

Before the
UNITED STATES SENATE COMMITTEE ON FINANCE
Washington, DC 20510-6200

In the Matter of

United States Senate Committee on Finance Bipartisan Mental Health Request
for Information

COMMENTS OF:



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Committee on Finance
United States Senate
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Submitted electronically via mentalhealthcare@finance.senate.gov

Re: United States Senate Committee on Finance Bipartisan Mental Health Request for Information

We are very grateful for the opportunity to comment on the United States Senate Committee on Finance Bipartisan Mental Health Request for Information (RFI). And we commend the United States Senate Committee on Finance for crowdsourcing innovative solutions to address behavioral health problems with creative and equitable policy solutions. The following comment will identify evidence-based ways in which statutory and regulatory changes can address mental health improvement and innovation as requested by the Committee on Finance, with a particular focus on considerations for equitable, high-quality, and sustainable implementation of digital solutions for pediatric behavioral health and neurodevelopment.

For reference, the authors have long-standing backgrounds in clinical practice, health policy, operating software businesses, and advocating for underserved populations. Dr. Andrey Ostrovsky was the former Chief Medical Officer of the US Medicaid program under the Obama administration. He is the Managing Partner at Social Innovation Ventures where he invests in and advises companies and nonprofits dedicated to eliminating disparities. He previously operated a series of methadone clinics in Baltimore, Maryland. Prior to working on the front line of the opioid use disorder crisis, he served as the Chief Medical Officer for the Center for Medicaid and CHIP Services, the nation's largest health insurer, where he advocated to protect the program against several legislative efforts to significantly dismantle the program. He also led efforts to streamline Medicaid and make it more customer-centric. Before leading the Medicaid program, he co-founded the software company, Care at Hand, an evidence-based predictive analytics platform that used insights of non-medical staff to prevent aging people from being hospitalized. Care at Hand was acquired in 2016 by Mindoula Health. Before Care at Hand, Dr. Ostrovsky led teams at the World Health Organization, United States Senate, and San Francisco Health Department toward health system strengthening. Dr. Ostrovsky has served on several boards and committees dedicated to behavioral health, interoperability standards, quality measurement, and home and community based services including the National Academies of Medicine, National Quality Forum, Institute for Healthcare Improvement, and the Commonwealth Fund. Dr. Ostrovsky holds a Medical Doctorate and undergraduate degrees in Chemistry and Psychology Magna cum Laude from Boston University and is a member of Phi Beta Kappa. Andrey completed his pediatrics residency training in the Boston Combined Residency Program at Boston Medical Center and Boston Children's Hospital where he

was a clinical instructor at Harvard Medical School. He is currently teaching faculty and attending physician at Children's National Medical Center.

Dr. Katherine Hobbs Knutson is an adult and child psychiatrist, and a national leader in transforming care delivery and payment for behavioral health. As the Chief of Behavioral Health at Blue Cross Blue Shield of North Carolina (Blue Cross NC), she led the transition to integrated payment for behavioral health; developed alternative payment models incentivizing access and quality of care; and advanced care delivery through clinical and technological innovations. Before Blue Cross NC, Katherine was the Chief Medical Officer for Alliance Health, a North Carolina Medicaid managed care entity serving approximately 400,000 covered lives. At Alliance, she was responsible for all clinical aspects of the organization, including medical expense management, medical policy, utilization/case management, quality, and population health. Katherine is an adjunct Assistant Professor at the Duke University School of Medicine, and she conducts pragmatic research through her work with health systems and payers. Katherine also serves on the Board of Directors and clinical advisory committees for early-stage health care companies, including Well.co and Ryse Health.

From 2015-17 at Duke Health, Katherine practiced in integrated care settings and helped develop and lead predictive modeling and other population-based approaches for improving health. From 2013-14 as the Associate Medical Director of Psychiatry for the Massachusetts Medicaid program, she helped lead state and local initiatives for value-based reimbursement for integrated care and quality for behavioral health managed care organizations. Finally, from 2012-14 as a fellow with the Kraft Center for Community Health through Massachusetts General Hospital and Partners Healthcare, Katherine completed a Master's Degree at the Harvard School of Public Health and conducted a pilot evaluation of behavioral health integration with pediatric primary care. She is dedicated to improving access and quality of health care, especially for people who are underserved by the current system.

Background

The COVID-19 pandemic triggered a rapid acceleration of digital health solutions, but the gains in access to virtual behavioral health and neurodevelopmental interventions were not equitable, unclear in quality, and with questionable sustainability.^{1,2} Recurrent school closures and loss of regular daily routines contributed to an unprecedented escalation in mental health issues and loss of milestones, with acutely worse outcomes among children and adolescents with lower socioeconomic status as well as non-white race.^{1, 2, 3, 4, 5} Payers and providers rapidly implemented digital solutions during the COVID-19 pandemic without much guidance or experience. The quality and outcomes of this expanded implementation of virtual care remain to be seen.⁶ The sustainability of virtual care also is unclear given that practices offering behavioral health services were generally ill-equipped for rapid technology transformation with as few as 20% of practices even having electronic health records (EHRs) in 2012.⁷ While EHR adoption has improved since 2012, the market penetration remains poor. Sustainability of virtual care is further limited by limitations to integration of digital health into the rest of the delivery system.^{8,9} To support implementation of equitable, high quality, and sustainable virtual behavioral health

and neurodevelopmental interventions in the pediatric population, we propose that payers and providers ensure innovations 1) are clinically effective, 2) are reimbursed fairly, 3) are comprehensive, and 4) integrate with primary care.

Clinical Effectiveness

Evidentiary support for the clinical effectiveness of digital solutions in behavioral health and neurodevelopment varies. While some digital health solutions have robust peer-reviewed literature demonstrating their impact, most digital health manufacturers have failed to publish studies to confirm the data presented in marketing materials.^{10,11} Payers and consumers of digital health solutions are frequently bombarded by noisy and unsubstantiated pitches from manufacturers, often drowning out true signals from manufacturers that have rigorously evaluated their solutions' impacts.

Of the virtual modalities to address behavioral health and neurodevelopment, tele-behavioral health (TBH) is among the most robustly supported by research. TBH has shown meaningful improvement in access to care and equivalent clinical outcomes compared to in-person care.¹² In children specifically, telehealth (TH) has demonstrated clinical benefits in multiple domains, including behavioral health and developmental delays.¹³ Emerging literature suggests that TBH programs serving young people are feasible, acceptable, sustainable and likely as effective as in-person services.¹⁴ Additionally, practitioners report positive experience overall, with the biggest challenges revolving around technological difficulties, rather than the services themselves.¹⁵ For neurodevelopmental issues, one meta-analysis of the use of TH for speech therapy in school aged children identified significant and similar improved outcomes for TH versus in-person services.¹⁶ Additionally, a study of client-centric, data-driven applied behavioral analysis (ABA) performed during COVID-19 found that children had significant improvement in function independent of whether supervision was provided virtually or in-person.¹⁷

The literature on virtual treatment of adolescent substance use disorders (SUDs) is sparse but digital health has been shown to be effective in adults for addressing SUDs, and notably these technologies can reach people who might not otherwise get access to brick and mortar treatment.^{18, 19}

In addition to TH, digital therapeutics and diagnostics have recently demonstrated meaningful clinical impact on pediatric behavioral health and neurodevelopment. Several studies have demonstrated that an FDA-cleared digital therapeutic, EndeavorRx, improved symptoms of attention-deficit hyperactivity disorder (ADHD).^{20, 21} Another FDA-cleared technology, CanvasDx, demonstrated timely digital autism diagnosis with comparable performance to in-person diagnostics and no differences in performance based on race/ethnicity, household income, or gender.²² While the digital health industry should invest more in generating randomized controlled trials to demonstrate effectiveness, there is sufficient literature for TH and a subset of digital therapeutic and diagnostic interventions that warrant broader coverage and payment for behavioral health and neurodevelopment. In particular, Congress should create a benefit category for prescription digital therapeutics and diagnostics. A productive template for legislative change is the bipartisan Prescription Digital Therapeutic Act.²³

Fair Reimbursement

Historically, there have been multiple barriers to TH coverage and payment, limiting its adoption in pediatric populations. At the federal level, there were site-of-care restrictions requiring TH to be delivered from one clinic site to another, as opposed to directly to patients regardless of their physical location. These site-of-care restrictions robbed providers and patients of some of the major benefits of TH, including removing the logistic barriers such as travel and time away from school or work.^{24, 25} At the state level, there were restrictions requiring a provider to be licensed in the same state where the patient was located when receiving treatment. Providers were challenged to obtain multiple state licenses to deliver care across state lines, and these state licensing restrictions may have contributed to the uneven distribution of providers nationally. At the health plan level, reimbursement rates for TH have been almost half that of in-person care^{26, 27}, due to presumed differences in overhead costs for the two modalities. With these federal, state, and carrier-level constraints, providers have been disincentivized from delivering services by TH.

With COVID-19, the Centers for Medicare and Medicaid Services (CMS) and other payers relaxed several of these requirements. Site-of-care restrictions were removed, and providers were reimbursed for video and audio-only visits delivered to patients regardless of their locations, whether in their homes or office spaces.²⁸ Provider licenses were allowed to transfer across state lines. TH was reimbursed on par with in-person care. These changes resulted in a substantial increase in the provision and uptake of TH.²⁹ Within weeks, access to care via TH increased substantially, and no-show rates at clinics declined precipitously.^{30, 31} Most importantly, many patients liked this modality of care and found it more convenient with less stigma.³² Similarly, many providers found that their ability to deliver treatment matched that of in-person care, and they gained new insight into patients' lives by being able to observe their personal surroundings in the background.

While many payers are planning to continue reimbursing for TBH on par with in-person, other payers are considering returning to lower reimbursement for TBH. The primary rationale for lower reimbursement for TBH is presumption that the overhead costs of delivering care are lower for delivering traditional in-person health services compared to TH. However, for behavioral health care, the difference in overhead is less pronounced. Therapists typically do not have many additional staff people such as nurses, and they lack equipment such as devices for physical exams or laboratories that are needed for physical health care. There are additional costs of delivering care virtually including HIPAA-compliant TH software and high-quality internet connection, among other costs. Therefore, while the overhead costs may be reduced slightly for behavioral health when performed virtually, it is likely not at the same rate as for physical health.

If payers return to substantially lower reimbursement rates for TH compared to in-person care, it will likely impact providers' willingness to deliver that care. Given that access to behavioral health care and neurodevelopmental services is a major problem, and TH has demonstrated an ability to improve access, policies that were initiated during COVID-19 that improved access should be continued indefinitely. In

alignment with Medicare’s recently proposed 2022 Physician Fee Schedule (PFS) for adults, universal coverage and payment for video and audio and audio only telemental health for children and adolescents is essential.³³ While omitted in the PFS, we believe there is sufficient emerging evidence to support coverage and payment for TH ABA supervision, speech therapy, and occupational therapy as well. Additionally, Congress should permanently remove the restriction on home as the originating site for telehealth as stipulated in section 1834m of the Social Security Act.³⁴

For digital therapeutics and diagnostics, we recommend a slightly more conservative approach to coverage and payment. FDA-cleared or approved solutions should be covered and reimbursed as long as manufacturers have research specific to the sub-populations in which their solution will be used. Most FDA-cleared digital therapeutics’ and diagnostics’ validation efforts focus on commercially-insured populations, but they under-represent Medicaid populations. These solutions should be provisionally approved for coverage and payment for use in Medicaid pediatric populations with the requirement to complete research including Medicaid beneficiaries within 2 years of coverage. Payers may consider reimbursing these solutions, especially where evidence has not yet been developed, based on outcomes to better align financial reward with clinical performance. Coverage of prescription digital therapeutics and diagnostics would address significant health disparities in behavioral health.³⁵

Comprehensive Solutions

Increased reimbursement for pediatric behavioral health technology likely will accelerate adoption of these important services. As the nascent pediatrics-focused digital health industry matures, manufacturers should avoid mirroring the siloed ecosystem of point-solutions serving adult behavioral health needs. For example, the parent of a child with speech delay and anxiety typically struggles to call dozens of providers only to wait months to get their appointments. Virtual services may improve access, but the virtual speech therapist and the virtual behavioral health therapist are typically part of different companies, limiting coordination and collaboration among providers, including the child’s primary care provider.

From a patient, family, and provider perspective, care delivery should be integrated across all providers to improve coordination, safety, and efficiency. From a payer perspective, fewer number and more integrated solutions are preferred over disparate point-solutions to minimize setup and administrative costs, improve coordination of care, and offer robust and comprehensive services across the membership.

As technologies evolve to serve children and adolescents, there should be a concerted effort to generate collaboration and interoperability across point solutions, so that children and families receive coordinated and comprehensive care. Technological interoperability has been accelerated by standards such as Fast Healthcare Interoperability Resources (FHIR). Manufacturers have an opportunity to create unique value by partnering and integrating with other solutions through application programming interfaces (APIs) and similar infrastructure. In the example above, if the virtual behavioral health and the

virtual speech therapy providers could partner, then their technologies, care processes, and revenue models would be coordinated to better serve patients and families. Additionally, these comprehensive solutions may be in a better position to contract with payers, delivering high-value care across the population. This partnership could create competitive advantage over other firms that operate in silos.

In addition to better integration of behavioral health solutions, patients would benefit from a “single front door” or “no wrong door” for entering the behavioral health system. A “single front door” may be more applicable to an integrated and centralized delivery system with a captive patient population. That system could roll out a uniform “single front door” to all of its providers and members that could serve as a conduit for a comprehensive suite of virtual behavioral and neurodevelopmental offerings. Benefits of the “single front door” approach include uniform assessment, care plan design, and triage. While their networks and treatment modalities are still limited, examples of platforms that are pursuing the “single front door” approach include Quartet Health and Two Chairs.

A “no wrong door” approach may be more applicable to providers outside of an integrated system whereby entry into a virtual modality of a behavioral health specialty would simultaneously integrate with primary care as well as other virtual behavioral specialties. An example of the “no wrong door” approach is the TH provider DotCom Therapy, which offers virtual speech therapy, occupational therapy, and mental health therapy for pediatric patients. DotCom Therapy has integrated care across school, healthcare, workplace, and sports settings to provide a “no wrong door” approach for children to access their services in over 270 schools, a dozen health systems, multiple employers, and the Little League International Organization.

Both the “single front door” and “no wrong door” approaches have potential to provide comprehensive management for the full spectrum of mental health, substance use disorders, and neurodevelopmental issues, including behavioral therapy and medication management.

Primary Care Integration

In addition to behavioral health and neurodevelopmental point solutions coalescing to provide more comprehensive services, these solutions also need to better integrate with primary care. There is an industry-wide shift away from behavioral health carve-outs toward reintegration of payment and care delivery for physical and behavioral health. The technology industry needs to support and accelerate this trend to better serve pediatric patients.

Primary care is the foundation of health care and the bedrock of pediatrics. In fact, a pediatrician, the late Dr. Cal Sia, invented the concept of the patient-centered medical home (PCMH), which seeded in pediatrics then grew to become the standard of comprehensive, continuous, team-based healthcare throughout the health care industry. Building on the PCMH, the Collaborative Care Model (CoCM) augments the primary care provider’s (PCP) ability to serve patient’s behavioral health needs.³⁶ The CoCM incorporates a team-based approach including a behavioral health care manager, such as a

psychiatric nurse or licensed clinical social worker, and a psychiatrist. This team practices measurement-based care for a registry of patients with a particular focus on mild to moderate mental health conditions, such as depression, anxiety or ADHD, which represents the majority of behavioral health conditions in youth. The CoCM has been shown to improve access and quality of behavioral health care and reduce stigma as behavioral health conditions are addressed alongside physical health.³⁷ CoCM also addresses workforce shortages as PCPs are equipped to serve the vast majority of mild-moderate behavioral health conditions, reserving the smaller portion of severe and complex conditions for the limited supply of specialists.

Collaborative care can be delivered in person, with embedded live care managers, or virtually. Many primary care practices do not have enough patient volume to support a live care manager. Therefore, these live behavioral health resources can be centralized at larger regional practices, and they can extend into smaller practices, including rural areas, through TH and digital supports, similar to the Project ECHO model and ECHO Autism.^{38, 39}

Less integrated approaches to supporting primary care with access to behavioral health services can also be productive. For practices with robust care coordination infrastructure, e-Consultations with behavioral health specialists through services like RubiconMD or state telephone psychiatry consultation services may be sufficient to provide integrated behavioral health services to its patients.⁴⁰

Through technology that augments or works within the context of the CoCM, Project ECHO, ECHO Autism, and/or e-Consultations, PCPs can help their patients access scarce behavioral health services in real time to reach a broader patient population. Given the central role of primary care, digital solutions for pediatric behavioral health and neurodevelopment should be designed not only for the patient and family, but also for PCPs as the end-users.

Conclusion

The initial trauma of school closures and other social distancing measures due to COVID-19 may be exacerbated by ongoing viral evolution like the Delta Variant which is forcing school districts and state regulators to revisit closures. The threats to children's behavioral health and neurodevelopment will continue. With the help of Congress and CMS, payers and technology companies can accelerate implementation of equitable, high quality, and sustainable virtual behavioral health and neurodevelopmental interventions in the pediatric population by ensuring innovations are clinically effective, reimbursed fairly, are comprehensive, and integrate with primary care. These recommendations can help innovators develop virtuous competitive advantages that help their companies succeed by helping children thrive.

Specific actions that Congress and CMS can take include

- Create a benefit category for prescription digital therapeutics

- Guarantee FDA-cleared digital therapeutics and diagnostics coverage and payment, at least provisionally
- Universal and sufficient coverage and payment for video and audio and audio-only telemental health for children and adolescents in parity with in-person services
- Universal coverage and payment for TH ABA supervision, speech therapy, and occupational therapy
- Permanently remove the restriction on home as the originating site for telehealth
- Move reimbursement away from behavioral health carve-out's and toward reintegration of payment and care delivery for physical and behavioral health

We thank the United States Senate Committee on Finance Bipartisan for the opportunity to comment. We welcome the opportunity to discuss these comments in further detail, as necessary. If you have any questions regarding these comments, please do not hesitate to contact us at 443-857-8199 or andrey@socialinnovationventures.com.

Respectfully submitted,

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Disclosure: Dr. Ostrovsky has investments in the following companies, several of which are referenced in the comment above: www.socialinnovationventures.com

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