AMERICAN PSYCHOLOGICAL ASSOCIATION

February 27, 2023

The Honorable Melony Griffith, Chair
The Honorable Katherine Klausmeier, Vice Chair
Senate Finance Committee
Maryland General Assembly
Miller Senate Office Building - 3 East
Annapolis, Maryland 21401

Re: Support for SB 441 with Amendment

Dear Chair Griffith and Vice Chair Klausmeier,

I am writing on behalf of the American Psychological Association (APA), in support of SB 441, which is currently before your committee. However, we would request a small but important amendment to the bill requiring the Maryland Medical Assistance Program to cover prescription digital therapeutics (DTx) for program recipients to ensure that all qualified health care providers may order those products.

As further described below, we ask that the following language be added to the proposed definition of "prescription digital therapeutic" under Md. Code, Health-Gen. § 15-101(f-1)(4): "or order pursuant to the requirements under 21 C.F.R. § 801.109 or any successor regulation." This addition would ensure that eligible health care providers may access these products for their patients consistent with US Food and Drug Administration (FDA) requirements.

APA is the largest scientific and professional organization representing psychology in the U.S., with a membership of more than 146,000 clinicians, researchers, educators, consultants, and students. Psychologists provide critically needed mental health, substance use disorder, and health behavior services, including psychotherapy to diagnose and treat mental health and substance use disorder conditions, testing for patients needing cognitive assessments, and health behavior assessments and interventions for beneficiaries struggling with physical health problems.

Digital therapeutics are part of the evolving digital health space and recognized by the FDA as evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage or treat a medical disorder. DTx products deliver therapeutic services and treatments directly to patients via software (typically through web-based or mobile applications) that is clinically evaluated and proven to increase accessibility and effectiveness of health care services.

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Not to be confused with general health and wellness apps easily accessible by consumers through app stores, DTx products are prescription medical devices available by order of a qualified health care provider. Despite the use of the term "prescription," access to DTx is not limited to only prescribing providers and pharmacies. FDA regulations around prescribing medical devices are significantly different from the rules for prescribing drugs. They allow for licensed health care professionals beyond physicians, dentists and veterinarians to issue an order or a prescription of medical devices if the diagnostic or therapeutic activity in which the device would be used falls within the licensed scope of practice for the health care professional.

Furthermore, through the use of labeling restrictions, FDA regulations require that the DTx identify the broad category of healthcare professionals that can order the device, not limited to only those who have prescribing authority under state law.[1] Therefore, our proffered amendment would be consistent with current FDA guidance and would ensure that the full range of qualified health care providers may order the products for use with their patients. And by adding the term "order" to the definition of DTx, it would make clear that these products are not regulated the same way as prescription drugs and therefore, are not limited to physicians only.

In fact, there are numerous examples of prescription medical devices currently being ordered or provided to patients by licensed healthcare professionals beyond doctors, dentists and veterinarians. These include acupuncture needles ordered by acupuncturists, manipulation devices ordered by chiropractors, voice-level recorders ordered by speech language pathologists, certain concussion assessment tools ordered by athletic trainers, exoskeletons systems ordered by physical therapists, and devices that help patients breathe easier during a panic attack ordered by psychologists. All of these items are classified as a prescription medical device under FDA law and do not require the need for physician involvement.

With regards to DTx products, it is worth noting that the majority of current FDA cleared DTx products focus on mental and behavioral health disorders, specifically providing digital cognitive behavioral therapy interventions for issues including anxiety and depression, ADHD, insomnia, pain management and opioid/substance use.[2] These interventions fall squarely within psychologists' scope of practice, not just physicians. Therefore, it makes sense that psychologists and other eligible providers be able to order those DTx products to use with their patients consistent with FDA labeling requirements.

Our proposed amendment would ensure that psychologists and other providers would be able to continue accessing these products. And we believe that this is consistent with the bill's intent to

[1] FDA regulations -- 21 CFR Sec. 801.109(a)(2) – creates a prescription device category, providing in part that a prescription 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." The regulations also state that the required labeling for DTx products must include "The symbol statement 'Rx only' or '℞ only' or the statement 'Caution: Federal law restricts this device to sale by or on the order of a ___,' the blank to be filled with the word 'physician,' 'dentist,' 'veterinarian,' or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

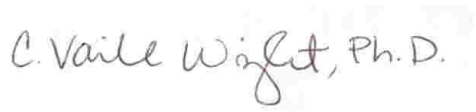
[2] See Digital Therapeutics Alliance DTx products library for current listings of approved products.

ensure that the Maryland Medical Assistance Program recipients are able to access the full range of evidence-based health care services and qualified providers.

We applaud Maryland for considering new approaches to ensure that people get the healthcare they need and deserve, particularly given the mental health crisis exacerbated by the COVID-19 pandemic. We urge you to support SB 441 with the requested amendment to ensure that all eligible providers may order (or prescribe) digital therapeutics for Maryland Medical Assistance Program recipients.

Please feel free to contact me at cwright@apa.org or Deborah Baker, JD at dbaker@apa.org should you have any questions on this issue.

Sincerely,



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

cc: Maryland Psychological Association