March 18, 2025

VIA Electronic Submission to federalrgister.gov

Office of Information and Regulatory Affairs
OMB
Attention: Desk Officer for DOJ
Washington, DC, 20503

Re: AHCA/NCAL Response to Proposed Rule: Special Registrations for Telemedicine and Limited State Telemedicine Registrations. (RIN 1117–AB40/Docket No. DEA–407)

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represents over 15,000 long term and post-acute care facilities, or 1.1 million skilled nursing facility (SNF) beds and over 300,000 assisted living (AL) beds. With such a membership base, the Association represents the majority of SNFs and a rapidly growing number of assisted living communities as well as residences for individuals with intellectual and developmental disabilities (ID/DD). We appreciate the opportunity to comment on the proposed rule: *Special Registrations for Telemedicine and Limited State Telemedicine Registrations*.

- **Before we discuss our specific concerns about this proposed rule, we first wish to state that while we support the need for protection against inappropriate diversion of controlled substances, we believe the telemedicine registration regulations as proposed would restrict access to necessary medications for residents in the long-term and post-acute care settings our organization represents, and therefore, we oppose this proposed rule as described and request that it be rescinded.**

- **The DEA should instead collaborate with impacted stakeholders and Congress to identify a better approach that best assures optimal patient access to virtual prescribing of needed medications in a timely manner, while mitigating for risks of diversion of such regulated medications from the intended patient for the intended purpose.**

We recognize that the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act) generally requires an in-person medical evaluation prior to the issuance of a prescription of controlled substances but provides an exception to this in-person medical evaluation requirement where the practitioner is engaged in the ‘‘practice of telemedicine” within the meaning of the Ryan Haight Act. However, we believe introducing regulatory changes establishing a Special Registration framework including three types of Special Registration, and that includes extensive prescription, recordkeeping, and reporting requirements, would create unintended access to care and negative health consequences. This is particularly true for individuals residing in already regulated long-term and post-acute care (LTPAC) settings, including those SNF/NF, AL, and ID/DD provider settings that our organization represents. We do not believe that such extensive and burdensome guardrails are targeted appropriately to permit timely and effective patient access to controlled substance medications via telemedicine while mitigating the risks of diversion.

Since early 2020 with the onset of the COVID-19 pandemic and resultant public health emergency (PHE), the joint actions of Congress, the DEA, and the Department of Health and Human Services (HHS) extended waivers permitting the use of virtual prescribing of controlled substances via telehealth and via audio-only telehealth in cases where two-way video telecommunications were not feasible. In the nearly five years that have passed since these flexibilities were introduced, our SNF, AL, and ID/DD provider members have seen many positive clinical outcomes where residents with impairments requiring residential or facility-based care for an emergent or ongoing condition were able to obtain the necessary care as a result of being to obtain a prescription for a controlled substance subject to the Ryan Haight Act provisions via a virtual consultation. Conversely, our members in these already regulated care settings have not seen instances where the tele-prescribing encounter resulted in inappropriate diversion of controlled substances.

We do not see evidence of the need for the DEA to establish such extensive and complex new regulatory requirements that would reduce patient access to virtual care options that have been very successful for the past five years, or that would delay timely access to medically necessary controlled substances to address emergent needs. This is not just a rural issue. Our members provide care for individuals in facility and residential-care settings because they have impairments that make it difficult or impossible to reside in the community – rural or urban. As such, to be forced to leave their residence for a face-to-face encounter to merely meet an arbitrary regulatory requirement the prescriber is subject can impose significant physical, emotional, and financial stress, when a telemedicine encounter would result in the same medication prescription. Similarly, in many cases, the prescriber may not be physically able to visit the patient at their SNF, AL, or ID/DD residence at the time of an emergent need for assessment but they, or a surrogate prescriber approved by the patient, might be able to perform the needed assessment via telehealth technology. We believe the proposed new policies do not reflect the various needs for flexibility that would be needed to overcome these real-world barriers to timely face-to-face encounters when a telehealth encounter would enable timely intervention and a successful clinical outcome.

In the following detailed comments, we discuss concerns we have regarding specific provisions in the proposed rule, and what we believe would be unintended consequences impacting SNF, AL, and ID/DD providers and the residents they care for that would result from this proposed rule being adopted as written. We also offer suggestion of a different approach through collaboration with impacted stakeholders that the DEA could undertake to achieve the desired intent of this proposed rule – to implement the telemedicine exception of the Ryan Haight Act while mitigating the risks of diversion.

Detailed AHCA/NCAL Comments

1. **Proposal to limit an individual from prescribing of Schedule II controlled substances via telemedicine to no more than 50 percent of all Schedule II controlled substances prescribed per month in 21 CFR 1306.45(c).**

    - **AHCA/NCAL opposes the proposed arbitrary limits discussed in the proposed rule at pages 90 FR 6556, 6561, 6591, and 6598.**

We have conferred with physician stakeholders, and it is our understanding that the proposal to require 50 percent of Schedule II prescriptions to be offered in-person would effectively block nearly all telemedicine offering Schedule II prescriptions. As we discussed in our opening comments, our members SNF, AL, and ID/DD provide care for individuals in facility and residential-care settings because they have impairments that make it difficult or impossible to reside in the community. As such, in the absence of a provider that could come to the residence to have a face-to-face assessment, a patient would be forced to leave their residence for a face-to-face encounter to merely meet an arbitrary regulatory requirement the prescriber is subject can impose significant physical, emotional, and financial stress, when a telemedicine encounter would result in the same

necessary medication prescription. The only alternative may be to be subject to delayed care or an admission to an emergency room or hospital which could introduce the patient to other health risks and financial costs to the healthcare system.

Given that the DEA acknowledged on page 90 FR 6573 of the proposed rule that *"Over 75 percent of all U.S. counties are classified as having mental health shortage areas, with 50 percent lacking any mental health professionals"* and that *"Long-distance travel for treatment remains a major accessibility barrier for individuals in rural areas with limited transportation options"* we contend that the proposed limits fail at overcoming these barriers and assuring ongoing patient accessibility to safe and effective needed care in a timely manner that residents residing in SNF, AL, and ID/DD communities have benefited from for the past five years. Telemedicine and tele-prescribing are tools in a practitioner's toolbox and should not be subject to severely restrictive arbitrary limits.

2. Proposal to include complex regulatory requirements for tele-prescribers to practice across state lines in 21 CFR 1301, 1304, and 1306.

- **AHCA/NCAL opposes the complex regulatory hurdles proposed for tele-prescribing across state lines discussed in the proposed rule at pages 90 FR 6551-60, 6556, 6590, and 6595 - 6597.**

Given the vast swaths of geographic areas nationwide facing a shortage of qualified mental health practitioners that could furnish prescribing services as the DEA acknowledged on page 90 FR 6573 of the proposed rule, it appears to be antithetical to propose complex and burdensome processes upon practitioners that would disincentivize the limited number of current but highly qualified professionals from helping to solve care access problems across state lines.

For example, an AHCA/NCAL member SNF, AL, and ID/DD community residents' healthcare practitioner that may be prescribing medications subject to the Ryan Haight Act provisions, may practice across a state line due to no nearby in-state practitioner. The added layers of requirements and costs to practice tele-prescribing across state lines may discourage that healthcare practitioner if they need to jump through additional regulatory hoops in order to be able to furnish appropriate and necessary tele-prescribing for that resident, thereby reducing that individual's access to needed healthcare or delay their access to care obtained via more burdensome and costly face-to-face processes as discussed above.

3. Proposal for restricting 'Audio-only' tele-prescribing to follow-ups in 21 CFR 1306.44

- **AHCA/NCAL opposes the proposed restrictions to audio-only tele-prescribing as discussed on pages 6555-6556 and 6597-6598 of the proposed rule.**

As we have discussed above, audio-only restrictions are a barrier for rural and underserved populations already facing higher barriers to accessing health care. We believe that this arbitrary restriction of <u>always</u> requiring a face-to-face or a two-way audio-video telemedicine encounter before a medication subject to the Ryan Haight Act is able to be prescribed during a subsequent audio-only encounter will be harmful to patients.

We note that Congress has acted to ensure access to audio-only telehealth continues as a care-delivery option on the healthcare practitioner's toolbox. Additionally, the Centers for Medicare and Medicaid Services (CMS) has recognized reasonable flexibility for the use of audio-only telehealth in cases of technology barriers (i.e. lack of local broadband service or temporary disruption of such service), as well as recognizing a patient right to receive healthcare services in a manner they are both capable of and comfortable with. We believe that at a minimum, the DEA should align their audio-only policies with those enacted by Congress and promulgated by CMS.

4. **The aggregate cost and burden impact off many of the other proposed complex regulatory requirements and fees on the tele-prescribers and pharmacies subject to the Ryan Haight Act provisions will be harmful to the ability of SNF, AL, and ID/DD residents from accessing necessary tele-prescribing services they have benefited significantly from over the past five years.**

    - **AHCA/NCAL encourages the DEA to carefully consider the recommendations submitted by physicians, mental health practitioners, telehealth providers, and pharmacies most directly impacted by the proposed policy provisions and consider alternative less burdensome policy levers to better balance the need to minimize risk for diversion, with the need to assure optimal access to necessary care.**

While our SNF, AL, and ID/DD members are not directly subject to the complex and burdensome tele-prescribing requirements put forth in this proposed rule, they would bear the burden of managing the resultant unintended negative health consequences of their residents who may now have no access to, or delayed access to necessary medications that they have benefited from during the past five years. While we appreciate that there are risks to diversion of controlled substances for certain mental health and substance abuse medications, the policies intended to limit such diversion should not be so excessive that they seriously restrict timely access to these medically necessary medications, especially for the most vulnerable populations located in rural and underserved locations, and those SNF, AL, and ID/DD residents that require facility or residential care due to physical and other impairments that make transportation to a practitioners difficult if not impossible, and that may have barriers for using two-way audio-video telemedicine technology.

Conclusion

AHCA/NCAL appreciates the opportunity to share insights and provide comments on the proposed rule: *Special Registrations for Telemedicine and Limited State Telemedicine Registrations.* We are eager to work with the DEA in identifying a pathway to overcome these challenges by finding a solution that achieves the stated objectives. If you have questions about any of our comments, please contact Daniel Ciolek at dciolek@ahca.org.

Sincerely,

Daniel E Ciolek
Associate Vice President, Therapy Advocacy