HANYS®
Always There for Healthcare

Marie B. Grause, RN, JD • President

Headquarters
One Empire Drive, Rensselaer, NY 12144
518.431.7600

Washington, DC Office
499 South Capitol Street SW, Suite 410
Washington, D.C. 20003
202.488.1272

January 4, 2021

Timothy J. Shea
Acting Administrator
Drug Enforcement Agency
Department of Justice, Attn:
DEA Federal Register Representative/DPW, Diversion Control Division
8701 Morrissette Drive, Springfield, VA 22152

Submitted electronically via regulations.gov

RE: RIN: 1117-AB55 Implementation of the "Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018" Dispensing and Administering Controlled Substances for Medication-Assisted Treatment (DEA-499)

Dear Acting Administrator Shea:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, welcomes the opportunity to respond to the Drug Enforcement Administration's interim final rule on the implementation of provisions in the SUPPORT Act, containing changes to 21 Code of Federal Regulations, Parts 1301 and 1306.

Healthcare providers continue to face barriers to prescribing evidence-based treatment like buprenorphine and other medication-assisted treatment. Previous caps on patient volume for MAT administration hindered the expansion and accessibility.

This rule would update regulations to reflect the increased cap on the number of patients that a physician or other clinician can treat, including up to 275 patients if they meet certain requirements. Previous caps at 30 and 100 arbitrarily limited the expansion of opioid use disorder treatment. HANYS supports raising the cap on the number of patients a qualified provider can treat.

HANYS supports efforts by the DEA to align regulations with the SUPPORT Act, and implement its requirements. The following flexibilities offered in the interim regulations have been especially important for expanding access to care:

- treatment of up to 100 patients in the first year providers become Drug Assisted Treatment Act-waivered instead of 30;
- ability for nurse practitioners and physician assistants to become DATA-waivered;

- inclusion of clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives among qualifying providers;
- eligibility for waiver status among medical school graduates with at least eight hours of training on treating and managing opioid-dependent patients; and
- allowance for medication to be dispensed to providers' registered locations, rather than only the ultimate user or research subject.

However, despite the allowance for more types of providers to become DATA-waivered, the 24-hour training requirement to become DATA-waiver eligible is a persistent barrier. HANYS urges DEA and other stakeholders to reassess the 24-hour training requirement.

Under the SUPPORT Act, providers have to administer injectable buprenorphine within 14 days of the date the medication is received. The SUPPORT Act grants DEA the authority to modify the 14-day administration limit; however, the interim final rule retains the 14-day limit.

This 14-day timeframe does not account for delays in shipping, insurance authorization and other external factors. Furthermore, if a long-acting injectable buprenorphine product is not administered within 14 days of receipt, it must be destroyed.

HANYS urges the DEA to increase the number of days a practitioner can administer buprenorphine after receipt of the medication from 14 days to 60 days pursuant to authority granted under the SUPPORT Act.

Thank you for the opportunity to provide feedback on this interim final rule. If you have questions regarding our comments, please contact Sarah DuVall, director, behavioral health, at (518) 431-7769 or sduvall@hanys.org.

Sincerely,

Jeffrey Gold
Senior Vice President and Special Counsel, Managed Care and Insurance