

April 19, 2018

The Honorable John Martin
Assistant Administrator
Diversion Control Division
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

RE: *Reducing Regulatory Barriers for Electronic Prescribing of Controlled Substances (EPCS)*

Dear Assistant Administrator Martin:

ACT | The App Association's Connected Health Initiative (CHI)¹ writes to urge the U.S. Drug Enforcement Administration (DEA) to update its regulations to foster innovation and competition in the electronic prescribing of controlled substances (EPCS).

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their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 enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. We believe the DEA should play a critical role in these issues considering its regulation of EPCS.

Data and 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, particularly for the chronically ill.² These tools, which include wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, are revolutionizing American healthcare by securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care.

¹ <http://www.connectedhi.com/>

² G. Hindricks, et al., *Implant-Based Multiparameter Telemonitoring of Patients With Heart Failure (IN-TIME): A Randomised Controlled Trial*, 384 *The Lancet* 583-90 (Aug. 2014).

CHI and its members are very concerned with the growing opioid epidemic plaguing the United States . The Centers for Disease Control and Prevention (CDC) reports that 115 Americans die from opioid-related overdoses every day,³ many of which result from patients fraudulently obtaining a prescription from a physician.⁴ Unfortunately, the current interim EPCS rules have effectively locked out new entrants, particularly small businesses, that would provide newer and more innovative solutions to physicians and healthcare facilities at lower costs.

President Trump issued Executive Order 13777,⁵ which seeks to identify and eliminate outdated or ineffective regulations, and the DEA intentionally made the current EPCS rules an interim solution to ensure they have the flexibility to address new developments in EPCS technology. We strongly encourage the DEA to initiate its rulemaking process to revise its EPCS regulations to reduce barriers to entry in this EPCS space.

We believe the DEA should reduce the regulatory burdens associated with its biometrics requirements, especially those that ignore advancements in technology and have kept costs unnecessarily high for physicians who electronically prescribe controlled substances. These regulations currently prevent innovators, and particularly small business innovators, from participating in the EPCS market. Specifically:

- The DEA's requirements under section 1311.116 that require testing by a DEA-approved certifying body are unnecessarily rigid. CHI recommends that digital healthcare innovators be given the flexibility to demonstrate compliance with DEA biometric subsystem requirements through attestations and documentation that demonstrates their compliance, while also being able to utilize testing by a DEA-approved certifying body. Such flexibility would preserve DEA oversight of EPCS service providers while eliminating a rigid and costly compliance barrier for digital health innovators.

³ See, e.g., Opioid Overdose Crisis, National Institute on Drug Abuse (last updated March 2018) Available at: <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one>.

⁴ Drugs for Dollars: How Medicaid Helps Fuel the Opioid Epidemic: Report of the Committee on Homeland Security and Governmental Affairs (Jan. 17, 2018) Available at: <https://www.hsgac.senate.gov/imo/media/doc/2018-01-17%20Drugs%20for%20Dollars%20How%20Medicaid%20Helps%20Fuel%20the%20Opioid%20Epidemic.pdf>; Michael Collins, *Medicaid Fraud is Helping Drive Opioid Crisis, New Congressional Report Concludes*, USA Today (Jan. 17, 2018) Available at: <https://www.usatoday.com/story/news/politics/2018/01/17/medicaid-fraud-helping-drive-opioid-crisis-new-congressional-report-concludes/1040695001/>.

⁵ <https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>.

- The DEA's requirements under section 1311.116 require the co-location of EPCS software with the physician's device to issue an electronic prescription. Advancements in technology make the need for co-location unnecessary and ignore the advent of secure cloud computing-enabled approaches that would allow independent devices to perform the same task. This would make EPCS offerings more efficient and affordable for clinicians.

CHI believes the DEA's attention to the concerns listed above will lower barriers to entry for digital health innovators. Addressing these challenges will bring new and secure approaches to EPCS that foster competition and ultimately lower implementation costs for physicians and healthcare facilities that seek to provide patients with the prescriptions they need, all while combatting the ongoing opioid crisis.

CHI thanks you in advance for your time and consideration on this important issue.

Sincerely,



Brian Scarpelli
Senior Policy Counsel

Joel Thayer
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005