American Pharmacists Association

February 28, 2025

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients (RIN 1117-AB78; 1117-AB40; 1117-AB88) (Docket No. DEA-948; DEA-407VA)

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Drug Enforcement Administration's (DEA) delay of effective dates for final rules titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients."

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including—but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

DEA is soliciting comments on the extension of the effective date of these two final rules to March 21, 2025. DEA is also soliciting comments on whether there may be a need for their effective dates to be extended beyond that date and address issues of fact, law, and policy raised by these rules for consideration by officials of the two agencies.

The final rule, "Expansion of Buprenorphine Treatment via Telemedicine Encounter," is unworkable as it currently fails to recognize DEA-registered pharmacists under existing state laws as telemedicine providers of controlled substances and prescribers of buprenorphine. The final rule also places an undue burden on the workflow of pharmacists by requiring pharmacists to police these prescriptions with an ID check prior to filling a prescription for buprenorphine. As written, APhA asks DEA and HHS not to effectuate this final rule. At a minimum, APhA urges the DEA to delay the implementation of this rule to rework the provisions that impact pharmacists prescribing and filling these prescriptions and decrease access to lifesaving medications for our patients.

Conversely, the final rule, "Continuity of Care via Telemedicine for Veterans Affairs Patients," improves access to care for Veterans Affairs (VA) patients by permitting VA practitioners, including pharmacists, to prescribe controlled substances via telemedicine to these patients when another VA practitioner has completed such evaluation. The VA final rule strikes a balance between expanding access to controlled substances via telemedicine and putting up safeguards to minimize the risk of diversion and misuse.

Expansion of Buprenorphine Treatment via Telemedicine Encounter (FR 6504)

This final rule "expand[s] the circumstances under which practitioners registered by the Drug Enforcement Administration are authorized to prescribe schedule III-V controlled substances approved by the Food and Drug Administration for the treatment of opioid use disorder via a telemedicine encounter, including an audio-only telemedicine encounter."[1] Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, practitioners are generally required to conduct an in-person medical evaluation of the patient before issuing them a controlled substance prescription.[2] This final rule is exempted from this requirement.[3] However, the final rule requires practitioners to review "the patient's prescription drug monitoring program data for the state in which the patient is located during the telemedicine encounter" before being able to "prescribe an initial six-month supply of such medications (split amongst several prescriptions totaling six calendar months) through audio-only means."[4] Practitioners may issue additional prescriptions to the patient after this initial prescription "under other forms of telemedicine as authorized under the Controlled Substances Act[] or after an in-person medical evaluation is conducted."[5] This final rule "also requires the pharmacist to verify the identity of the patient prior to filling a prescription."[6] It is also important to note that this final rule "does not affect practitioner-patient relationships in cases where an in-person medical evaluation has previously occurred."[7]

Pharmacist Prescriptive Authority Includes Buprenorphine

After the passing of the Consolidated Appropriations Act of 2023, practitioner prescribing of buprenorphine expanded because those authorized by the DEA to prescribe Schedule III drugs were permitted to do so without a DATA waiver.[8] This paved the way for states to begin combating the opioid epidemic by authorizing pharmacists to prescribe medications for opioid use disorder. Currently, there are at least thirteen states that permit pharmacists to prescribe

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[1] Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6504 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01049/p-3.
[2] *Id.* at 6505. Available at: https://www.federalregister.gov/d/2025-01049/p-17.
[3] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-17.
[4] *Id.* at 6504. Available at: https://www.federalregister.gov/d/2025-01049/p-3.
[5] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-3.
[6] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-3.
[7] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-3.
[8] *Id.* at 6506. Available at: https://www.federalregister.gov/d/2025-01049/p-50.

controlled substances, including buprenorphine, for the treatment of opioid use disorder. Per the most recent update of the DEA's "Mid-Level Practitioners - Controlled Substance Authority by Discipline within State" chart, there are ten states that DEA has recognized that have given pharmacists this authority.[9] DEA still needs to update the chart to align with state laws in Colorado, Nevada, and Oregon.

States govern the authority to define and regulate the practice of pharmacy and medicine, and DEA appropriately recognizes this authority for mid-level practitioners, including pharmacists. Accordingly, APhA strongly recommends DEA clarify that DEA-registered pharmacists can prescribe and dispense buprenorphine under this final rule or risk causing irreparable harm to patient access to lifesaving medication and inserting the federal government into a matter protected by and belonging to the states. DEA and HHS even acknowledge that "[f]our commenters requested clarification as to whether DEA-registered pharmacists who are granted controlled substance prescriptive authority within their state would be allowed to prescribe and dispense medications under this rule, and whether they could conduct the in-person medical evaluation (or serve as the referring provider) under the framework proposed" in Section VI of this final rule but offers no guidance.[10] APhA encourages DEA and HHS to defer to state law when deciding which providers have the authority to prescribe controlled medications, as states regulate the practice of medicine. APhA asks DEA and HHS to explicitly state that DEA-registered pharmacists authorized to prescribe controlled substances, including buprenorphine, via their state licensure are included within this final rule.

DEA and HHS provide that the goal of this final rule is to "balance the need to increase patient access to legitimate medical treatment with the goal of providing effective controls against diversion."[11] Pharmacists prescribing medications for opioid use disorder advance this goal.

APhA acknowledges that 21 U.S.C. 802(54) defines telemedicine to be "the practice of medicine in accordance with applicable Federal and state law by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42."[12] However, the preceding phrase "and state law" likely negates the "other than a pharmacist" language and is likely inapplicable to the state governed practice of medicine. APhA notes that DEA has recognized an exception in 21 U.S.C. 802(54) in other rules, including the "Continuity of Care via Telemedicine for Veterans Affairs Patients" final

[9] Diversion Control Diversion. Mid-Level Practitioners Authorization by State. Drug Enforcement Agency. Available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/practioners.html (noting that the chart was last updated February 14, 2025).
[10] Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6513 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01049/p-111.
[11] *Id.* at 6519. Available at: https://www.federalregister.gov/d/2025-01049/p-195.
[12] *Id.* at 6505. Available at: https://www.federalregister.gov/d/2025-01049/p-17.

rule.[13] In the "Continuity of Care via Telemedicine for Veterans Affairs Patients" final rule, the definition's footnote from DEA explicitly and appropriately states, "This definition of telemedicine does not exclude a pharmacist functioning as a mid-level practitioner authorized to prescribe controlled substances."[14] In addition to this final rule, DEA also utilizes a footnote within the "Special Registration for Telemedicine and Limited State Telemedicine Registration" proposed rule to ensure that DEA-registered pharmacists "acting in their capacity as a mid-level practitioner[s], authorized to dispense controlled substances in accordance with their state licensure" are excluded from this exception.[15] To clear up any confusion that could impact patient access to lifesaving medications, APhA asks DEA and HHS to explicitly state that pharmacists "functioning as [] mid-level practitioner[s] authorized to prescribe controlled substances" are included within the practice of telemedicine as it relates to this rule. In addition to this clarification within this final rule, APhA asks that DEA and HHS utilize standard language, including pharmacist prescriptive authority of controlled substances, in future rules or regulations related to similar topics to recognize states' authority to define and regulate the practice of pharmacy and medicine.

Further, 21 CFR 1306.51(b) provides that "[a] practitioner may issue a prescription for schedule III-V controlled substances listed in 42 CFR 8.12(h)(2) as approved by the Food and Drug Administration (FDA) for use in the treatment of Opioid Use Disorder (OUD), defined as the use of an effective medication such as buprenorphine to treat OUD, pursuant to a communication between the prescribing practitioner and the patient using an interactive telecommunications system, including an audio-only telecommunications system, as described in 42 CFR 410.78(a)(3), if" §§ 1306.51(b)(1)-(7) conditions are met.[16]

21 CFR 1306.51(b)(1) requires that the prescribing practitioner "be authorized to access the applicable prescription drug monitoring (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter."[17] Pharmacists are authorized to access PDMP data. 21 CFR 1306.51(b)(2) outlines the time limits associated with prescribing the initial prescription and how practitioners can issue additional prescriptions following the issuance of the first prescription.[18] Pharmacists can comply with these timing limitations for the prescriptions they prescribe. 21 CFR 1306.51(b)(3) notes what practitioners must do when a practitioner cannot access PDMP data.[19] Pharmacists prescribing controlled substances in accordance with this final rule can follow these guidelines when PDMP data is inaccessible or unavailable.

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[13] Continuity of Care via Telemedicine for Veterans Affairs Patients, 90 Fed. Reg. 6524 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01044/p-21.
[14] *Id.* Available at: https://www.federalregister.gov/d/2025-01044/p-23.
[15] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6544 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-73.
[16] Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6522 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01049/p-243.
[17] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-244.
[18] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-245.
[19] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-248.

21 CFR 1306.51(b)(4) states that "pharmacist[s] shall verify the identity of the patient prior to filling a controlled substance prescription issued under the authority of this section."[20] Pharmacists acting as prescribers can issue prescriptions like all other practitioners authorized to prescribe controlled substances, as this section concerns the pharmacist dispensing the medication to the patient. 21 CFR 1306.51(b)(5) provides that "[c]ontrolled substance prescriptions issued pursuant to this section may only be issued for the treatment of OUD."[21] Pharmacists are able to abide by this requirement when prescribing controlled substances via this final rule. 21 CFR 1306.51(b)(6) provides that "this final rule only applies to practitioners who are already registered, or otherwise exempt from registration, to dispense buprenorphine."[22] Pharmacists have DEA registration and are permitted to dispense buprenorphine in several states. 21 CFR 1306.51(b)(7) states that the controlled substances prescribed under this final rule must comply with other pertinent DEA regulations.[23] Pharmacists can ensure that the prescriptions meet these requirements.

As outlined in the analysis above, DEA-registered pharmacists are clearly authorized to dispense controlled substances via their state licensure and satisfy all the requirements laid out within this final rule. As such, APhA strongly encourages DEA and HHS to explicitly state that DEA-registered pharmacists in states that permit pharmacist prescriptive authority of controlled substances, including buprenorphine, be included as prescribing practitioners within this final rule.

ID Requirement for Pharmacists (FR 6515)

ID Checks Significantly Disrupt Workflow

DEA and HHS acknowledge that "*even absent the ID provision* [emphasis added], … requirements proposed in the NPRM [notice of proposed rulemaking] and modified as a result of public comments and promulgated herein *would be sufficient to mitigate and provide effective controls against diversion under this framework [emphasis added].*"[24]Under this final rule, pharmacy staff will have to contact the prescriber on every buprenorphine prescription presented at the pharmacy, as there is no way to differentiate in-person and telemedicine prescriptions. Contacting the prescriber for each of these prescriptions will take significant time out of the pharmacist's workday and could result in delays in the patient receiving their buprenorphine. Any delay in the treatment of patients needing buprenorphine could be detrimental to the patient's health and treatment. Alternatively, requiring an element on telemedicine prescriptions for buprenorphine may result in additional barriers to care and stigma. Given the disruption to pharmacists' workflow that the ID check would cause, APhA urges DEA and HHS

[20] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-249.
[21] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-250.
[22] *Id.* at 6516. Available at: https://www.federalregister.gov/d/2025-01049/p-147.
[23] *Id.* at 6522. Available at: https://www.federalregister.gov/d/2025-01049/p-254.
[24] *Id.* at 6516. Available at: https://www.federalregister.gov/d/2025-01049/p-141.

to reconsider this requirement, which "would require pharmacists to "police" the practice of telemedicine, placing an undue burden on pharmacists and overwhelming pharmacy operations."[25] Further, as DEA and HHS both note, most states already require ID checks. This final rule would require the pharmacist to verify the identity of the patient prior to filling the prescription, which is not the norm in all states. Thus, without modifying this final rule, DEA and HHS are disrupting the workflow of pharmacies that check patient identity at other times during the dispensing process. As such, APhA asks DEA and HHS to defer to states on this requirement to not impose additional, unnecessary burdens on pharmacies and pharmacists.

If DEA and HHS insist on keeping the ID provision, APhA recommends delaying implementation for pharmacies and pharmacists to familiarize themselves with the final rule and adjust their workflows accordingly. DEA and HHS note that "[t]he situations in which identification verification is required varies: some states require verification outright, some states indicate that the pharmacist "may" verify identification, and some states only require verification if the patient is "unknown" to the pharmacist."[26] They also acknowledge that "states vary as to what medications require verification: some states only require it for schedule II controlled substances, some for controlled substances found within schedules II-V, and some for ephedrine or pseudoephedrine products or precursors."[27] As such, APhA believes a delayed implementation of this final rule is necessary and recommends DEA undertake an analysis of ID requirements among all of the states to understand the variation in state requirements. APhA also encourages the DEA to provide clear instruction and communication when educating pharmacists about these changes, especially those in states that currently do not have identity verification requirements. APhA invites the DEA to utilize APhA, its members, and its resources to connect with pharmacists in states with varying requirements and to aid in the dissemination of information to pharmacists throughout the nation.

APhA also notes that pharmacists continue to be asked to do more when reviewing prescription medications, especially controlled substances, before dispensing. At the same time, DEA should understand that reimbursement rates for providing these services have not risen, and often do not exist, in order to adjust for a pharmacist's expertise or the costs of operating a pharmacy, which are causes of increased pharmacy deserts throughout the country. In fact, since 2020, more than 2,200 community pharmacies have closed.[28] Confirming every patient's identity for buprenorphine prescriptions will require pharmacists to spend more time verifying these prescriptions. APhA urges DEA to recognize that any additional unfunded mandate without adequate reimbursement for the additional time needed to verify a patient's identity only decreases patient access to care. Adequately reimbursing pharmacists for their services is

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[25] *Id.* at 6513. Available at: https://www.federalregister.gov/d/2025-01049/p-111.
[26] *Id.* at 6516. Available at: https://www.federalregister.gov/d/2025-01049/p-143.
[27] *Id.* Available at: https://www.federalregister.gov/d/2025-01049/p-143.
[28] Local Pharmacies on the Brink, New Survey Reveals. National Community Pharmacists Association (Feb. 27, 2024). Available at: https://ncpa.org/newsroom/news-releases/2024/02/27/local-pharmacies-brink-new-survey-reveals.

required prior to any new requirements in order to keep pharmacies open and allow them to continue providing care for patients nationwide.

APhA also requests that DEA and HHS make certain at what step the patient's identity must be verified, as the language within the final rule varies. Most instances use the phrase "prior to filling," but at least one statement uses "prior to dispensing" when describing when the pharmacist must verify the patient's identity. Additionally, APhA seeks clarification on whether the patient's identity verification is required for each subsequent prescription if the pharmacy maintains a record of the patient's ID or appropriate document. These clarifications are necessary to assist pharmacies' and pharmacists' compliance with the final rule.

If an ID requirement remains, APhA does support DEA's proposal allowing patients without state or government-issued photographic identification to utilize other forms of documentation to minimize this barrier to access to care. APhA asks that DEA and HHS provide additional guidance regarding these acceptable documents to assist pharmacies and pharmacists in fully complying with a final rule. Additionally, APhA encourages DEA and HHS to ensure that any further guidance does not equate to an exhaustive list, so patients with uncommon circumstances are not excluded from being able to receive care in this fashion.

Continuity of Care via Telemedicine for Veterans Affairs Patients

This final rule permits Department of Veterans Affairs (VA) practitioners "to prescribe controlled substances via telemedicine to a VA patient with whom they have not conducted an in-person medical evaluation" when they are practicing within their scope of VA employment and "another VA practitioner has, at any time, previously conducted an in-person medical evaluation of the VA patient."[29]

Pharmacist Prescriptive Authority of Controlled Substances

This final rule appropriately acknowledges and promotes pharmacist prescriptive authority of controlled substances. Within this final rule, the footnote states, "This definition of telemedicine *does not exclude a pharmacist functioning as a mid-level practitioner authorized to prescribe controlled substances* [emphasis added]."[30] APhA strongly supports DEA and HHS explicitly stating that pharmacists are permitted to prescribe controlled substances and are included in the definition to practice telemedicine. APhA notes that the utilization of pharmacists in providing these services is not confined to the VA, as at least thirteen states have authorized pharmacists to prescribe controlled substances. As stated above, DEA recognizes that ten states have given pharmacists prescriptive authority of controlled substances in its most recently updated "Mid-

[29] Continuity of Care via Telemedicine for Veterans Affairs Patients, 90 Fed. Reg. 6523 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01044/p-3.
[30] *Id.* Available at: https://www.federalregister.gov/d/2025-01044/p-23.

Level Practitioners - Controlled Substance Authority by Discipline within State" chart.[31] See our comments above on necessary updates for additional states to be added to this chart. APhA strongly encourages DEA and HHS to standardize the incorporation of this language in all future telemedicine-related rules to ensure that state-recognized pharmacist scope of practice is acknowledged so as not to inhibit patient access to care.

APhA encourages the DEA and HHS not to delay its implementation of the "Continuity of Care via Telemedicine for Veterans Affairs Patients" final rule as it expands access to care for controlled substances to VA patients while safeguarding against the risk of diversion or misuse.

APhA appreciates the opportunity to respond to DEA's delay of effective dates and request for comments on these final rules. APhA requests that the DEA consider APhA's comments to remove administrative burdens and recognize the states' authority to define and regulate the practice of pharmacy and medicine, specifically pharmacists' ability to prescribe buprenorphine, so as not to decrease patients' access to lifesaving medications delivered through telemedicine. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter
Vice President, Government Affairs

[31] Diversion Control Diversion. Mid-Level Practitioners Authorization by State. Drug Enforcement Agency. Available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/practioners.html (noting that the chart was last updated February 14, 2025).