

# DAY ONE PROJECT

Creating a National Infrastructure for  
Digital Mental Health Services

Stephen Schueller

May 2021

*The Day One Project offers a platform for ideas that represent a broad range of perspectives across S&T disciplines. The views and opinions expressed in this proposal are those of the author and do not reflect the views and opinions of the Day One Project or its S&T Leadership Council.*

## Summary

The COVID-19 pandemic is exacerbating an existing mental health crisis to such a degree that many fear it will overwhelm the fragmented mental health delivery system in the United States.<sup>1</sup> Rates of mental health problems—including depression, trauma- and stressor-related disorders, substance abuse, suicidal ideation, and suicide attempts—have increased during the COVID-19 pandemic.<sup>2</sup> Scarce access to mental health services compounds the problem. Nearly 25 million Americans with mental health needs go untreated each year,<sup>3</sup> and half of U.S. counties have no access to mental health care whatsoever.<sup>4</sup> However, the current moment presents an opportunity. Even as the pandemic increased needs for mental health services, so too did pandemic-related shifts reveal the broad utility of and interest in digital solutions such as mobile apps, digital therapeutics, and digital therapy.

In the absence of regulation, however, ineffective and potentially harmful digital mental health products may make their way into consumer hands. Estimates suggest that over 20,000 digital mental health products exist, yet only five have received Food and Drug Administration (FDA) clearance. The FDA temporarily reduced their enforcement and review of these products due to COVID-19.<sup>5</sup> But moving forward, addressing the largely unregulated space of digital mental health products is critical to mitigate harm of unverified digital mental health solutions. As examples of potential harms, companies have used digital products to offer services but from unlicensed providers,<sup>6</sup> withheld client information from providers,<sup>7</sup> or made data available to various third parties without following stated terms of services.<sup>8</sup> Developing an infrastructure to regulate these products while also helping provide and reimburse effective and safe digital mental health solutions is essential to meet the overwhelming need for mental health services and ensure quality and equity in mental health care.

---

<sup>1</sup> Charles Ingoglia, "Behavioral health providers need emergency funding to avert collapse," National Council for Mental Wellbeing, April 13, 2020.

<sup>2</sup> Mark É. Czeisler, "Follow-up survey of US adult reports of mental health, substance use, and suicidal ideation during the COVID-19 pandemic, September 2020," *JAMA Network Open* 4, no. 2 (2021): e2037665. <https://doi.org/10.1001/jamanetworkopen.2020.37665>

<sup>3</sup> Maddy Reinert, Theresa Nguyen, and Danielle Fritze, "The state of mental health in America," Mental Health America, 2021.

<sup>4</sup> Lena H. Sun, "Why it's so hard to find a mental health professional," *The Washington Post*, October 22, 2015.

<sup>5</sup> U.S. Food and Drug Administration, "Enforcement policy for digital health devices for treating psychiatric disorders during the Coronavirus Disease 2019 (COVID-19) public health emergency," April 2020.

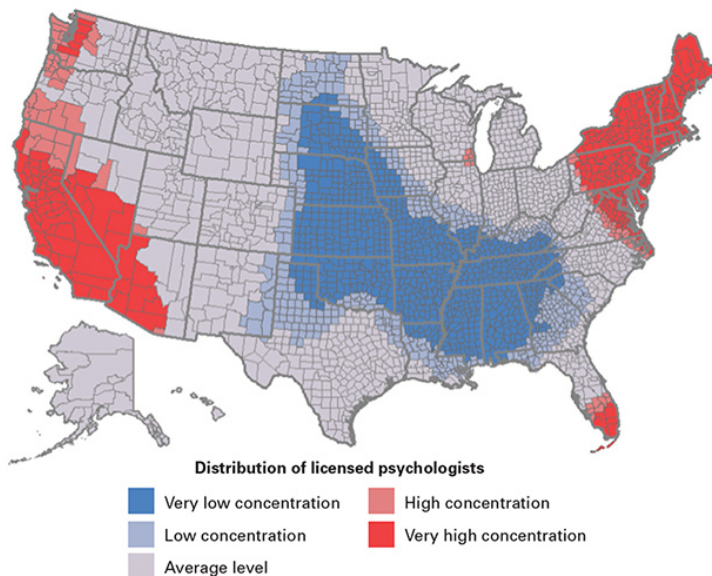
<sup>6</sup> Angela Chen, "Mental health startup Basis wants to replace therapy, but mostly provides a friend for a fee," *The Verge*, October 11, 2018.

<sup>7</sup> Cat Ferguson, "Breakdown: Inside the messy world of anonymous therapy app Talkspace," *The Verge*, December 19, 2016.

<sup>8</sup> Kit Huckvale, John Torous, and Mark E. Larsen, "Assessment of the data sharing and privacy practices of smartphone apps for depression and smoking cessation" *JAMA Network Open* 2, no. 4 (2019): e192542, <https://doi.org/10.1001/jamanetworkopen.2019.2542>.

## Challenge and Opportunity

Mental health services are grossly underfunded, creating a massive imbalance between supply and demand. Nearly 25 million Americans with mental health problems go untreated every year. Over half of U.S. counties are mental health shortage areas, including most rural counties (Figure 1)—many of which have been especially hard hit by the opioid crisis and COVID-19 pandemic. The supply/demand gap is so large that we could double the size of the U.S. mental health workforce and still lack capacity. Hence investment in the U.S. mental health workforce alone is necessary but not sufficient to meet mental health needs of all Americans.



**Figure 1. County-level distribution of licensed psychologists, 2012–2015.** Source: American Psychological Association. Datapoint: Where are the highest concentrations of licensed psychologists. Center for Workforce Studies, 47 no. 3 (2016).

Increasing the use of scalable digital interventions key for meeting our nation’s mental health demands. Digital mental health interventions, such as mobile apps, digital therapeutics, and virtual mental health care, are already integrated into the healthcare systems of other countries. For example, Australia has funded the MindSpot Clinic, a digital mental health clinic that provides digitally supported remote care for tens of thousands of Australians.<sup>9</sup> The United Kingdom has integrated digital mental health products into its Increasing Access to Psychological Therapies (IAPT) program.<sup>10</sup> The Australian Commission of Safety and Quality in Health Care recently released National Safety and Quality Digital Mental Health Standards that set standards for clinical and technical aspects of digital mental health products as well as service safeguards such as risk assessment and risk mitigation.<sup>11</sup> These examples indicate that the U.S.

<sup>9</sup> Nikolai Titov, et al., “User characteristics and outcomes from a national digital mental health service: an observational study of registrants of the Australian MindSpot Clinic,” *The Lancet Digital Health* 2, no. 11 (2020): e582–e593, [https://doi.org/10.1016/S2589-7500\(20\)30224-7](https://doi.org/10.1016/S2589-7500(20)30224-7).

<sup>10</sup> National Institute for Health and Care Excellence, “Improving Access to Psychological Therapies (IAPT).”

<sup>11</sup> Australian Commission on Safety and Quality in Health Care, “National Safety and Quality Digital Mental Health Standards.”

# DAY ONE PROJECT

government is lagging peer nations in regulating and promoting strategic use of digital tools to increase access to and quality of mental health care.

The longer the U.S. government waits to begin regulating digital mental health interventions, the more difficult regulation will ultimately be. Funded by huge amounts of U.S.-based venture capital, U.S.-based businesses are developing digital mental health products at breakneck pace. \$2.4 billion in venture-capital (VC) funding was invested into digital mental health companies in 2020 alone.<sup>12</sup> Estimates suggest that over 20,000 digital mental health products already exist, including self-help offerings like mobile apps and wellness products, digital therapeutics that make specific treatment claims, and virtual mental health care that combines digital interventions with professional care (Figure 2).

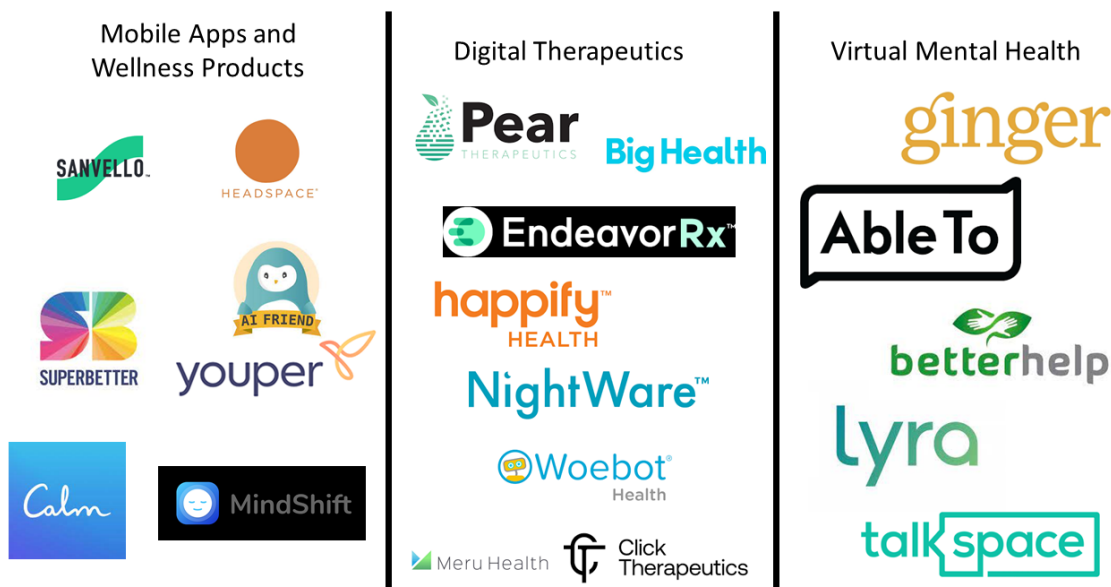


Figure 2. Examples of existing digital mental health products.

2018 saw the FDA grant its first Breakthrough Designation and authorization to a digital mental health product. But since then, only five digital mental health products (reSET, reSET-O, Somryst, EndeavorRx, and NightWare) have received FDA clearance. The rapid expansion of digital mental health products amid a fragmented and limited regulatory landscape is a major issue. Regulation is fragmented because different regulatory issues apply depending on the type of product in quest. Products that make treatment claims fall under the FDA regulation of Software as a Medical Device. Products that involve licensed professionals are only regulated based on state licensure requirements, which predate digital mental health services and provide no capacity for interstate practice. Many purely digital products avoid making overt treatment claims to avoid any type of FDA oversight. The results are that (i) few digital mental health products are

<sup>12</sup> Elaine Wang and Megan Zweig, "A defining moment for digital behavioral health: Four market trends," Rock Health, 2021.

# DAY ONE PROJECT

evaluated against standards that make sense, (ii) potential manufacturers of products that could expand access to quality mental health services are dissuaded by a confusing regulatory environment from entering the market, and (iii) consumers are minimally protected from harmful products. Indeed, the sensitivity of mental health makes ensuring quality and protecting consumers especially critical.

Although various quality-assurance frameworks for digital mental health products have been created—including domestically by the American Psychiatric Association<sup>13</sup> and One Mind PsyberGuide,<sup>14</sup> and internationally by Australia—no national standards for digital mental health products exist. There is also no mechanism for enforcing such standards (outside of the limited applications of FDA clearance). This is despite calls from the National Institute of Mental Health that an evaluative structure should be implemented.<sup>15</sup>

Lack of clear standards for identifying effective and safe products is just one of the obstacles facing expansion of digital mental health solutions in the United States. Another problem is the fact that insurance providers do not typically reimburse for digital mental health products—in part because the lack of standards makes it impossible for insurers to determine which products are reasonable to reimburse. There is also a lack of non-VC funding to support development of digital mental health products. This has resulted in (i) a dearth of products designed for diverse populations, and (ii) products rushed to market despite little rigorous evaluation to demonstrate effectiveness.

There is a massive need for the federal government to improve quality of and equitable access to mental health care by advancing development and delivery of digital mental health products. Failure to act will lead to continued proliferation of digital mental health products that are at best ineffective and at worst harmful, while missing the opportunity to support delivery of care that could truly benefit millions.

## Plan of Action

Establishing a national infrastructure for digital mental health services will require (1) legislative action to create standards for regulating digital mental health products, (2) updated reimbursement pathways including reimbursement under Medicare, technical assistance to states for reimbursement under Medicaid, and federal guidance for the use of statutory funding lines such as mental health block grant funds, (3) expanded funding for developing and delivering new digital mental health products.

---

<sup>13</sup> American Psychiatric Association, "The App Evaluation Model."

<sup>14</sup> One Mind PsyberGuide. "About One Mind PsyberGuide."

<sup>15</sup> National Institutes of Health, "Opportunities and challenges of developing information technologies on behavioral and social science clinical research," National Advisory Mental Health Council Workgroup.

## *Part 1: Legislative action*

The United States House Energy and Commerce Subcommittee on Health or the Senate Committee on Health, Education, Labor, and Pensions should draft legislation to allow the U.S. Department of Health and Human Services (HHS) to propose standards for digital mental health products. Standards should govern clinical effectiveness, technical specifications (e.g., data protection and privacy), and provisions for assessing safety and mitigating risk. These standards could be created with contributions from the Agency for Healthcare Research and Quality (AHRQ), the National Institute of Mental Health (NIMH), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the FDA (especially FDA's newly established Digital Health Center of Excellence). Clinical-effectiveness standards should specify digital interventions with sufficient evidence to support use for a given treatment target, such as digital cognitive-behavioral therapy for depression, anxiety, or post-traumatic stress disorder.<sup>16</sup> Clinical-effectiveness standards should also specify the level of clinical-effectiveness data required for newly developed clinical interventions. Technical specifications should include benchmarks for usability and accessibility (such as 508 compliance) as well as for data protection and privacy (e.g., data encryption; data autonomy for consumers including limitations on data sharing with third-parties). Safety and risk standards should guide how digital products assess of clinical risk and elevate at-risk patients to crisis-support services as consistent with clinical-practice guidelines (including duty to warn and duty to protect).

Once standards are established, adherence should be mandatory for any product seeking reimbursement through Medicare. Legislation should also establish a new National Center for Digital Mental Health at HHS, which would maintain a database of approved products (e.g., an "app library") that meet the aforementioned standards. For digital mental health products that include licensed professionals, pathways for license portability should be included in recognition of the interstate commerce that digital solutions generate.

## *Part 2: Updated Reimbursement Pathways*

Approved digital mental health products should be reimbursable through Medicare. Technical assistance should be provided to states to support potential reimbursement through Medicaid or use of statutory funding lines. These actions would require new billing codes that make it possible to reimburse a range of digital mental health products. Although some such products do involve the use of a licensed professional (such as a psychologist, psychiatrist, or social worker), many products are either stand-alone, self-guided digital interventions or digital interventions provided with non-professional human support. Moreover, even products that involve licensed professionals often include some self-guided components to reduce the amount

---

<sup>16</sup> David C. Mohr, et al., "Banbury forum consensus statement on the path forward for digital mental health treatment," *Psychiatric Services*, January 20, 2021, <https://doi.org/10.1176/appi.ps.202000561>.

of professional time. The availability of digital mental health interventions that are not wholly reliant on licensed professionals could substantially increase the efficiency, cost-effectiveness, and scalability of mental health care. But because conventional reimbursement is based on provider time, many digital mental health interventions are not currently reimbursable.

Legislation that explicitly permits reimbursement of digital mental health products through Medicare could help provide a safety net of effective and safe digital mental health interventions for those most in need. S.3532, the Prescription Digital Therapeutics to Support Recovery Act, was introduced in 2020 to allow Medicare and Medicaid coverage of prescription digital therapeutics for treating mental health and substance-use disorders. Unfortunately, this legislation only addressed products with FDA clearance and is therefore too narrow to cover the full market of digital mental health products. Policymakers should consider revisiting and expanding the proposed law. In addition, the federal government should issue guidance allowing use of statutory funding lines (such as mental health block grant funds) to fund digital mental health products. This action would make it easier to use digital products to leverage federal investment in mental health services (such as investment via H.R. 1475, the Pursuing Equity in Mental Health Act). Creating new mechanisms for federal reimbursement of digital mental health products will increase access to mental health care and increase mental health parity nationwide.

### *Part 3. Expanded funding for developing and delivering new digital mental health products*

\$25 million in funding for each of fiscal years 2022 to 2026 should be provided to SAMHSA to establish of a National Center for Digital Mental Health (NCDMH). The NCDMH would serve several important functions to support development and delivery of new digital mental health products. First, as stated above, the NCDMH would maintain a database of approved digital products (e.g., an “app library”) that meet federal standards. Second, the NCDMH would provide training and technical assistance to support delivery of digital mental health services. This could include development of formal certifications recognizing psychiatrists, psychologists, community-health workers, and peer-wellness specialists with demonstrated competency in digital mental health services. Such a nationally recognized certification help sustain a diverse and competent workforce capable of providing care through digital services, and would enable trained professionals to engage in interstate practice through digital platforms—something that is critical given the fact that many Americans in need of mental health care are not geographically proximate to mental health providers. Third, the NCDMH would provide technical assistance to help developers of digital mental health products comply with national standards.

Additionally, \$25 million for each of fiscal years 2022 through 2026 should be provided to the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute (PCORI) to support research on best practices for delivering digital mental health services. NIMH

# DAY ONE PROJECT

has committed \$2.25 million to funding digital mental health projects that require industry and academic collaboration,<sup>17</sup> but additional funding is sorely needed.

## Conclusion

Millions of Americans are suffering from untreated mental health conditions, a problem that worsened during the COVID-19 pandemic. This suffering could be alleviated by investment in high-quality and scalable digital mental health products. Unfortunately, these products exist today in a largely unregulated space, and few mechanisms exist to make sure they are available and affordable for all those in need. New legislation and expanded federal funding are needed to improve regulation, delivery, and reimbursement of digital mental health products. Failure to act will result in harm to Americans from unregulated products, an unchecked epidemic of unmet mental health needs, and continued erosion of U.S. leadership at the intersection of health and technology.

---

<sup>17</sup> U.S. Department of Health and Human Services, "Laboratories to optimize digital health (R01 clinical trial required)," November 25, 2019.



## Frequently Asked Questions

### **What is a digital mental health product and how are they regulated?**

At least 20,000 digital mental health products exist today. These products range from mobile and computer apps that anyone can download, premium wellness offerings (e.g., Headspace, Calm, SilverCloud), digital therapeutics (e.g., Pear Therapeutics, Happify Health, Click Therapeutics), and virtual mental health services (e.g., Ginger, Talkspace, AbleTo). Only a narrow subset of these—digital therapeutics that make treatment claims and therefore meet the definition of “Software as a Medical Device”—were subject to FDA approval when it was being exercised (i.e., before approval of digital health products was temporarily suspended in light of COVID-19). The remainder are subject to minimal regulation. For instance, mental health apps need only meet app store guidelines before being made available to consumers.

### **Where are digital mental health products being used?**

Digital mental health products are being used around the world. Australia’s MindSpot digital mental health clinic provides free mental health assessment and treatment using digital tools. The United Kingdom’s National Institute for Health and Care Excellence has recommended the use of digital mental health interventions for depression and anxiety as frontline treatments. Such interventions are being used in the UK’s Increasing Access to Psychological Treatments (IAPT) program. Canada, Germany, and the Netherlands are among other nations that have created frameworks and standards governing delivery digital mental health services.

### **Are digital mental health products being used at scale anywhere in the United States?**

Many insurance providers—including Kaiser Permanente, Health Net, United Healthcare, Aetna, and Cigna—provide access to digital mental health products for those they cover. Some employers are also purchasing digital mental health products for their employees. California and Reno have undertaken innovative pilot projects to provide digital mental health products for their residents.

### **Wouldn’t federal money be better spent paying for more mental health professionals in the United States?**

Nearly 25 million Americans with mental health concerns are going untreated. It will be extremely difficult and costly to train enough mental health professionals to meet this demand. Additionally, technology has traditionally had very poor uptake among mental health professionals. Psychiatry is one of the medical fields with the lowest adoption rates of electronic health records (EHRs). Investing in digital mental health products is a cost-effective way to supplement and augment the services provided by traditional mental health professionals. The more ways people have to access quality mental health care, the better off they will be.

## Could investment in digital mental health services increase disparities in care access?

The use of technology does have the potential to increase disparities in care access. For instance, not all Americans have access to reliable computers and high-speed internet. Even those with access may lack the technical capacity to use digital tools effectively. Government intervention is needed to proactively address these problems. For instance, federal funding can prioritize digital mental health interventions that rely on technologies that do not require high-speed internet, such as text messaging. Federal funding can also support services and resources that help people take advantage of digital tools.<sup>18</sup> Overall, the federal government can promote development and delivery of digital mental health products targeted at underserved Americans even as the private sector tends to focus on products for those who already have access to traditional mental health care.

---

<sup>18</sup>Philip E. Auerswald, "Delivering healthcare services to the American home," Day One Project, January, 2021.

# DAY ONE PROJECT



## About the Author

**Stephen Schueller** is a clinical psychologist, mental health services researcher, and an Associate Professor of Psychological Science and Informatics at the University of California, Irvine. Stephen's research focuses on making mental health services more accessible and available through scalable interventions, especially those using technology. He is also the Executive Director of One Mind PsyberGuide, a nonprofit project that identifies, evaluates, and disseminates information about digital mental health products to empower consumers to make informed choices. He received his Ph.D. in clinical psychology from the University of Pennsylvania and completed his clinical internship at the University of California, San Francisco.



## About the Day One Project

The Day One Project is dedicated to democratizing the policymaking process by working with new and expert voices across the science and technology community to develop actionable policies that can improve the lives of all Americans. For more about the Day One Project, visit [dayoneproject.org](http://dayoneproject.org)