October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Electronic Prescribing of Controlled Substances Request for Information [RIN: 0938-AU25]

Dear Administrator Verma,

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Electronic Prescribing of Controlled Substances (EPCS) Request for Information (RFI). Our comments are outlined below.

ABHW is the trade association which serves as the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in both the public and private sectors to treat mental health, substance use disorders (SUDs), and other behaviors that impact health and wellness.

ABHW supports measures that prevent fraud, waste, and abuse in the healthcare system. CMS data has shown that EPCS can deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. As such, ABHW agrees with the mandate in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) for Medicare Part D providers to use EPCS beginning January 2021. However, despite this mandate, we believe there are barriers to the success of EPCS.

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1. *Burdensome Evaluation Requirement*

The Ryan Haight Act, originally passed to combat the rise of rogue online pharmacies, requires an in-person evaluation before a provider can utilize EPCS. This safeguard has proven to actually suppress treating SUDs by telehealth,[1] thus likely hindering the use of EPCS. While the Ryan Haight Act allows for providers to use EPCS when engaged in the "practice of medicine," it is nearly impossible for providers to do so. The definition of "practice of telemedicine" includes seven categories in which a provider could meet the in-person requirement through a virtual care platform, including under a special registration granted by the Drug Enforcement Administration (DEA). However, the DEA never created that registration process. With the Special Registration for Telemedicine Act of 2018, which was part of the SUPPORT Act, the DEA had until October 24, 2019 to outline rules for providers with a special registration to prescribe controlled substances. That deadline passed without action, severely impeding those with SUDs from receiving the care they need.

Not all people with SUDs are able to have an initial in-person visit with a provider that is in-person due to behavioral health provider shortages or physical difficulty traveling. Furthermore, there is little evidence to support this requirement, which ultimately creates a barrier to medically necessary care. In light of the COVID-19 pandemic, the DEA has suspended the requirement for an in-person visit before EPCS can be employed, which has temporarily allowed individuals to safely get the medications they need to treat SUDs. We request CMS urge DEA to take the action mandated by Congress to provide a permanent path for providers to treat SUDs via telehealth and thereby use EPCS to its full potential.

2. *Lack of Access to Medication Assisted Treatment*

Treatment for opioid use disorder (OUD) is most effective with medication assisted treatment (MAT).[2] The Office of the Inspector General (OIG) for the U.S. Department of Health and Human Services has recently flagged that patients with OUDs may experience difficulty accessing MAT, resulting in under-utilization of an effective treatment.[3] OIG is so concerned about the lack of MAT access that an audit on the utilization of MAT to treat OUDs is currently underway.[4]

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[1] Kayla R. Bryant, *Health Law Daily Wrap up, Strategic Perspectives: States Fail to Fully Use Telemedicine to Fight the Public Health Crisis,* Wolters Kluwer (September 28, 2018), p.2.
[2] *Id.*
[3] Office of Inspector General, *Data Snapshot: Medication-Assisted Treatment from Providers Waivered at the Highest Patient-Limit Level*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000483.asp. Last visited September 2, 2020.
[4] *Id.*

The DEA requires that practitioners apply for a waiver as well as separately register with the DEA in each state where they may prescribe buprenorphine to treat OUDs. This creates a major hurdle to prescribing, as it severely limits the number of providers available to offer MAT to individuals experiencing OUDs. Currently, there is legislation pending, the Mainstreaming Addiction Treatment Act of 2019 (H.R. 2482 and S. 2074) to address this problem by removing the separate DEA registration requirement from the Controlled Substance Act. We urge CMS to work with DEA and Congress to ensure this barrier is removed to increase access to MAT. This combined with removing the in-person visit requirement discussed above may greatly improve the efficacy of EPCS.

Furthermore, it may be challenging to find providers willing to offer OUD treatment due to perceived stigma or misinformation about MAT. We encourage CMS to work with DEA to invest resources into provider education and the importance of providing MAT services to individuals with OUDs. ABHW launched the Stamp Out Stigma campaign aimed at reducing the stigma surrounding mental illness and SUDs. We welcome the opportunity to partner with CMS and DEA to utilize this platform.

3. *Do Not Delay the EPCS Mandate*

EPCS provides multiple advantages over the traditional processing of prescriptions.[5] In addition to improving workflow efficiencies, EPCS can deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes as well as provide more timely and accurate data than paper prescriptions.[6] By allowing for the direct transmission of electronic prescriptions for controlled substances between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies.[7]

Recently, The American Medical Association has reported that more than 40 states have detected increases in deaths related to opioid use in 2020.[8] Additionally, the Overdose Detection Mapping Application Program, a surveillance system that provides near real-time suspected overdose data nationally, reported more than 60% of participating counties

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[5] Phillips et. al. "Market Guide for Identity Proofing and Corroboration." April 24, 2018. Gartner, Inc. Retrieved from *https://www.fedscoop.com/gartner-guide-identity-proofing-corroboration-2018/*, *last visited* Sept 28, 2020.

[6] *Id.*

[7] *Id.*

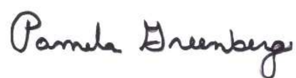
[8] American Medical Association, "Issue brief: Reports of increases in opioid-related overdose and other concerns during COVID pandemic" https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf.

experienced an increase in overdose submissions since the pandemic began.[9] This increase in opioid use underscores the need for tools such as EPCS to help detect and combat the opioid epidemic.

ABHW members are committed to policy measures aimed at preventing opioid misuse and helping individuals and families in recovery and therefore supports the requirement of EPCS as an important tool to combat the opioid epidemic. As such, we urge CMS to reconsider delaying the Congressional mandate for EPCS. We recommend CMS adhere to the January 1, 2021 mandate outlined in the SUPPORT Act, and instead of delaying implementation, exercise enforcement discretion until January 2022.

Thank you for the opportunity to comment on this important issue. Please feel free to contact Deepti Loharikar, Director of Regulatory Affairs, at loharikar@abhw.org or (202) 505-1834 with any questions.

Sincerely,



Pamela Greenberg, MPP
President and CEO

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[9] Overdose Detection Mapping Application Program, "COVID-19 Impact on US National Overdose Crisis" http://www.odmap.org/Content/docs/news/2020/ODMAP-Report-June-2020.pdf.