehealth and audio-only services increases their ability to participate in treatment; for example, many people with disabilities either cannot drive and lack services to transport them to in-person appointments, or experience heightened anxiety during in-person appointments and require the familiarity of their own homes to fully engage in treatment. The availability of audio-only telehealth is particularly beneficial to many older patients who may lack the familiarity with or access to the technology necessary for an audio/video telehealth appointment.

Despite the rapid adoption of telehealth, many barriers to the delivery of mental health care remain to be addressed, including disparities in broadband access for older adults, marginalized racial/ethnic communities, and rural residents. While few are arguing that all telehealth restrictions should be permanently removed, at a minimum, ensuring that services can continue to be provided in the patient’s home, that audio-only services are reimbursed, and that all appropriate telehealth services are being reimbursed at the same rate as in-person services are critical changes to law and policies needed to address the population mental health needs as a result of the pandemic.

Mobile Mental Health Apps

The rapid growth of the mental health app space holds promise for addressing access to care and equity gaps, including stigma, cost, and lack of providers; however, the technology has, to date, outpaced the research in determining whether a product is effective and safe for consumers. APA advocates for the development and implementation of an evaluation framework, such as the one proposed recently by [AHRQ](#), that could be used by mental health organizations and advocacy agencies, consumers and families, health care providers, employers and payers, and app developers to better inform the utilization of these innovative treatment interventions. From a consumer protection standpoint, it is important that such apps not only demonstrate an evidence base but also have appropriate data privacy and security protocols, interoperability features and usability/accessibility consistent with the Federal Health IT Strategic Plan. Further, adoption of effective, evidence-based mobile mental health apps is likely to continue to be stymied due to the lack of a clear regulatory body overseeing these products, and inconsistent, or even non-existent, payment models to reimburse for their use. APA recommends that mobile mental health treatments products and services should be reimbursable to support integration into the U.S. health care landscape.

Digital Therapeutics

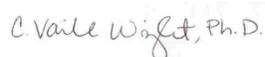
Increasing access to mental and behavioral health care via digital therapeutics is a priority for APA, as well as ensuring that psychologists and other non-physicians have access to utilize these innovative interventions with their patients. Mental health digital therapeutics involve the use of software programs to deliver evidence-based and validated interventions to treat or manage mental and behavioral health disorders, such as chronic insomnia and substance use disorders. They can be used independently or as an adjunct to medications or other therapies to optimize patient care and health outcomes. Digital therapeutics are not typically direct-to-consumer mental health apps you can download on your own.

By definition, digital therapeutics meet classification for [Software as a Medical Device](#) and, therefore, fall under FDA oversight. However, confusion abounds regarding what this oversight means, and a pervasive, but false, belief that a prescription digital therapeutic product can only be made available to patients through physicians, dentists and veterinarians who have prescribing authority under state law. Additional health care professionals have the ability to order the use of prescription medical devices including psychologists, speech language pathologists, and physical therapists.

We recommend that CMS and the FDA provide some clarity to manufacturers and other interested stakeholders by encouraging the inclusion of language that aligns with existing FDA statute for the device category ([21 CFR Sec. 801.109\(a\)\(2\)](#)) in new and existing FDA applications and any current or future federal legislation for digital therapeutics which provides in part that a device must be “sold only to or on the prescription **or other order of such practitioner** for use in the course of his professional practice.” Failure to include language both ‘ordered’ and ‘practitioner’ could have several significant unintended consequences in Medicare coverage that will drive access constrictions at a critical time for patients. For example, psychologists, counselors, and licensed clinical social workers treat mental health and substance use disorders but would not be able to incorporate digital therapeutics into their practice if legislation and manufacturer applications limits prescribing and ordering status to physicians. Further, a digital therapeutic does not need to be labeled as “prescription” in order to demonstrate it is evidence-based and effective, but such labeling would limit all practitioners’ treatment options, which only serves to amplify the existing workforce shortage in mental and behavioral health care and the need for more, not fewer treatment options for our patients.

APA wishes to thank OSTP for this opportunity to provide comments on the (RFI) on Strengthening Community Health Through Technology. If your staff have any questions, you are welcome to contact our Director of Operations and Innovation, Nicole Owings-Fonner, MA, PMP by email (nowings-fonner@apa.org).

Cordially,



C. Vaile Wright, PhD
Senior Director, Health Care Innovation, American Psychological Association