

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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Dated: November 15, 2021

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 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.

We are a collection of practicing physicians with vast experience in pediatric behavioral healthcare. Our experience covers a vast array of clinical practice, research and advocacy. We join in this effort to propose changes to current federal laws with the intent to increase access to care for children, expand insurance coverage and promote healthcare innovation that will fill in the gaps in healthcare. Besides being practicing physicians, we also use our medical training and clinical experience in the work we do for Cognoa. Cognoa is a pediatric behavioral health company developing diagnostic and therapeutic products with the goals of enabling earlier and more equitable access to care to improve the lives and outcomes of children and families living with behavioral health conditions, starting with autism.

Sharief Taraman, MD, DABPN, DABPM, FAAP

Sharief Taraman, MD is the Chief Medical Officer at Cognoa. He is dual board-certified in Neurology with special qualifications in Child Neurology from the American Board of Psychiatry and Neurology and Clinical Informatics from the American Board of Preventive Medicine. He completed his medical education at Wayne State University School of Medicine in 2006 and went on to complete residency training in pediatrics and pediatric neurology at the Children's Hospital of Michigan. Dr. Taraman serves as Division Chief of Pediatric Neurology for Children's Health of Orange County, Associate Clinical Professor at the University of California-Irvine School of Medicine, Affiliate Professor at Chapman University Dale E. and Sarah Ann Fowler School of Engineering, President of the American Academy of Pediatrics-Orange County Chapter (AAP-OC), and on the Board of Directors for AAP-OC, AAP-California, and the International Society for Pediatric Innovation. Dr. Taraman is enthusiastic about using artificial intelligence to diagnose and treat neurodevelopmental and neurobehavioral disorders early to help children reach their fullest potential. In his community, he volunteers his time on the Medical Advisory Board of the Irvine Unified School District, with the Capistrano Unified School District, and Girl Scouts of America.

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Colleen A. Kraft, MD, MBA, FAAP is the Senior Medical Director for Clinical Adoption at Cognoa. Dr. Kraft is also Professor of Pediatrics at the Keck School of Medicine, University of Southern California, and primary care pediatrician at the Children's Hospital Los Angeles. Dr. Kraft served as the 2018 President of the American Academy of Pediatrics. Her background includes work in primary care pediatrics, pediatric education, pediatric practice transformation, and health care financing. Dr. Kraft received her undergraduate degree at Virginia Tech and her M.D. from Virginia Commonwealth University, and her MBA from the University of Cincinnati. She completed her residency in Pediatrics at Virginia Commonwealth University.

Andrey Ostrovsky, MD, FAAP

Dr. Ostrovsky has a long-standing background in clinical practice, health policy, operating software businesses, and advocating for underserved populations. Dr. Andrey Ostrovsky 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, 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. Dr. Ostrovsky has 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.

Together, we have identified 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. Our response supports implementation of equitable, high quality, and sustainable virtual behavioral health and neurodevelopmental interventions in the pediatric population. Our focus is on the following two areas: i) Increasing Integration, Coordination, and ii) Access to Care and Improving Access to Care for Children and Young People.

I. Increasing Integration, Coordination, and Access to Care

What are the best practices for integrating behavioral health with primary care?

The best practices for integrating behavioral health with primary care consist of a team-based coordinated approach to care that is flexible and responsive to the needs of the family and the community. Public policies must support innovation and implementation flexibility allowing for the distinct characteristics, location, and varying resources of the healthcare practice to determine the model that works best.

Pediatric-Psychiatry Collaboratives

Many states have Pediatric-Psychiatry collaboratives, where primary care clinicians can access a psychiatrist and social workers for care coordination for their patients. Patients can work with the social worker to find behavioral health therapy, and the psychiatrist can mentor the clinician in medication management, with escalation to crisis support, intensive outpatient, partial hospitalization and inpatient services if needed. This program encourages primary care clinicians to care for people with behavioral health disorders because there is backup for patients whose concerns are beyond the experience of the clinician.

“Single Door” and “No Wrong Door” Approaches to Integrated Care

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.

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 telehealth 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.

Team-based Collaborative Care

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. A medical home is an approach to providing comprehensive primary care that facilitates partnerships between patients, clinicians, medical staff, and families. The medical home extends beyond the four walls of a clinical practice, including specialty care, educational services, family support and more. Building on the PCMH, the Collaborative Care Model (CoCM) augments the primary care provider’s (PCP) ability to serve patient’s behavioral health needs.¹ 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.² 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.

Flexible Use of Virtual Specialty Care as Part of the Collaborative Care Team

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 telehealth and digital supports, similar to the Project ECHO model and ECHO Autism.^{3, 4}

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.⁵

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, thereby expanding the reach of those services and overcoming logistical and/or geographic concerns of patients. 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.

What federal payment policies would best support care integration?

Payment policies that support funding Pediatric-Specialist collaboratives and care coordinators are important and would support care integration. Many practices employ care coordinators to help patients connect to behavioral health resources, follow up questionnaires (that identify patients who may have active suicide intent), and serve as a first contact for families.

Some practices are experimenting with a virtual visit with both the primary care clinician and the behavioral health therapist--the ability for both professionals to bill and be paid for that service on the same day would support care integration. Therefore, federal payment policies should support primary care practitioners' use of digital diagnostics and therapeutics in terms of reimbursement to the medical device manufacturer and the clinician's interpretation.

Currently, the FDA has applied a medical device pathway to software and applied the medical device requirement standard to software. However, the coding and reimbursement pathways have not been established to support the medical software innovations. There needs to be a coding pathway established that enables reimbursement and can recognize the distinct attributes of software as compared to traditional devices or even pharmacological products. In the meantime, we are cobbling together a system that is currently limiting uptake of innovations that can deliver operational efficiencies, scalable standards of care and cost savings.

What programs, policies, data, or technology are needed to improve access to care across the continuum of behavioral health services?

Colocation of medical and therapy services, technology to support HIPAA compliant communication between therapist and clinician, and payment for medical and behavioral health services on the same day are needed to improve access to care across the continuum of behavioral healthcare services. Integration of medical records between medical and behavioral health so that all information can be seen in the same place is also necessary.

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. If the virtual behavioral health and the virtual speech therapy providers cited previously could partner, then their technologies, care processes, and revenue models would be coordinated to better serve patients and families.

Legislation is also needed to establish medical software products as unique products separate and distinct from medical devices and pharmaceutical products. Healthcare professionals use CPT codes to describe the medical services they provide to patients. CPT codes can also be described as benefit codes. There are coding pathways for drugs and coding pathways for devices. However, there are no coding pathways for software designating

their function or service provided, even when the software has met the regulatory standards of the FDA. As a result, software devices are left without a CPT code, in a coding limbo of sorts where they are neither something that you put in your body and more multifaceted than a device. The very nature of software distinguishes itself by how it can be transformed into new products with new capability through regular updates and new releases. It is time policies reflected the evolution of technology in healthcare by establishing a CPT benefit code for medical software products.

What programs, policies, data, or technology are needed to improve patient transitions between levels of care and providers?

True electronic health record interoperability and ability to exchange health records across institutions is essential. For example, a clinician should be able to share records electronically to another clinician using a different electronic health record at a different institution seamlessly and that information should be able to be ingested as discrete data elements within the receiving electronic health record.

Payment for psychiatric specialists to consult and communicate with primary care as well as ability for primary care to bill for this communication will also facilitate communication.

What policies could improve and ensure equitable access to and quality of care for minority populations and geographically underserved communities?

Equity access and quality of care for minority and underserved communities requires policies that provide assured access to providers, use innovative tools, receive fair reimbursement and implement care coordination in ways that are responsive to community needs to establish healthcare equity.

Programs

Authorized under 330 of the Public Service Act, the expansion of the federally qualified health center program is needed to improve access to care across the continuum of behavioral health services. These Centers located in underserved urban and rural areas are able to provide care and adhere to federal requirements to meet or surpass quality measures. These Centers should be able to innovate and use FDA diagnostic technology reinforcing their legacy of progressive medicine and Centers of excellence in the communities they serve.

Community based training programs should also be supported since these programs provide a pipeline of professionals who gain experience working in underserved urban and rural communities. Not only should training opportunities be supported but tuition reimbursement, loan forgiveness and salary supplements are excellent methods of ensuring value.

Policies that support funding for graduate medical school education such as the National Health Service Corps would strengthen the physician pipeline.

Access To Innovative Tools

Using technology in innovative ways can be transformative for children who have limited access to care. For example, some states have waiting lists for up to two and a half years to see specialists who can diagnose autism spectrum disorder (ASD). Delayed ASD diagnosis in children of color is more common than white children and can have significant life long consequences. For example:

In a recent study, Constantino et al. found that the average age of diagnosis for Black children was over 5 years and over 3 years after parents' first concerns about their child's development. Although the study did not include a comparable sample of non-Latinx White children, this is consistent with research that has found delay in diagnosis to be more pronounced in children of color. In a study of over 260,000 children younger than 8 years of age, up to one-fourth of children were undiagnosed, with most of these children being Black or Latinx. Another study found that White children were 19% and 65% more likely to receive a diagnosis of ASD than Black and Latinx children, respectively.¹⁴ Sadly, the findings of Constantino et al. mirror previous studies, some of which were published almost 2 decades ago and suggest little progress in equitable care and that health disparities for children of color with ASD persist.⁶

The delays in determining an ASD diagnosis delay appropriate interventions. As a result, caregivers are not able to have the benefit of learning how best to interact with their children. In addition, parents of color experience a myriad of systemic healthcare obstacles that further impede their ability to have their child diagnosed. Without a diagnosis, often children do not qualify for interventions that enable children with ASD to develop effective social skills. Interventions early on could alleviate speech or behavior challenges as the child ages.

Given the shortage of specialists who can diagnose ASD and the excessive waiting period for diagnosis, other options must be considered. Canvas Dx is a Software as a Medical Device (SaMD) that aids physicians in diagnosing autism spectrum disorder (ASD) in children 18 months to 6 years.⁷ Canvas Dx has the potential to increase access to care by enabling the primary care physician to provide an informed diagnosis early on as opposed to waiting months to years until a specialist with specific ASD diagnosis training becomes available. Minority populations and underserved rural and urban communities are best served when new methods of care that expand access to diagnostic capability and other services are readily available and reimbursable.

As policies are written, drafters must take into account the growing reliance on digital devices and tools. However, it should be noted that just as these devices improve care, these devices also widen the gap between those who have access to them and those who do not. For those who can afford to pay for digital-based services, they will continue to get the benefit of innovative and effective products. However, those who do not have the resources to pay out of pocket for diagnostic tools, will not benefit from the same level of healthcare. Policies that could improve and ensure equitable access to and quality of care for minority populations and geographically underserved communities would benefit from grant programs or public assistance opportunities to improve access to smartphones and internet connectivity in areas where vulnerable populations are located.

Fair Reimbursement

For digital therapeutics and diagnostics, we recommend a 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. Clear pathways to reimbursement for pediatric behavioral health technology will likely accelerate adoption of these important services.

Care Coordination

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 must call dozens of providers only to have to wait months to get 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. Policies and incentives to support care coordination can reduce waste and redundancy within the healthcare system.

It is also important to note that customizing services to accommodate patient needs can improve customer compliance and improve outcomes. For instance, co-location of behavioral health specialists in primary care settings is crucial. The current assumption is that these professionals are co-located in primary care but policies supporting this must be clear. For example, co-location of primary care and behavioral healthcare services enable access for patients who have difficulty with transportation to receive care from both professionals on the same day.

Other policy, intentionally developed, can address common but often overlooked issues. For example, expanded virtual behavioral health platforms with Broadband access in poor neighborhoods and in school-based health centers can enable patients to keep their appointments. Other types of responsive policies would allow for students to have access to virtual behavioral health during the school day for students to participate in these services without academic penalty.

How can crisis intervention models, like CAHOOTS, help connect people to a more coordinated and accessible system of care as well as wraparound services?

This is a very important concept---if we want primary care clinicians to be involved in caring for behavioral health patients in practice, then primary care physicians have to include their opinions on patient level of care when there is a crisis. Dr. Colleen Kraft shares the following illustrative story:

Patient X is a 17-year-old who saw me after she was still depressed after being in therapy for about 4 months. She had no suicidal intent and was started on medication with support from her family and therapist. She was followed weekly, and one month later was not better--she was in fact mentioning suicidal intent but did not have a plan. She had a safety plan. Medication was changed, and we sought out a psychiatrist. There was only one psychiatrist who took her insurance, and she had a 6 month wait to be seen. She got on waitlists for intensive outpatient therapy and partial hospitalization programs but was waiting 4 weeks later. Her medication was changed a third time--still no access to intensive outpatient care or psychiatry. She was followed weekly, and one week later voiced that she was sleeping, eating, and feeling better.

Two days later she overdosed on all her psychiatric medication. She was taken to the intensive care unit where she was intubated.

Three days later she was extubated and saw the crisis intervention group, who decided that she could go home with only a safety plan. Her therapist and I argued with the team for over an hour before we changed their mind--we couldn't believe that they would send home a patient who just survived a real suicide attempt. But even though we spent so much time and energy with this patient, it didn't seem to matter to the crisis team.

Communication and respect for primary care clinicians who care for behavioral health patients is crucial.

II. Improving Access for Children and Young People

How should shortages of providers specializing in children's behavioral health care be addressed?

As the U.S. faces ever-growing shortages of providers specializing in children's behavioral health, it is imperative that we provide adequate tools, reimbursement, and support for primary care physicians to be able to diagnose and treat.

This shortage of specialists is even more pronounced in low-income and communities of color that rely on Medicaid, thus leading to even greater delays for families living in these areas. Moreover, low rates of Medicaid reimbursement for diagnostic services can make it challenging to support and maintain or expand workforce capacity. Compared with White children, Black and Latinx children have been found to have increased difficulty in accessing specialty care for developmental disabilities and ASD.⁸

In addition, provision of virtual behavioral health therapists during school and in other settings where children spend the day would be helpful. Payment for peer mentors, care coordinators, and other support staff to work in team-based settings would also provide significant support.

Are there different considerations for care integration for children's health needs compared to adults' health needs?

Yes, children's behavioral health has to be aligned with their developmental stage. Care integration can include ABA and other behavioral interventions, sensory integration therapy, trauma informed therapies, and therapies that involve caregivers and children together (called Parent-Child Integration Therapy). Care coordination and family support are much more supportive for children's behavioral health because the person arranging care is not the patient. Also, care for the parent is an essential factor in the care of the child--so the parent-child dyad therapy for postpartum depression, etc., is necessary in the care of children.

What key factors should be considered with respect to implementing and expanding telehealth services for the pediatric population?

Key factors include telehealth services during school with no academic repercussions, assessing broadband access at home, recognition of whether and how patients that utilize telehealth services are progressing, and other forms of virtual healthcare are important factors to be considered.

Given the unequal distributions of specialist clinicians, patients should be allowed to seek specialist care via telehealth across state lines. Patients of a lower socio-economic standing should be provided access to smartphones and internet connectivity through governmental assistance programs.

Of the virtual modalities to address behavioral health and neurodevelopment, telemental health is among the most robustly supported by research. Tele-behavioral health has shown meaningful improvement in access to care and equivalent clinical outcomes compared to in-person care.⁹ In children specifically, telehealth has demonstrated clinical benefits in multiple domains, including behavioral health and developmental delays.¹⁰ Emerging literature suggests that tele-behavioral health programs serving young people are feasible, acceptable, sustainable and likely as effective as in-person services.¹¹ Additionally, practitioners report positive experience overall, with the biggest challenges revolving around technological difficulties, rather than the services themselves.¹² For neurodevelopmental issues, one meta-analysis of the use of telehealth for speech therapy in school aged children identified significant and similar improved outcomes for telehealth versus in-person services.¹³ 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. Universal coverage and payment for telehealth ABA supervision, speech therapy, and occupational therapy should be considered by the Committee. In addition, the Committee may also consider universal coverage and payment for video and audio and audio-only tele-mental health for children and

adolescents. Universal coverage for children and adolescents should include commercial insurance and public insurance such as Medicaid, CHIP and healthcare exchange populations.

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.^{14, 15}

In addition to telehealth, 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).^{16, 17} Another FDA-authorized Software as a Medical Device (SaMD), 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.¹⁸ There is sufficient literature for telehealth and a subset of digital therapeutic and diagnostic interventions to warrant broader coverage and payment for behavioral health and neurodevelopment supports. 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.

Conclusion

With the help of Congress and CMS, providers, 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

- Establish policies that support funding for Pediatric-Psychiatry collaboratives and care coordinators;
- Implement same-day billing (primary and behavioral healthcare services delivered on the same day)
- Create a benefit category for prescription digital therapeutics;
- Guarantee FDA-regulated digital therapeutics and diagnostics coverage and payment provisionally;
- Establish universal coverage and payment for video and audio and audio-only telemental health for children and adolescents;
- Universal coverage and payment for telehealth ABA supervision, speech therapy, and occupational therapy;
- Permanently remove the restriction on home as the originating site for telehealth and implement telehealth solutions that address clinical, school and at home issues;
- Move reimbursement away from behavioral health carve-out and toward reintegration of payment and care delivery for physical and behavioral health;
- Provide Electronic Health Record Interoperability; and
- Establish the provision of virtual behavioral health therapists during school and in other settings where children spend.

We thank the United States Senate Committee on Finance Bipartisan for the opportunity to comment. If you have any questions regarding these comments, please do not hesitate to contact Cognoa's Executive Director of Policy and Government Affairs, Jillian Hudspeth can be contacted at: jillian.hudspeth@cognoa.com or (202) 734-9765.

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