Gochenaur FINAL Pear Written Testimony - Maryland
Uploaded by: Angela Gochenaur
Position: FAV

TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Clarence K. Lam

FROM: Angie Gochenaur, Director of Government Affairs, Pear Therapeutics

DATE: February 28, 2023

RE: **SUPPORT** – Senate Bill 441 – *Maryland Medical Assistance Program - Prescription Digital Therapeutics*

Pear Therapeutics (US), Inc. ("Pear") welcomes the opportunity to provide public comment on Senate Bill 441 (Lam). Pear is a commercial-stage healthcare company pioneering a new class of software-based medicines, sometimes referred to as Prescription Digital Therapeutics ("PDTs"), which use software to treat diseases directly. Our vision is to advance healthcare through the widespread use of PDTs with an initial focus on supporting patients struggling with behavioral and mental health conditions. In particular, Pear's reSET® and reSET- O® are the first mobile applications to be authorized to treat disease by the FDA. These products specifically treat Substance Use Disorder ("SUD") and Opioid Use Disorder ("OUD"), respectively[1,2].

PDTs are prescribed by a licensed prescriber, either alone or in combination with drugs. Similar to pharmaceuticals, PDTs undergo rigorous clinical development via clinical trials designed to seek FDA authorization to safely and effectively treat disease. PDTs are evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. PDTs are only available via consultation with a licensed healthcare professional who then prescribes the digital therapeutic as clinically appropriate. PDTs are designed to expand access and convenience for patients and improve reach for clinicians. Additionally, PDTs may lower cost for payors by reducing and/or augmenting human intervention, providing for more efficient care. PDTs can help mitigate many treatment barriers by offering accessible and consistent evidence-based treatments, available to patients 24/7.

To treat serious disease, it is imperative that the treatments patients use are recommended by a licensed provider or fit within an existing care plan. Whether it is a pill, electronic device, or mobile app - treatments for serious disease must adhere to a high standard as patients trust these products to improve their health outcomes. Provider recommendation is important, yet there are hundreds of mobile apps that purport to help treat disease - and we know that providers do not have the time to vet all of them. FDA authorization provides a smaller set of already vetted products for providers to review - products which have been shown to have a statistical

correlation with positive health outcomes. Being prescription-only means that manufacturers cannot reach patients without the provider involved. In other words, the only way that manufacturers can support patient access is by educating providers and payers on the clinical value the product provides to patients. Products available directly to consumers can use direct-to-patient marketing techniques without undergoing the level of clinical rigor that PDTs are subject to. The incentives are therefore different for PDT manufacturers - where PDTs are judged by their clinical value to patients and other apps can be judged by their ability to market well to patients.

In summary, Senate Bill 441 is a bill which further expands Maryland's leadership role in pioneering the use of FDA authorized prescription digital therapeutics to treat serious disease. This bill further supports providers by giving them more evidence-based and vetted tools to support patients and does so in a way that integrates these tools directly into care plans for patients. PDTs can help make care more accessible for people who struggle with conditions and provide support in times when providers may not be available. Pear supports this legislation and applauds the state of Maryland for its continued commitments to patients.

Respectfully,
Angela Gochenaur
Director, State Government Affairs

References

1. reSET Clinician directions for use. Pear Therapeutics, Inc. 2020.
2. reSET-O Clinician directions for use. Pear Therapeutics, Inc. 2020.

SB0441 FAV_MedCHI - PH - MD Med. Ass. Prog. - Pres

Uploaded by: Christine Krone

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MedChi

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TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Clarence K. Lam

FROM: Christine K. Krone
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Andrew G. Vetter
410-244-7000

DATE: February 28, 2023

RE: **SUPPORT** – Senate Bill 441 – *Maryland Medical Assistance Program – Prescription Digital Therapeutics*

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **supports** Senate Bill 441.

Senate Bill 441 requires Medicaid to provide coverage for "prescription digital therapeutics." It defines "prescription digital therapeutics" as a product, a device, an internet application, or any other technology that: (1) is approved, cleared, or classified by the federal food and drug administration; (2) has an approved or cleared indication for the prevention, management, or treatment of a medical disease, condition, or disorder; (3) primarily uses software to achieve its intended result; and (4) can be dispensed only in accordance with a prescription.

Digital therapeutics are becoming increasingly popular in the delivery of health care. Common digital therapeutics are remote monitoring devices that help patients manage diseases and conditions such as hypertension or diabetes. These remote monitoring devices allow practitioners and patients to perform ongoing virtual monitoring and treatment and have also provided practitioners with more accurate and consistent results. For example, patients with hypertension who experience anxiety leading up to an in-person appointment will yield higher than normal blood pressure results. Remote monitoring allows for an accurate reading while the patient is in the comfort of their own home. Similarly, managing diabetes with blood glucose monitoring can be performed using various types of non-invasive remote patient monitoring devices. Practitioners can use the data captured by a remote blood glucose monitoring device to detect potential alarming changes in glucose levels and take immediate action. Overall, digital therapeutics have the potential to transform the way we deliver healthcare, making it more accessible, personalized, and effective. MedChi urges a favorable report.

LAM_SB441_FAV.pdf
Uploaded by: Clarence Lam
Position: FAV

CLARENCE K. LAM, M.D., M.P.H.
Legislative District 12
Anne Arundel and Howard Counties

Finance Committee
Executive Nominations Committee

Joint Committee on Ending Homelessness

Senate Chair
Joint Audit and Evaluation Committee
Joint Committee on Fair Practices and State Personnel Oversight

Chair
Howard County Senate Delegation
Secretary
Asian-American & Pacific-Islander Caucus

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Support of SB 441 Maryland Medical Assistance Program - Prescription Digital Therapeutics

The Issue:

- A shortage of healthcare providers, particularly in primary care, that mostly affects rural and low-income communities
- An aging population that requires greater healthcare needs
- A lack of emphasis on preventative care that leads to the development of more chronic health conditions and more emergency department visits
- An expensive healthcare system with few low-cost treatment options

What are Digital Therapeutics (DTx)?

- Technology that uses software primarily to deliver evidence-based interventions to prevent, manage, or treat a disease
- Must undergo randomized controlled clinical trials that demonstrate safety and efficacy
- Must be authorized for use by the Food and Drug Administration (FDA)
- Must adhere to current Good Manufacturing Practices
- Must be prescribed by a provider

The Benefits of Digital Therapeutics:

- Low cost
- Usually can be used anywhere at any time
- Customizable to the needs of the patient
- Increases the timeliness and accuracy of clinical decisions made by providers

Examples of Digital Therapeutics:

- Somryst is an app that uses cognitive behavioral therapy (CBT) to treat adults with chronic insomnia
- Welldoc makes digital coaching apps that empower patients to self-manage chronic conditions, such as diabetes, while keeping the provider informed
- Woebot is a chatbot app that provides counseling to patients with adolescent or postpartum depression
- MedRhythms uses music to improve mobility in patients with neurological conditions, such as Parkinson's disease

What SB441 Does:

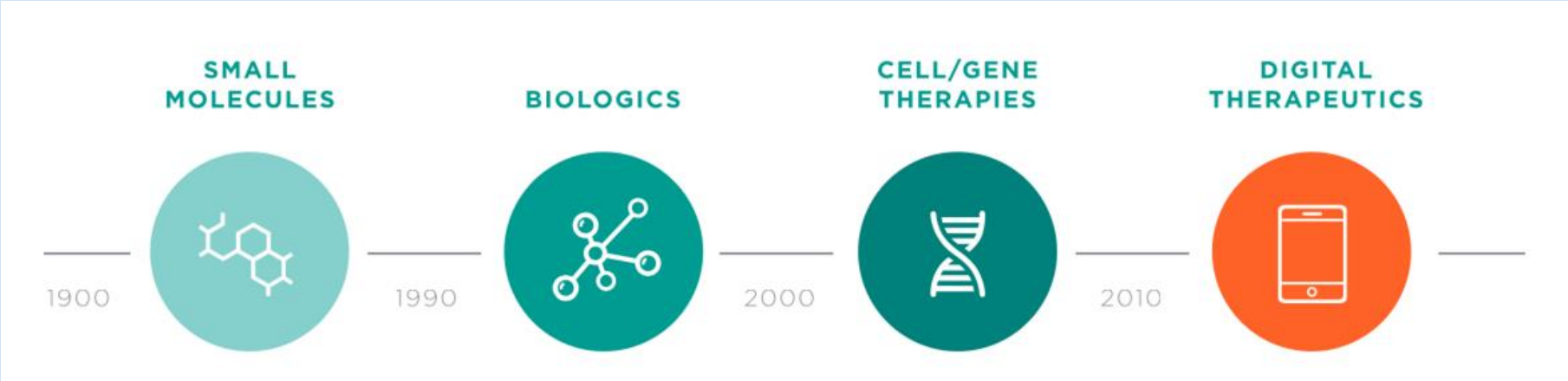
SB441 requires the Maryland Medical Assistance Program to provide coverage for prescription digital therapeutics, thus increasing access to DTx for a greater number of patients and helping bridge any gaps in care.

Lam_SB441_Slides.pdf
Uploaded by: Clarence Lam
Position: FAV

SB441: Maryland Medical Assistance Program – Prescription Digital Therapeutics

Senator Clarence Lam, District 12

The Evolution of Medical Therapy



Source: https://peartherapeutics.com/science/prescription-digital-therapeutics/

Digital Therapeutics Criteria

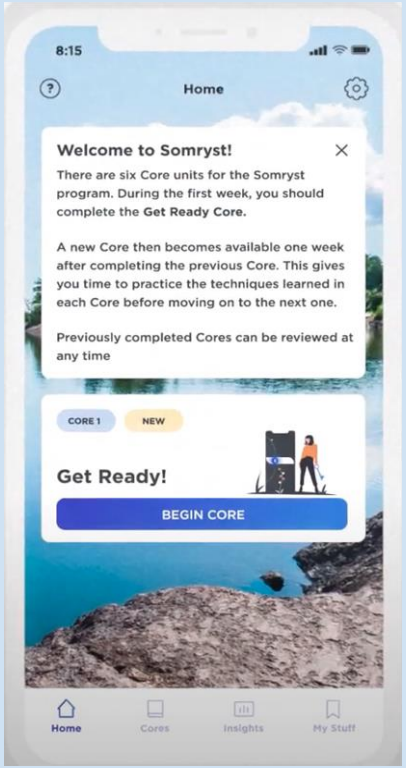
Prescription Digital Therapeutics, or PDTs, are a new therapeutic class.

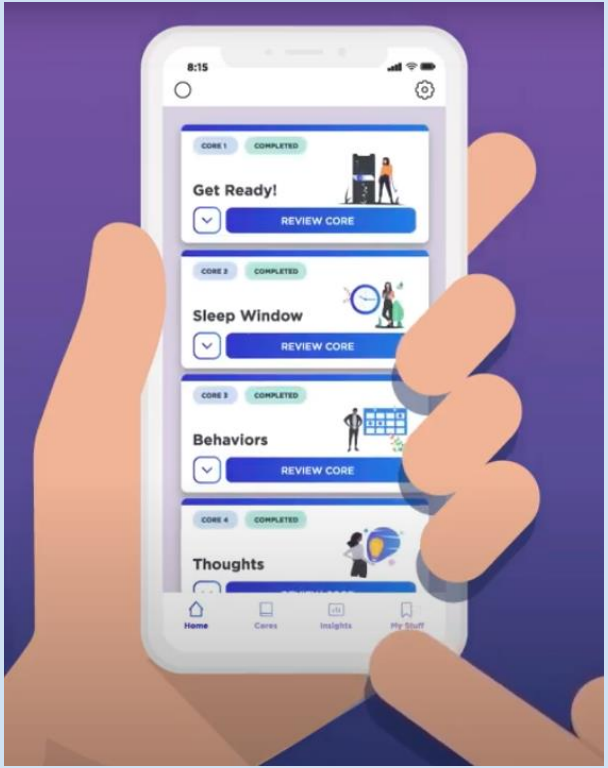
Similar to traditional biologics or drugs, PDTs:

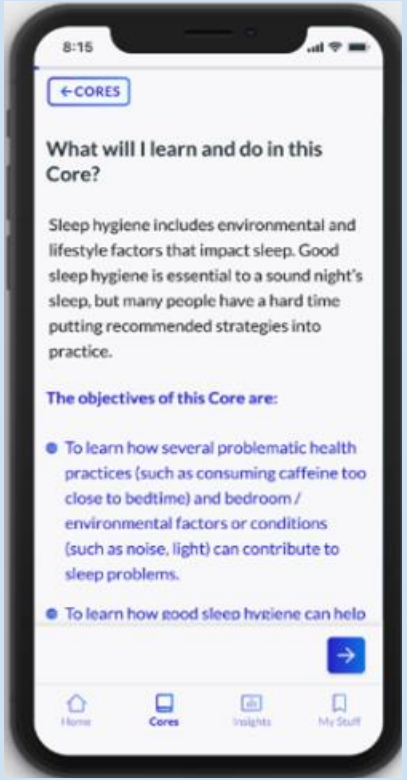
- Directly treat serious diseases
- Are built under current Good Manufacturing Practices
- Demonstrate safety and efficacy in randomized clinical trials
- Receive labeled claims from the FDA
- Are used by physician prescription

Source: https://peartherapeutics.com/science/prescription-digital-therapeutics/

Somryst – For Chronic Insomnia in Adults



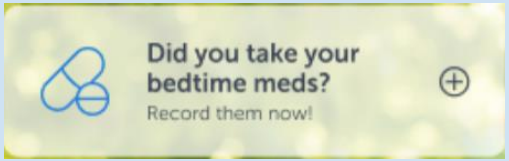


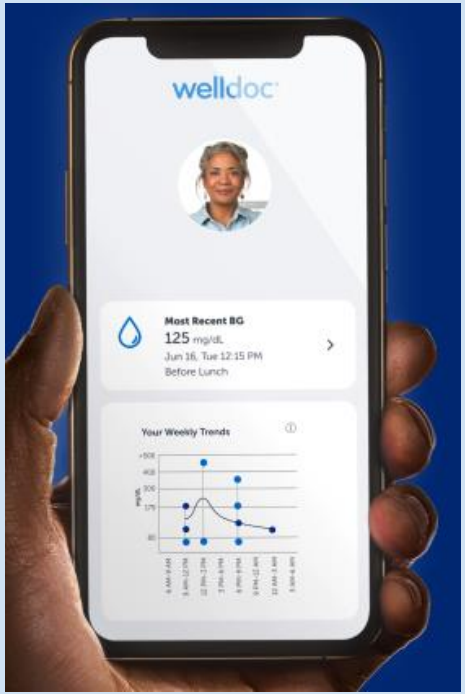


Source: https://www.somryst.com

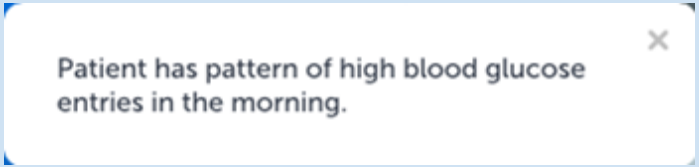
Welldoc - For Diabetes, Hypertension, and Heart Failure

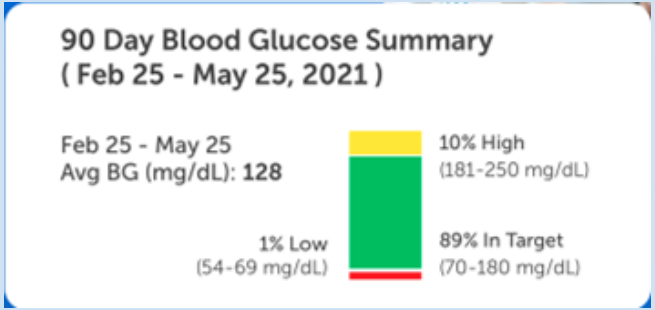
For the Patient





For the Provider

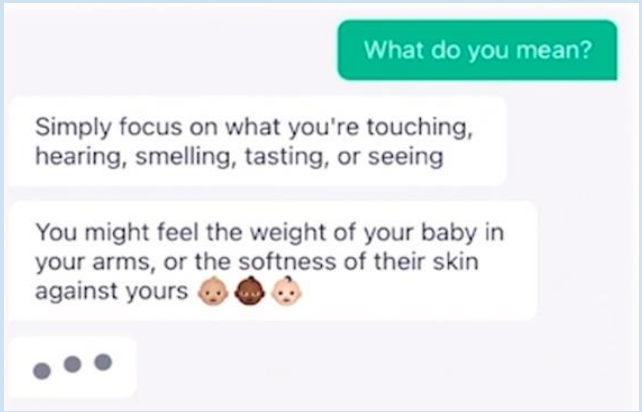


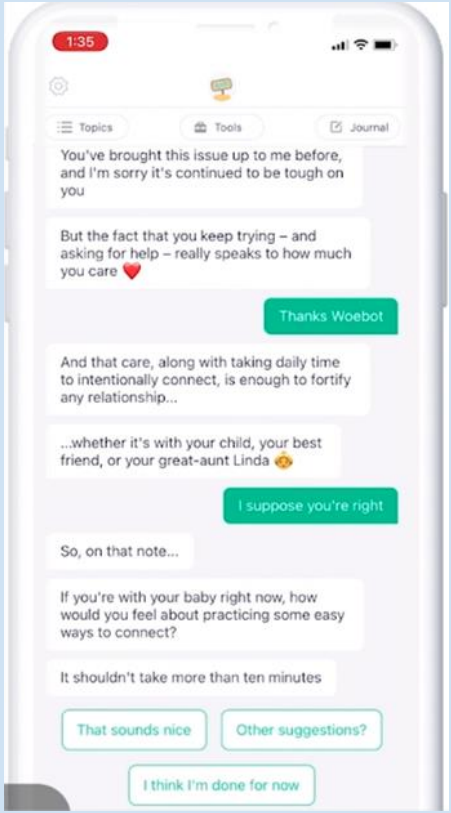


Source: https://www.welldoc.com

Woebot - For Adolescent Depression and Postpartum Depression

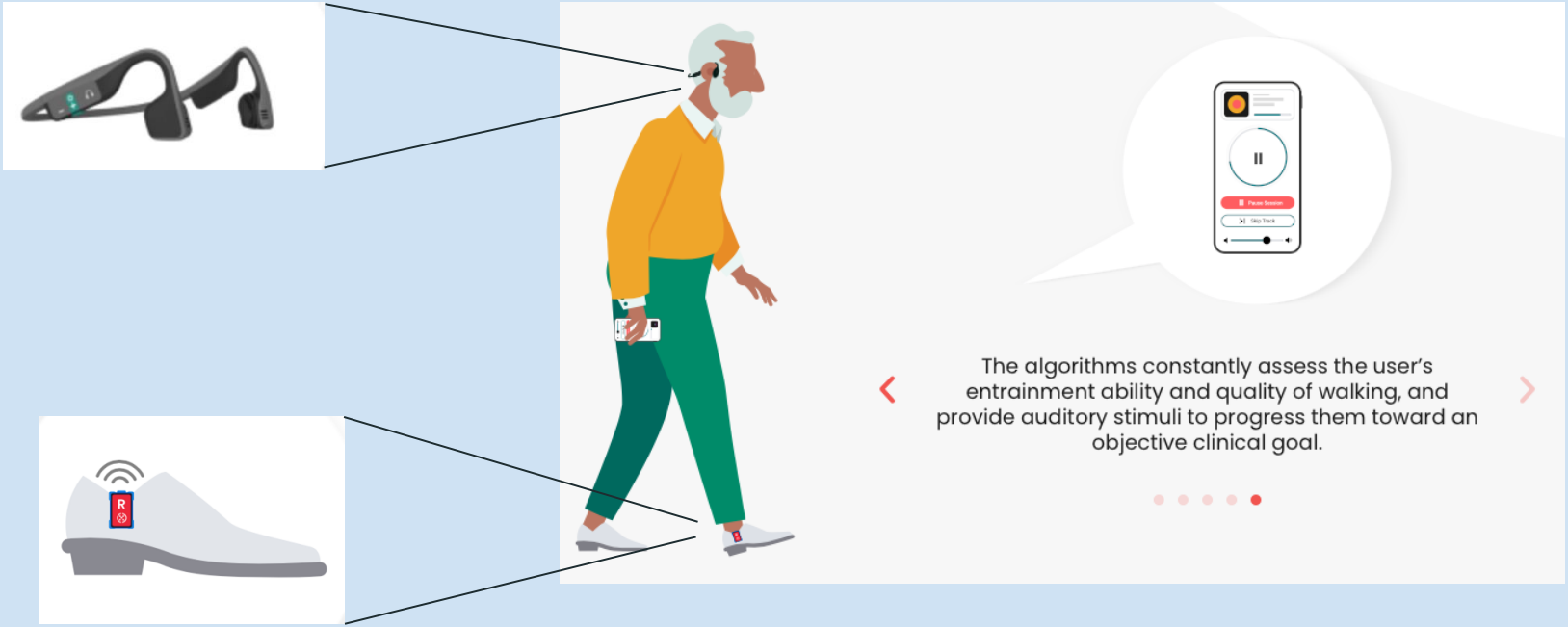
A natural conversation powered by AI that meaningfully engages





Source: https://woebothealth.com/postpartum-depression/

MedRhythms - For Stroke, Multiple Sclerosis, and Parkinson's



Source: https://medrhythms.com/technology/#platform

SB0441 digital therapeutics.pdf
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Senate Bill 441 Maryland Medical Assistance Program - Prescription Digital Therapeutics
Senate Finance Committee
February 28, 2023
TESTIMONY IN SUPPORT

The Mental Health Association of Maryland is a nonprofit education and advocacy organization that brings together consumers, families, clinicians, advocates and concerned citizens for unified action in all aspects of mental health and substance use disorders (collectively referred to as behavioral health). We appreciate the opportunity to provide this testimony in support of Senate Bill 441.

SB 441 requires the Maryland Medical Assistance Program to provide coverage for prescription digital therapeutics.

Demand for mental health care is at an all-time high. A 2021 report from the Maryland Behavioral Health Administration identified a 35% increase in total suicide attempt emergency department visits from 2020-2021 across all age groups, including a 46% increase in children and a 40% increase in Marylanders over 65.[1]

At the same time, the state is working to address a persistent and longstanding behavioral health workforce shortage. Federal data[2] released just this month found that Maryland has 63 federally designated mental health professional shortage areas (HPSAs)[3], including 11 entire counties. These shortage areas, in which less than 20% of residents are getting their mental health needs met, impact over 1.7 million Marylanders. Another indicator found that 17 of Maryland's 24 jurisdictions come in below the national average (350:1) in terms of population to mental health providers, with a number that are considerably lower.[4]

Digital mental health treatments (DMHTs) can help. They provide an effective and scalable method for extending the reach of quality mental health care. DMHTs support patients and clinicians in managing mental health through the use of smartphone and Web applications, with growing research investigating therapeutic video games, virtual reality, and conversation agents.[5] Research has shown that DMHTs are effective for treating PTSD and depression/anxiety with mild, moderate, or severe symptoms; DMHT treatment efficiency for common mental health conditions is comparable to standard face-to-face therapies; and they

[1] Behavioral Health Administration Update to the Maryland Behavioral Health Advisory Council, November 16, 2021.
[2] https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport
[3] A HPSA is a geographic area, population group, or health care facility that has been designated by the US Health Resources and Services Administration (HRSA) as having a shortage of health professionals in one of three categories – primary care, dental health, and mental health
[4] https://www.countyhealthrankings.org/explore-health-rankings/maryland?year=2022&measure=Mental+Health+Providers&tab=1
[5] Psychiatric Services doi: 10.1176/appi.ps.202000561. https://ps.psychiatryonline.org/doi/10.1176/appi.ps.202000561

are shown to be effective across the lifespan, with a growing number of studies indicating effectiveness among children and adolescents, as well as older adults.[6]

A recent forum of national and international experts representing health care organizations, insurance companies and payers, employers, patients, researchers, policy makers, health economists, and more called for expanded access to and reimbursement for DMHTs, and a broad integration of these therapies into the U.S. health care landscape.[7]

An increasing demand for mental health care amidst a persistent behavioral health workforce shortage calls for new and innovative solutions. **For these reasons, MHAMD supports SB 441 and urges a favorable report.**

[6] Id.
[7] Id.

MATOD - 2023 SB 441 FAV - Digital Therapeutics - S

Uploaded by: Joshua Grollmes

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Senate Finance Committee
February 28, 2023
Support of Senate Bill 441
Maryland Medical Assistance Program – Prescription Digital Therapeutics

The Maryland Association for the Treatment of Opioid Dependence (MATOD) urges a favorable report on Senate Bill 441.

On December 10, 2018, the Food & Drug Administration (FDA) approved mobile medical applications to help increase retention in outpatient treatment program. Per FDA Commissioner Scott Gottlieb, "As part of our efforts to address the misuse and abuse of opioids, we especially focused on new tools and therapies that can help more patients with opioid use disorder successfully treat their addiction. Medical devices, including digital health devices like mobile medical apps, have the potential to play a unique and Important role in contributing to these treatment efforts."

Addiction is a chronic relapsing disease that needs continuous support and easy access to treatment. Digital health devices that are available by prescription offer a cognitive behavioral therapy to help the patient abstain from substance use and to help them stay in treatment. Prescription digital health devices are available for use with opioids, alcohol, THC, cocaine. Patients need all the tools available to keep them engaged. This is an option to support patients to remain in treatment and help them succeed.

For these reasons, we urge your support of Senate Bill 441.

MATOD members include community and hospital based Opioid Treatment Programs, local Health Departments, local Addiction and Behavioral Health Authorities and Maryland organizations that support evidence-based Medication Assisted Treatment. MATOD members include thousands of highly trained and dedicated addiction counselors, clinical social workers, physicians, nurse practitioners, physician assistants, nurses, peer recovery specialists and dedicated staff who work every day to save and transform lives.

NCADD-MD - 2023 SB 441 FAV - Digital Therapeutics

Uploaded by: Nancy Rosen-Cohen

Position: FAV

Senate Finance Committee
February 28, 2023

Senate Bill 441
Maryland Medical Assistance Program - Prescription Digital Therapeutics
Support

NCADD-Maryland supports Senate Bill 441 to require Medicaid cover digital therapeutics available by prescription. Prescription digital therapeutics are a new and growing technology that is being used to help people with various kinds of diseases and conditions. We are lucky that there are products on the market to help people with substance use disorders including people with opioid use disorders. This is a new tool that can be utilized to stop the growing number of overdose deaths in Maryland.

These additional tools are proven effective as they are authorized by the Food and Drug Administration (FDA) and provide a different kind of support that works for many people. People who are in treatment do not have access to their counselors or therapists 24/7. This kind of application on an individual's phone or tablet allows them access to a program that, for example, could help them with strategies when they experience cravings.

Many of us use all kinds of these wellness applications and some of us find them very helpful. But those applications that we buy on the app store do not come with any kind of proof of efficacy. Further, there is no requirement that your personal data remain private. These digital therapeutics that are authorized by the FDA, meaning they are available only by prescription and only when medically necessary, are proven effective and have to be compliant with HIPAA laws when it comes to data privacy.

States are figuring out how to cover this new technology. The federal government is working on guidance on developing the right path to coverage. Private insurance companies are beginning to cover these products and the state must consider how we can make them available to people enrolled in Medicaid.

We urge a favorable report on Senate Bill 441.

The Maryland Affiliate of the National Council on Alcoholism and Drug Dependence (NCADD-Maryland) is a statewide organization that works to influence public and private policies on addiction, treatment, and recovery, reduce the stigma associated with the disease, and improve the understanding of addictions and the recovery process. We advocate for and with individuals and families who are affected by alcoholism and drug addiction.

National Council on Alcoholism & Drug Dependence – Maryland Chapter
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DTA- SB0441 Testimony .docx.pdf
Uploaded by: Sara Elalamy
Position: FAV

DIGITAL THERAPEUTICS ALLIANCE

The Honorable Melony Griffith
The Honorable Katherine Klausmeier
Miller Senate Office Building
Annapolis, Maryland 21401

RE: SB0441 - Maryland Medical Assistance Program - Prescription Digital Therapeutics

Chair, Vice-Chair, and Members of the Committee,

On behalf of the Digital Therapeutics Alliance, we are pleased to SUPPORT your SB0441, which would define "prescription digital therapeutic" as a product, a device, an Internet application, or any other technology approved by the federal Food and Drug Administration that has an approved indication for the prevention, management, or treatment of certain medical conditions, primarily uses software to achieve results, and requires a prescription. This bill also requires the Maryland Medical Assistance Program to provide coverage for prescription digital therapeutics for Program recipients.

The Digital Therapeutics Alliance (DTA) was founded in 2017 as a 501(c)(6) non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on DTx thought leadership and education, DTA provides patients, clinicians, payors, and policymakers with the necessary tools to evaluate and utilize DTx products.

Digital therapeutics are transforming healthcare by increasing patient access to safe and effective therapies, by extending clinicians' ability to care for patients, and offering payors scalable and cost-effective interventions.

There are currently 9 FDA approved DTx products, which are prescribed by your healthcare provider and intended to supplement but not replace visits, and unlike the general health apps you see on your phone, these DTx products are proven effective by the FDA and protected under HIPAA.

Digital therapeutics range in capabilities-- from calculating insulin doses to delivering cognitive behavioral therapy, these platforms can help track and manage symptoms as well as improve medication adherence.

To describe just a few—

Freespira is an FDA-cleared therapeutic that incorporates a proprietary sensor, physiological feedback display, and coaching to train patients over 28-days to normalize the respiratory irregularities underlying a key physiological driver of anxiety attacks and PTSD symptoms.

The impact of this PDT? Users were 86% panic attack free immediately post-treatment and 73% panic attack free at 12 months post-treatment. As for PTSD, At 6-months post-treatment, 89% reported significant decrease in symptoms based on CAPS-5 Score (validated PTSD assessment) and 50% were in remission.

Then there is Nervivio, which is a wireless wearable neuromodulation unit controlled by a smartphone app. Treatments with Nerivio are self-administered by the user at the onset of a migraine attack.

The impact? 7 migraine patients out of 10 using Nerivio saw significant pain relief; 4 out of 10 experienced pain freedom.

And EndeavorRx, which is a digital therapeutic indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue.

Patients who engaged with EndeavorRx demonstrated improvements in a digitally assessed measure of sustained and selective attention. EndeavorRx demonstrated improvements in ADHD impairment with responder rates ranging 48*-50%** after 1-month treatment and 68%** following a second month of treatment.

These digital therapeutics work and this bill would help patients access them. For these reasons, we respectfully request your support for SB 411.

MDDCSAM - 2023 SB 441 FAV - Prescription Digital T

Uploaded by: Scott Whetsell

Position: FAV

Maryland-DC Society of Addiction Medicine
A Chapter of American Society of Addiction Medicine

Senate Bill 441 - Maryland Medical Assistance Program - Prescription Digital Therapeutics

SUPPORT

Senate Finance Committee

February 28, 2023

MDDCSAM is a chapter of the American Society of Addiction Medicine (ASAM) and represents physicians and associated healthcare professionals from different disciplines with expertise in treatment of addiction. Our goals are to diagnose, treat, and advocate for people with the chronic disease of addiction and its related problems.

MDDCSAM supports Senate Bill 441, which would require Maryland Medicaid to add to its benefit coverage of digital therapeutics available by prescription. The demand for mental health and substance use disorder treatment continues to outpace access. To effectively meet the behavioral health needs of our patients, we must take advantage of all the evidence-based tools available. Prescription digital therapeutics (PDTs) are one such evidence-based solution.

PDTs are authorized by the FDA, which means they've been proven to be effective. Since the first PDT was authorized in 2018, about a dozen more have been authorized, including those for mental health and substance use disorders.

As Addiction Medicine physicians and other healthcare professionals, we recognize the importance of PDTs as useful, evidence-based treatment extenders. Via clinical software, PDTs offer patients 24/7 access to validated behavioral treatments, while also offering patient engagement and tools for tracking patient progress for the providers who prescribe them. However, many patients, particularly those with low socioeconomic status, are denied access to these tools due to the absence of insurance coverage. Absence of Medicaid benefit coverage for PDTs risks furthering already existing income, race, and ethnicity-associated inequities in treatment access.

Given that Maryland continues to see an increase in the number of people dying from overdoses, we believe all effective tools should be available to providers and patients. We urge your support for Senate Bill 441.

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2023 MD SB 441 - APA DTx Testimony.pdf
Uploaded by: C. Vaile Wright
Position: FWA

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.

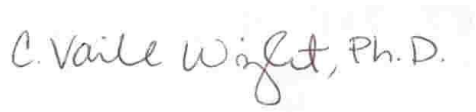
[2] See Digital Therapeutics Alliance DTx products library for current listings of approved products.

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

MPA Testimony 2023 - Support with Amendments - Sen

Uploaded by: Paul Berman

Position: FWA

MARYLAND PSYCHOLOGICAL ASSOCIATION

10480 Little Patuxent Parkway, Ste 910, Columbia, MD 21044. Office 410-992-4258. Fax: 410-992-7732. www.marylandpsychology.org

February 27, 2023

Senator Melony Griffith, Chair
Senator Katherine Klausmeier, Vice Chair
Finance Committee
Miller Senate Office Building, 3 East
Annapolis, MD 21401

RE: SB 441 - Maryland Medical Assistance Program – Prescription Digital Therapeutics
Position: Support *with Amendments*

Dear Chair, Vice-Chair and Members of the Committee:

The Maryland Psychological Association, (MPA), which represents over 1,000 doctoral level psychologists throughout the state, asks the House Health and Government Operations Committee to **FAVORABLY report on SB 441 with the Amendment below.** Prescription Digital Therapeutics are software-based treatments for medical, mental health, and substance use disorders. Prescription Digital Therapeutics must be tested for safety and efficacy in clinical trials and then evaluated and cleared for use by the Food and Drug Administration. The FDA regulation which created this prescription device category (21 CFR Sec. 801.109(a)(2)) provides 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 MPA recognizes the Committee's leadership with regard to Prescription Digital Therapeutics. The current bill, however, precludes the vast majority of Maryland Medical Assistance clients with substance use disorders and depression from accessing these treatments because they are not receiving services from prescribing practitioners (e.g., physicians, physician assistants, nurse practitioners). The proposed amendment ensures that Maryland Medical Assistance clients who are in treatment with psychologists and other licensed health care professionals can access these effective treatments via an appropriate Order, consistent with FDA regulations.

The suggested amendment would be inserted on p.2, line 13:
4) CAN BE DISPENSED ONLY IN ACCORDANCE WITH A PRESCRIPTION [.] **OR ORDER PURSUANT TO THE REQUIREMENTS UNDER 21 C.F.R. § 801.109 OR ANY SUCCESSOR REGULATION**.

Thank you for considering our comments on SB 441. If we can be of any further assistance as the Senate Finance Committee considers this bill, please do not hesitate to contact MPA's Legislative Chair, Dr. Pat Savage at mpalegislativecommittee@gmail.com.

Respectfully submitted,

Rebecca Resnick, Psy.D.

Rebecca Resnick, Psy.D.
President

R. Patrick Savage, Jr., Ph.D.

R. Patrick Savage, Jr., Ph.D.
Chair, MPA Legislative Committee

cc: Richard Bloch, Esq., Counsel for Maryland Psychological Association
Barbara Brocato & Dan Shattuck, MPA Government Affairs

2023 SB441 Written Testimony.pdf
Uploaded by: Deborah Brocato
Position: UNF

Opposition Statement SB441
Maryland Medical Assistance Program - Prescription Digital Therapeutics
Deborah Brocato, Legislative Consultant
Maryland Right to Life

We Oppose SB441

On behalf of our 200,000 followers across the state, we respectfully object to SB441. This bill expands the Maryland Medical Assistance Program through coverage of prescriptions obtained via the internet. We oppose funds for this program being used for abortion services. We oppose expanding the Maryland Medical Assistance Program without excluding funding for abortion.

The Maryland Medical Assistance Program and the Maryland Children's Health Program (MHCP) are the two primary programs used for publicly funded reimbursements to abortion providers in Maryland. The Maryland Department of Legislative Services, in their *Analysis of the FY 2022 Maryland Executive Budget*, shows that Maryland taxpayers are forced to fund elective abortions. For the years 2018, 2019 and 2020, over $6 million was spent each year for almost 10,000 abortions each year. In that same report, we see that for Fiscal 2020, less than 10 of the almost 10,000 abortions were due to rape, incest or to save the life of the mother. With the advent of chemical abortion, those prescriptions are easily obtained via the internet.

Abortion is about revenue. The state of Maryland forces taxpayers to subsidize the abortion industry through direct Maryland Medicaid reimbursements to abortion providers, through various state grants and contracts, and through pass-through funding in various state programs. Health insurance carriers are required to provide reproductive health coverage to participate with the Maryland Health Choice program.

D-I-Y Abortions endanger women. Public policy has failed to keep pace with the abortion industry's rapid deployment of chemical abortion pills. The Assembly removed the final safeguard in law for women seeking abortion when they enacted the Abortion Care Access Act of 2022 and removed the physician only requirement. Chemical abortion is 4 times more likely to result in complications than surgical abortion. The abortion industry itself calls these pills "Do-It-Yourself" abortions. Telehealth has made these pills easily accessible making women and girls victims of the predatory abortion industry. A telehealth prescription removes any serious assessment of the woman or girl's physical condition and whether or not she is getting this prescription voluntarily or by coercion. Do not assist sex traffickers and other abusers to continue their criminal behavior.

Opposition Statement SB441, page 2 of 2
Maryland Medical Assistance Program - Prescription Digital Therapeutics
Deborah Brocato, Legislative Consultant
Maryland Right to Life

Maryland is one of only 4 states that forces taxpayer funding of abortion. Maryland taxpayers are forced to subsidize the abortion industry through direct Maryland Medicaid reimbursements to abortion providers, through various state grants and contracts, and through pass-through funding in various state programs. Health insurance carriers are required to provide reproductive health coverage to participate with the Maryland Health Choice program. Programs involved in reproductive health policy include the Maryland State Department of Education, Maryland Department of Health, Maryland Family Planning Program, maternal and Child Health Bureau, the Children's Cabinet, maryland Council on School Based Health Centers, Maryland for the Advancement of School Based Health, Community Health Resource Commission, Maryland Children's Health Program (MCHP) and Maryland Stem Cell Research Fund.

Abortion is not healthcare and abortion is never medically necessary. A miscarriage is the ending of a pregnancy *after* the baby has died; an ectopic pregnancy is not a viable pregnancy and the baby cannot continue to develop. Abortion is the destruction of a developing human being and often causes physical and psychological injury to the mother. In the black community, abortion has reached epidemic proportions with half of pregnancies of Black women ending in abortion. The abortion industry has long targeted the Black community with 78% of abortion clinics located in minority communities. **Abortion is the leading killer of black lives.** See www.BlackGenocide.org.

Americans oppose taxpayer funding of abortion. Taxpayers should not be forced to fund elective abortions, which make up the vast majority of abortions committed in Maryland. The 2023 Marist poll shows that 60% of Americans, pro-life and pro-choice, oppose taxpayer funding of abortion. 81% of Americans favor public funds being prioritized for health and family planning services that save the lives of mothers and their children including programs for improving maternal health and birth and delivery outcomes, well baby care and parenting classes.

Funding restrictions are constitutional. The Supreme Court of the United States, in *Dobbs v. Jackson Women's Health* (2022), overturned *Roe v. Wade* (1973) and held that there is no right to abortion found in the Constitution of the United States. As early as 1980 the Supreme Court affirmed in *Harris v. McRae*, that *Roe* had created a limitation on government, not a government funding entitlement. The Court ruled that the government may distinguish between abortion and other procedures in funding decisions -- noting that "*no other procedure involves the purposeful termination of a potential life*", and held that there is "*no limitation on the authority of a State to make a value judgment favoring childbirth over abortion, and to implement that judgment by the allocation of public funds*."

Maryland urges the addition of an amendment to exclude any funding for this bill to be used for abortion purposes. Without this amendment, we ask that you oppose this **SB441** in its entirety.

MD SBHC Reproductive Health Standards (1).pdf
Uploaded by: Deborah Brocato
Position: UNF

Developmentally appropriate reproductive care must be provided according to community acceptance, documented need and community norms. Reproductive health services are not in lieu of reproductive health services provided by community base health providers, SBHC are encouraged to partner with other community-based providers.

Reproductive Health Services	**Level I Core**	**Level II Expanded**	**Level III Comprehensive**
d. General Reproductive Health Services			
Reproductive health exam (inclusive of pap, pelvic, testicular exam)	Recommended	Recommended	Recommended
Abstinence education	Onsite	Onsite	Onsite
Referral for community based reproductive healthcare services	Onsite	Onsite	Onsite
Case management	Onsite	Onsite	Onsite
Pregnancy testing	Onsite	Onsite	Onsite
Reproductive Health Education	Onsite	Onsite	Onsite
e. Family Planning Services	**Level I Core**	**Level II Expanded**	**Level III Comprehensive**
Family Planning Services	Recommended	Recommended	Recommended
Prescriptions for contraceptives	Recommended	Recommended	Recommended
Comprehensive pregnancy options/ pregnancy counseling	Recommended	Recommended	Recommended
Case management	Onsite	Onsite	Onsite
Referral for community based reproductive healthcare services	Onsite	Onsite	Onsite
Condom availability	Recommended	Recommended	Recommended
Prenatal care	Referral	Referral	Referral
Informing and referring for birth control	Onsite	Onsite	Onsite
Dispensing contraceptives	Onsite or Referral	Onsite or Referral	Onsite or Referral
f. STD/STI Services	**Level I Core**	**Level II Expanded**	**Level III Comprehensive**
Case management	Onsite	Onsite	Onsite
STD/STI treatment and testing	Onsite	Onsite	Onsite
Condom availability	Recommended	Recommended	Recommended
HIV pre- and post-test counseling/HIV testing	Recommended	Recommended	Recommended
HIV/AIDS treatment	Referral	Referral	Referral

Mental Health Services must be provided in collaboration with a licensed provider for those students requiring psychotropic drugs as part of their treatment.

g. Mental Health Services	**Level I Core**	**Level II Expanded**	**Level III Comprehensive**
Individual mental health assessment	Referral	Onsite	Onsite
Mental health treatment	Referral	Onsite	Onsite
Mental health crisis intervention	Referral	Onsite	Onsite
Group therapy	Referral	Onsite	Onsite
Family therapy	Referral	Onsite	Onsite
Consultation with school administrators, parent/guardian, teachers and students	Onsite	Onsite	Onsite
Psychiatric evaluation	Onsite or Referral	Onsite or Referral	Onsite or Referral
Psychiatric medication management	Onsite or Referral	Onsite or Referral	Onsite or Referral

8 - SB 441 - FIN - MDH - LOC.pdf
Uploaded by: State of Maryland (MD)
Position: UNF

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 28, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 441 – Maryland Medical Assistance Program – Prescription Digital Therapeutics – Letter of Concern

Dear Chair Griffith and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of concern on Senate Bill (SB) 441 – Maryland Medical Assistance Program – Prescription Digital Therapeutics. SB 441 will require the Maryland Medicaid Program to provide coverage for prescription digital therapeutics (PDTs) for Medicaid participants, subject to the limitations of the state budget. The bill defines PDTs as a software-based product, device, and/or internet application that is approved by the federal Food and Drug Administration to treat health conditions and are prescribed to patients.

PDTs encompass a broad variety of technologies from a rapidly growing industry. Everything from virtual reality technologies, to cell phone applications, to physiological feedback sensors, to computer games, have been cleared by the FDA to treat various conditions. For example, Freespirad is a PDT designed to monitor and reduce panic symptoms through a respiration rate sensor and guided breathing exercises. While RelieVRx is an at-home adjunctive daily immersive virtual reality pain treatment for chronic lower back pain. Providing coverage for PDT technologies will add to costs because they supplement, not supplant, existing treatment and services. Lastly, there is limited data on the current and potential uptake of these broad range of therapeutics in the Maryland Medicaid population; therefore, MDH cannot estimate the potential fiscal impact to cover these services.

If you would like to discuss this further, have any questions, please contact Megan Peters, Acting Director of Governmental Affairs, at megan.peters@maryland.gov or (410) 260-3190.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary