

ConnectedHealthInitiative

February 14, 2023

Robert Baillieu, MD, MPH
U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Room 13-E-30
Rockville, Maryland 20857

RE: *Connected Health Initiative Comments to the Department of Health and Human Services on Medications for the Treatment of Opioid Use Disorder [87 FR 77330]*

Dear Dr. Baillieu:

The Connected Health Initiative (CHI) writes to provide input to the Department of Health and Human Services' (HHS') Substance Abuse and Mental Health Services Administration (SAMHSA) on its proposal to modify its regulations regarding medications for the treatment of opioid use disorder.¹ CHI supports HHS' steps to make flexibilities that enable the use of telehealth in prescribing lifesaving medication permanent in conjunction with an "Opioid Treatment Program" (OTP).²

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. CHI is a longtime active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease, specifically regarding clinical trials and investigations. For more information, see www.connectedhi.com.

The opioid abuse continued to ravage American families, with over 100,000 lives lost in a single 12-month period in 2022, a striking new record.³ CHI applauds HHS' chronic disease management approach to addressing the opioid epidemic by mitigating barriers to providing individualized care. Digital health technologies can, and must, play a key role in addressing the national opioid epidemic through OTPs. Healthcare providers and administrators rely on continuity in health data regulations and requirements to ensure

¹ 87 FR 77330.

² 21 U.S.C. 823(g)(1).

³ CDC National Center for Health Statistics, *Provisional Drug Overdose Death Counts*
<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

patients that suffer from substance use disorders can benefit from digital health technology.

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, especially regarding substance use disorders (SUDs).⁴ Digital and connected health tools that utilize wireless health products for remote patient monitoring (RPM), remote therapeutic management (RTM), mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, can fundamentally improve and transform American healthcare. By paving the way for increased utilization of telehealth and securely enabling the exchange of health information, these tools can render significant and actionable outcomes.

CHI commends SAMHSA for recognizing the need to advance COVID-19 Public Health Emergency (PHE) flexibilities with respect to the provision of unsupervised doses of methadone and the use of telehealth in initiating buprenorphine.⁵ As SAMHSA discusses in its proposed rule, these flexibilities provided much-needed exemptions to protect the public's health, promote social distancing and to preserve patient and staff safety among OTPs, and further evidence continues to build showing that they facilitated access to treatment and eliminated stigma for people in need of care from OTPs.

CHI also supports proposals by SAMHSA, past making PHE flexibilities that have responsibly enabled the use of digital health tools by OTPs, to update standards to reflect an accreditation and treatment environment that has evolved since those rules were put into place over 20 years ago. We agree that, generally, these proposed regulatory updates will promote practitioner autonomy; remove stigmatizing or outdated language; create a patient-centered perspective; and reduce barriers to receiving care. CHI specifically notes its strong support for SAMHSA proposals that would expand access to evidence-based practices using digital health tools. CHI notes its support for the use of digital modalities for accreditation and certification standards purposes. This overdue allowance will modernize program rules and operations in a manner that reflects established practice.

⁴ Oesterle TS, Kolla B, Risma CJ, Breiting SA, Rakocevic DB, Loukianova LL, Hall-Flavin DK, Gentry MT, Rummans TA, Chauhan M, Gold MS. Substance Use Disorders and Telehealth in the COVID-19 Pandemic Era: A New Outlook. *Mayo Clin Proc.* 2020 Dec;95(12):2709-2718. doi: 10.1016/j.mayocp.2020.10.011. Epub 2020 Oct 21. PMID: 33276843; PMCID: PMC7577694.

⁵ 87 FR 77330.

On net, SAMHSA's proposed updates to its rules will make treatment in OTPs more accessible to patients, easier to deliver for providers, and supportive of evidence-based and patient-centered care. SAMSHA action is vita given the need to expand access to care in the face of a growing overdose epidemic, and which has been exacerbated by the COVID-19 PHE. SAMHSA's actions are also consistent with opioid crisis public health emergency, which has been in effect since 2017. Finally, SAMSHA's proposed updates will, by expanding access to care, advance key equity goals of the Administration and the healthcare sector writ large.

CHI appreciates the opportunity to submit its comments to SAMHSA and urges its thoughtful consideration of the above input.

Sincerely,



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