February 14, 2025

The Honorable Derek Maltz
Acting Administrator
Drug Enforcement Administration
600-700 7th Street, NW
Washington, D.C. 20537

Dear Administrator Maltz,

RE: ATA Action Response to Drug Enforcement Administration (DEA) Final Rule Expansion of Buprenorphine Treatment via Telemedicine Encounter Docket (No. DEA–948)

On behalf of ATA Action, the affiliated trade association of the American Telemedicine Association, we would like to express our appreciation for the revisions made in the final rule related to the expansion of buprenorphine treatment via telemedicine. We particularly commend the increase in the initial prescription supply limitation via audio-only telemedicine encounters from 30 days to a six-calendar month supply. Additionally, the removal of the in-person medical evaluation requirement is a positive step forward for increasing access to care for individuals in need of buprenorphine treatment.

Despite these improvements and clear effort the DEA has put into finalizing this rule, it is imperative that the special registration framework, whenever it is finalized, is structured correctly, or telemedicine access for buprenorphine will effectively be eliminated. If special registration imposes excessive burdens, unclear requirements, or unnecessary restrictions, it will undermine the progress made in this final rule and create new barriers to treatment at a time when continuity of care is critical.

While the final rule includes several important improvements, we would like to raise a few clarifying questions to ensure that the implementation of the rule is as clear and effective as possible. These questions center on the interaction between the final rule and the proposed rule on Special Registrations for Telemedicine and Limited State Telemedicine Registrations, as well as the ongoing application of COVID-19 pandemic-era flexibilities.

1. What happens after the initial six-month prescription supply, particularly if the Special Registrations for Telemedicine and Limited State Telemedicine Registrations proposed rule is not finalized?

The final rule seems to be interdependent on the proposed Special Registrations for Telemedicine and Limited State Telemedicine Registrations rule. After the initial six-month supply, practitioners will be able to issue additional prescriptions only if they meet one of the following conditions:

- Conduct an in-person medical examination,

- Meet one of the seven narrow exceptions under the Ryan Haight Act for telemedicine practitioners, or
- Transfer care to a provider with a Special Registration to prescribe buprenorphine.

Accordingly, if the Special Registrations rule is not finalized before the initial six-month prescription supply expires, patients will be required to have an in-person visit with a DEA-licensed provider in order to receive a prescription refill whether or not such a visit may be required by the standard of care. This creates an access issue, as it introduces a significant barrier for patients who have been receiving care remotely over the past few years, especially for those in underserved areas. We seek clarification on how this situation will be handled and what options patients will have if the Special Registrations rule is not finalized in time.

2. What will happen to patients who have been treated via telemedicine during the COVID-19 pandemic era flexibilities?

Many providers have used telemedicine to initiate and maintain buprenorphine treatment with patients under the flexibilities allowed during and after the COVID-19 pandemic. Under the buprenorphine final rule, will these patients be required to adhere to the new six-month prescription limitation? Or will there be an opportunity for continuity of care for existing patients, particularly those who have been receiving treatment consistently and without interruption during the pandemic?

3. Does the COVID-19 pandemic-era in-person waiver for telemedicine prescribing of controlled substances remain in effect through CY2025 before this final rule takes effect?

Clarification is needed on whether the COVID-19-era in-person waiver, which expanded access to telemedicine prescribing of controlled substances by waiving the in-person requirements under the Ryan Haight Act, remains in effect for all relevant controlled substances through the end of calendar year 2025. Specifically, does this waiver continue to allow prescribers to establish and maintain a prescribing relationship via telemedicine without requiring an in-person visit and will the final rule for buprenorphine impact the duration of the in-person waiver for substance use disorder (SUD) treatment? Given the six-month prescription limit outlined in the final rule, it is critical to understand whether the broader waiver still applies to buprenorphine prescribing beyond that timeframe. The continued applicability of the waiver directly affects the rule's implementation and its ability to ensure uninterrupted access to necessary care for vulnerable patients now receiving SUD treatment.

4. Will the implementation of the Special Registrations for Telemedicine rule cause a disruption in care after six months?

Without a Special Registration process in place, telemedicine access to buprenorphine will effectively end after six months for those practitioners who are not eligible to meet the in-person or Ryan Haight exceptions. This situation creates a "cliff" where ongoing care may not be possible without a physical visit or transfer to a provider with the proper registration, which could lead to significant disruptions for patients who have been receiving consistent care through telemedicine. We seek further clarity on how this issue will be addressed, particularly given the

urgency of establishing the Special Registration process but understanding there are significant concerns that need to be addressed before being finalized.

In conclusion, ATA Action commends the DEA for making positive strides toward expanding access to buprenorphine treatment via telemedicine, particularly the increase in the initial prescription supply and removal of the in-person evaluation requirement. However, we believe that addressing these clarifying questions is crucial for ensuring that the final rule is implemented in a way that supports continuity of care and minimizes disruption for patients. Equally critical is ensuring that the special registration framework is structured appropriately—without an effective and practical **special registration** framework, telemedicine access for buprenorphine will be functionally eliminated, reversing much of the progress this rule seeks to achieve. We look forward to your response and appreciate your attention to these important issues.

Thank you for your consideration. If you have any questions, please reach out to me at kzebley@ataaction.org.

Kind regards,

Kyle Zebley
Executive Director
ATA Action