American Pharmacists Association

March 18, 2025

Derek Maltz
Acting Administrator
Drug Enforcement Administration (DEA)
8701 Morrissette Drive
Springfield, VA 22152

RE: [RIN 1117-AB40] Special Registration for Telemedicine and Limited State Telemedicine Registration

Submitted electronically via www.regulations.gov to Docket No. DEA–407

Dear Acting Administrator Maltz,

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on DEA's notice of proposed rulemaking (NPRM), "Special Registration for Telemedicine and Limited State Telemedicine Registration." This NPRM would permit the issuance of valid controlled substance prescriptions via telemedicine in limited circumstances where practitioners have not performed an in-person medical evaluation. APhA supports expanding patient access to medications and care via telemedicine; however, APhA also requests that DEA explicitly state that pharmacists are authorized to dispense controlled substances in accordance with their state licensure and are included within the practice of telemedicine as it relates to this NPRM. APhA also raises points of concern regarding the current state of prescription drug monitoring programs (PDMPs) and is concerned with the greater workload of adding another verification step to the prescription filling process and the increased burden of the recordkeeping and reporting requirements outlined in the NPRM.

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.

Registration Requirements under 21 CFR Part 1301 (FR 6548)

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, practitioners are generally required to conduct an in-person medical evaluation of patients before issuing them a controlled substance prescription.[1] This proposed rule would establish three types of Special Registration for telemedicine related to prescribing controlled substances to patients for whom the prescriber has not conducted an in-person medical evaluation.

The three categories of Special Registrations are Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration, and Telemedicine Platform Registration. The Telemedicine Prescribing Registration "would authorize the prescribing of Schedules III through V controlled substances by clinician practitioners,"[2] which the proposed rule defines as "properly registered physicians and *mid-level practitioners* [emphasis added]."[3] The Advanced Telemedicine Prescribing Registration "would authorize certain specialized clinician practitioners the privilege to prescribe not only Schedule III through V controlled substances, but Schedule II controlled substances as well."[4] The Telemedicine Platform Registration "would authorize covered online telemedicine platforms to dispense Schedules II through V controlled substances through a clinician practitioner possessing either a Telemedicine Prescribing Registration or an Advanced Telemedicine Prescribing Registration."[5]

Defining Telemedicine to Reflect the State-Governed Practice of Medicine

21 U.S.C. 802(54) defines the practice of 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."[6] This proposed rule adds "which also falls within one of seven distinct categories that Congress determined were appropriate to allow for the prescribing of controlled substances via telemedicine despite the practitioner never having conducted an in-person medical evaluation of the patient" to the end of that definition.[7] Additionally, the proposed rule utilizes a footnote within the definition of the "practice of telemedicine" to note that "While this statutory definition of the practice of telemedicine explicitly excludes pharmacists, such exclusion does not apply to situations where a pharmacist is acting in their capacity as a mid-level practitioner, authorized to dispense controlled substances in accordance

[1] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6543-44 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-68.
[2] *Id.* at 6549. Available at: https://www.federalregister.gov/d/2025-01099/p-134.
[3] *Id.* at 6542. Available at: https://www.federalregister.gov/d/2025-01099/p-55.
[4] *Id.* at 6549. Available at: https://www.federalregister.gov/d/2025-01099/p-134.
[5] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-134.
[6] *Id.* at 6544. Available at: https://www.federalregister.gov/d/2025-01099/p-72.
[7] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-72.

with their state licensure."[8] While this footnote appears to recognize an exception to the prohibition of pharmacists outlined in 21 U.S.C. 802(54), APhA urges DEA to explicitly state that pharmacists authorized to dispense controlled substances in accordance with their state licensure are included within the practice of telemedicine as it relates to this NPRM.

This clarification is critical to alleviate any misinterpretation of current law and by pharmacists reviewing other rules put out by DEA. For example, DEA's final rule titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" defined the practice of telemedicine in accordance with 21 U.S.C. 802(54) only, without an exception for pharmacists "acting in their capacity as a mid-level practitioner[s], authorized to dispense controlled substances in accordance with their state licensure."[9] Another final rule by the Department of Justice, Department of Health and Human Services, and DEA titled "Continuity of Care via Telemedicine for Veterans Affairs Patients" does include a footnote that provides an exception for the exclusion of pharmacists in 21 U.S.C. 802(54)'s definition of telemedicine.[10] The footnote within that final rule provides, "This definition of telemedicine does not exclude a pharmacist functioning as a mid-level practitioner authorized to prescribe controlled substances."[11] Given the varying language, APhA encourages DEA to standardize this language to ensure that the state-recognized pharmacist scope of practice is acknowledged so as not to unintentionally inhibit patient access to care.

While APhA acknowledges that the footnote within this proposed rule does appear to permit pharmacists to practice telemedicine under this rule, APhA stresses that the preceding ***"and state law*** **[emphasis added]"** likely negates the "other than a pharmacist" language and is likely inapplicable to the state-governed practice of medicine. Therefore, APhA strongly encourages DEA to rework this misinterpretation of the definition of "telemedicine" and its utilization of this definition to more explicitly state that pharmacists authorized to dispense controlled substances in accordance with their state licensure are included within the practice of telemedicine. While well-intended, without clarification, the DEA is unintentionally inserting a federal agency into the state-regulated practice of medicine.

Telemedicine Prescribing Registration Eligibility

Under proposed § 1301.11(c)(2), clinician practitioners seeking a Telemedicine Prescribing Registration "would need to demonstrate that they have a legitimate need for a Special Registration."[12] The notice provides that "DEA has determined that physicians and board-

[8] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-73.
[9] Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6505 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01049/p-17.
[10] HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information, 90 Fed. Reg. 6524 (Jan. 6, 2025). Available at: https://www.federalregister.gov/d/2025-01044/p-21.
[11] *Id.* Available at: https://www.federalregister.gov/d/2025-01044/p-23.
[12] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6549 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-143.

certified *mid-level practitioners* [emphasis added] (defined under 21 CFR 1300.01) have a legitimate need to prescribe Schedules III through V controlled substances when they anticipate that they will be treating patients for whom requiring in-person medical evaluations prior to prescribing Schedule III-V controlled substances could impose significant burdens on bona fide practitioner-patient relationships."[13] 21 CFR 1300.01 defines a mid-level practitioner as "an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, ***but are not limited to*** **[emphasis added]**, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the State in which they practice."[14] Not only does this definition not exclude pharmacists, but it accurately references the prescriptive authority provided by the states. Currently, fifteen[15] states permit pharmacists to prescribe controlled substances in some fashion.[16] As such, APhA strongly urges DEA to follow state law that recognizes pharmacists as mid-level practitioners and, in turn, allows them to be eligible for Telemedicine Prescribing Registration.

Additionally, DEA recognizes pharmacist prescriptive authority of controlled substances in its "Mid-Level Practitioners - Controlled Substance Authority by Discipline within State" chart.[17] In its February 14, 2025, update of this chart, DEA recognized pharmacists' prescriptive authority of controlled substances in ten different states.[18] In addition to these ten states, APhA counts five more states – Colorado, Iowa, Nevada, North Dakota, and Oregon – that recognize pharmacist prescriptive authority in some manner but are not currently listed in this chart.[19] APhA and several other pharmacy associations have sent a letter to DEA asking them to update

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[13] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-143.
[14] 21 CFR 1300.01. Available at https://www.ecfr.gov/current/title-21/part-1300/section-1300.01#p-1300.01(Mid-level%20practitioner).
[15] California, Colorado, Idaho, Iowa, Massachusetts, Montana, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Tennessee, Utah, and Washington.
[16] 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, and listed 10 states); American Pharmacists Association. Letter to DEA, Update to DEA Registration Process for Pharmacists to Reflect State Law Changes (Mar. 3, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=9e7G3gPVeDE%3d (noting five states that have recently authorized pharmacists to prescribe controlled substances in some manner).
[17] Diversion Control Diversion. Mid-Level Practitioners Authorization by State. Drug Enforcement Agency. Available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/practioners.html.
[18] *Id.*
[19] Letter to DEA, Update to DEA Registration Process for Pharmacists to Reflect State Law Changes (Mar. 3, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=9e7G3gPVeDE%3d.

this chart so pharmacists in these states do not face any barriers when applying for DEA registration.[20]

Special Registration Prescriptions Issued by Clinician Special Registrants under 21 CFR Part 1306 (FR 6553)

In addition to the prescription requirements outlined in 21 U.S.C. 823(g), special registration prescriptions will also be required to comply with proposed 21 CFR 1306.41 through 1306.47, which "address the manner in which prescriptions are issued by clinician special registrants[] and certain elements required to be a part of special registration prescriptions."[21] By requiring these additional standards, DEA hopes to "ensure[] that the quality and integrity of medical practice are maintained, even in the evolving landscape of remote healthcare services."[22]

Manner of Issuance of Special Registration Prescriptions (FR 6553)

Proposed 21 CFR 1306.42 provides that clinician special registrants must issue special registration prescriptions through electronic prescribing.[23] By requiring the utilization of electronic prescribing for controlled substances, clinician special registrants would use a secure platform to issue these prescriptions, which in turn should reduce the number of forged prescriptions and aid in the reduction of the misuse of these medications.[24] APhA supports DEA regulations and policies that require practitioners to utilize electronic prescribing of controlled substances as a way to reduce fraudulent prescriptions.

Nationwide Prescription Drug Monitoring Program (PDMP) Check (FR 6554)

Clinician special registrants would be required to check relevant PDMPs under proposed 21 CFR 1306.43.[25] During the first three years from the date that the final rule becomes effective, "individual special registrant[s] would be required to check the PDMPs for: (1) the state or territory where the patient is located; (2) state or territory where the clinician practitioner is located; and (3) any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the clinician practitioner is located."[26] Following this initial period of three years, "individual special registrant[s] would be required, before issuing any special registrant prescription for controlled substances to a patient, to check the PDMPs of all 50 states of the United States and any other U.S. district or

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[20] *Id.*
[21] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6553 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-190.
[22] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-190.
[23] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-193.
[24] *Id.* at 6553-54. Available at: https://www.federalregister.gov/d/2025-01099/p-193.
[25] *Id.* at 6554. Available at: https://www.federalregister.gov/d/2025-01099/p-197.
[26] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-197.

territory that maintains its own PDMP."[27] DEA has implemented this delayed approach to give registrants and those within the industry time to adjust to ensure compliance with this new requirement when it takes effect. DEA notes the delayed implementation of this requirement accounts for the fragmented nature of PDMPs today and the challenges this fragmentation presents to providers in their quest to review comprehensive patient data to prevent diversion.[28]

APhA appreciates DEA's delayed implementation of this requirement as APhA agrees that the current state of the interoperability of PDMPs nationwide is limited and incapable of complying with DEA's new requirements outlined in this NPRM. APhA supports the creation of a uniform, nationwide PDMP that allows pharmacists and other health care providers to review accurate, real-time patient data from federal, state, and territory databases simultaneously. However, APhA encourages the responsibility of checking the PDMP as outlined in this proposed rule to remain with the clinician special registrants rather than the pharmacists filling the special registration prescriptions. As the number of data points increases with checking the PDMPs of all fifty states, APhA notes that clinician special registrants may encounter more "false positives," which could lead to delays in access to care. Additionally, APhA encourages DEA or those in the industry to seek out the expertise and input of pharmacists when designing an integrated, nationwide PDMP and any standards or policies associated with its development, upkeep, and continual improvement. APhA also urges DEA to support education and training for registrants utilizing the new integrated, nationwide PDMP to ensure appropriate use and compliance with new DEA regulations and policies.

Additional Elements on a Special Registration Prescription (FR 6557)

Under proposed 21 CFR 1306.47, clinician practitioners would be required to put two additional pieces of information on "special registration prescriptions: (1) the Special Registration numbers of the clinician practitioner and, if a platform practitioner facilitated the prescription, the platform practitioner; and (2) State Telemedicine Registration numbers of the clinician practitioner and, if a platform practitioner facilitated the prescription, the platform practitioner (unless exempted from obtaining a State Telemedicine Registration under proposed 21 CFR 1301.11(d))."[29] Proposed 21 CFR 1306.47(c) states, "A corresponding liability rests upon the pharmacist who fills a special registration prescription that is not prepared in the form required by this regulation."[30] Given DEA's framework of this proposed rule, the pharmacist would need to know the Special Registration numbers of the clinician and platform practitioners (if applicable) to determine if their Schedule II prescriptions are valid. From a pharmacist's perspective, the special registrant number differentiates special registrant prescriptions written by those with a Telemedicine Prescribing Registration and an Advanced Telemedicine

[27] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-198.
[28] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-199.
[29] *Id.* at 6557. Available at: https://www.federalregister.gov/d/2025-01099/p-233.
[30] *Id.* at 6598. Available at: https://www.federalregister.gov/d/2025-01099/p-746.

Prescribing Registration. DEA notes that "pharmacists would be able to verify these registration numbers on DEA's CSA Registration Validation Tool."[31]

While APhA recognizes that efforts to ensure the validity of controlled substance prescriptions are important, APhA stresses that verifying the additional elements of special registration prescriptions under this proposed rule is overly burdensome for pharmacists and pharmacies. APhA is also concerned about the corresponding liability language from the NPRM, as DEA should not punish pharmacists and pharmacies for the actions or lack of actions of clinician special registrants. Additionally, APhA notes that the proposed rule could lead to pharmacist confusion. For example, if a clinician special registrant does not include the required elements on a special registration prescription, it may be difficult for a pharmacist to know that the prescription was prescribed under the NRPM. This is just one example of how difficult it would be for pharmacists to ascertain information about whether clinician special registrants are satisfying their obligations under this proposed rule. As such, APhA urges DEA to remove the "corresponding liability rests upon the pharmacist" language from the proposed rule. Further, any mistake related to the additional requirements on special registration prescriptions will result in delays in care and increased workload on the pharmacist or pharmacy staff in correcting the error.

If this NPRM is implemented, APhA acknowledges pharmacists' professional accountability would include checking these two additional elements on special registration prescriptions. As such, APhA encourages DEA to provide clear instruction and communication when educating practitioners and pharmacists about these new types of registrations and the additional requirements on prescriptions written by clinician special registrants. APhA invites DEA to utilize APhA, its members, and its resources to aid in the dissemination of information to pharmacists throughout the nation. Additionally, APhA requests DEA to clearly provide that it will not penalize pharmacists or pharmacies for the failure of clinician special registrants to meet their other obligations outlined within the proposed rule (i.e., PDMP checks, patient verification, presence in the same state as a patient for Schedule II prescriptions, etc.).

APhA also notes that pharmacists continue to be asked to do more when reviewing prescription medications before dispensing. At the same time, reimbursement rates for these services have not risen to adjust for a pharmacist's expertise or the costs of operating a pharmacy, causing pharmacy deserts throughout the country. As DEA may know, over 2,200 community pharmacies have closed since 2020.[32] Reviewing DEA's CSA Registration Validation Tool will result in a new unfunded mandate that would require pharmacists to spend more time verifying prescriptions. As such, APhA urges DEA to promote adequate reimbursement for pharmacists or ensure other federal agencies provide financial incentives to compensate pharmacists for the additional time needed to verify special registration prescriptions.

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[31] *Id.* at 6557. Available at: https://www.federalregister.gov/d/2025-01099/p-236.

[32] *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.

Adequately reimbursing pharmacists for their services will keep pharmacies open and allow them to continue providing care for patients nationwide.

Further, APhA recommends that DEA examine the potential costs of requiring pharmacists to verify the additional elements on special registration prescriptions by checking the DEA's CSA Registration Validation Tool before finalizing this rule. One study looking at pharmacists querying PDMPs found that if pharmacists were to check the PDMP for every opioid and benzodiazepine filled, pharmacies would see a substantial increase in the time they expended on filling these prescriptions and the costs associated with filling them.[33] If this NPRM is implemented, pharmacies could see a similar increase in labor and costs. As such, APhA reiterates its previous point that verifying the additional elements on special registration prescriptions under this NPRM is overly burdensome on pharmacists and pharmacies.

Additionally, APhA draws attention to DEA's final rule titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter," as the ID check provision within this final rule, which may need to be revised, will also result in the addition of another step in the prescription filling process. As our previous comments outline, APhA believes this requirement significantly disrupts pharmacists' workflow and amounts to pharmacists policing the practice of telemedicine.[34] Therefore, APhA urges DEA to take the opportunity within this proposed rule to rescind this policy.

DEA also notes that adding these two elements will help pharmacists validate legitimate prescriptions previously marked as "red flags" due to doubts caused by factors like geographical distance. APhA appreciates DEA's efforts in creating mechanisms to allow pharmacists to ascertain the validity of controlled substance prescriptions but points out that such processes should not supersede pharmacists' professional judgment.

Recordkeeping and Reporting under 21 CFR Part 1304 (FR 6557)

In addition to the recordkeeping and reporting requirements within 21 U.S.C. 823(g), clinician special registrants would be required to follow additional requirements outlined within the proposed rule.[35] The proposed rule provides that "[c]linician special registrants would be required to establish and maintain photographic records for patient verification and maintain their special registration prescription records at their designated special registered location,"

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[33] Charlie Upton, Stephanie A. Gernant, Nathaniel M. Rickles, *Prescription Drug Monitoring Programs in Community Pharmacy: An Exploration of Pharmacist Time Requirements and Labor Cost*, 60 JAPhA 943 (2020).
[34] American Pharmacists Association. Comments to DEA on Docket No. DEA-948, Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients, Final Rule with Delay for Effective Dates and Request for Comments (Feb. 28, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=YiqazhVBrdA%3d.
[35] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6557 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-238.

while platform special registrants "would be required to maintain and update credential verification and documentation needs."[36] Regarding data reporting, "pharmacies dispensing special registration prescriptions would be required to report monthly aggregated special registration prescription data on Schedule II controlled substances and certain Schedule III-V controlled substances, and special registrants would be required to report annually aggregated information about their telemedicine practice, including the number of new patients they treat through telemedicine, and the total number of special registration prescriptions for Schedule II controlled substances, and certain Schedule III-V controlled substances, they dispensed for the preceding year."[37]

Patient Verification Photographic Record (FR 6557)

Under proposed 21 CFR 1304.04(i), clinician special registrants or delegated employees under their direct supervision must "verify the identity of a patient seeking treatment via telemedicine by requiring that the patient present a state or federal government-issued photo identification card through the camera of the audio-visual telecommunications system."[38] Proposed 21 CFR 1304.04(i)(1) permits clinical special registrants or delegated employees under their direct supervision to verify a patient's identity using other forms of documentation when the patient does not have a federal or state-issued photo identification card. During this "first telemedicine encounter, the clinician special registrant would also be required to capture a photographic record of the patient presenting their federal or state-issued photo identification or other acceptable documents and use the photographic records to confirm the patient's identity in subsequent telemedicine encounters."[39] The special registrant would be required to maintain the photographic record for at least two years.[40] APhA appreciates DEA's inclusion of other acceptable forms of patient identification in the NPRM. Permitting other ways to verify a patient's identity should minimize access issues related to a patient's lack of a state or federal government-issued photo identification card while balancing the risks of prescribing controlled substances via telemedicine without an in-person medical evaluation. Additionally, APhA requests DEA ensure that the requirements outlined within this NPRM regarding patient verification photographic records remain with the clinician special registrant and are not also placed on the dispensing pharmacist or pharmacy.

Special Registration Telemedicine Encounter Record (FR 6558)

When a clinician special registrant prescribes a special registration prescription, the clinician special registrant is required to "maintain a record of the date and time of the telemedicine encounter, the address of the patient during the telemedicine encounter, and the home address

[36] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-238.
[37] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-238.
[38] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-239.
[39] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-239.
[40] *Id.* at 6557-58. Available at: https://www.federalregister.gov/d/2025-01099/p-241.

of the patient" under proposed 21 CFR 1304.04(j).[41] The proposed rule would also require these records to be maintained for at least two years.[42] APhA recognizes the need to record additional information during applicable telemedicine visits that result in prescribing controlled substances. APhA requests that DEA clearly and effectively communicate these changes to clinician special registrants to ensure they comply with these new requirements. APhA encourages DEA to ensure that this information is made available by clinician special registrants to pharmacists filling special registration prescriptions when requested. APhA stresses that pharmacists must have access to electronic health records (EHRs) and that the interoperability of electronic health records is critical to realizing the full potential of integrated health care. Any lack of access to EHRs by pharmacists is considered "information blocking" under federal law and regulations.[43]

Pharmacy Reporting of Special Registration Prescription Data (FR 6558)

Under proposed 21 CFR 1304.60, pharmacies must "report aggregate data, within the first seven (7) days of the start of every month, for the special registration prescriptions filled during the preceding month for each Schedule II controlled substance and certain Schedule III-V controlled substances, including Ketamine, Tramadol, and any depressants that constitute a benzodiazepine (including their salts, isomers, and salt of isomers)."[44] While DEA notes that pharmacies only must report data on the Schedule III-V controlled substances explicitly listed in proposed 21 CFR 1304.06 at this time, the proposed rule does state that "additional Schedule III-V controlled substances may be included in the future via regulation based on trends in diversion and misuse."[45] APhA believes that this additional reporting requirement will be a burden on pharmacists and pharmacies. As such, APhA requests DEA remove this reporting requirement. Further, the NPRM states, "DEA assumes similar reports are already being submitted to state PDMPs electronically and pharmacists would be able to submit reports as required by § 1304.60 with minimal additional costs."[46] APhA has concerns that DEA underestimates the resources and costs of complying with this requirement.

If DEA implements this NPRM, APhA requests DEA establish clear guidelines on which drugs should be reported and processes to effectively communicate these guidelines and future changes to collecting this aggregate data to pharmacies and pharmacists. Additionally, APhA encourages DEA to provide an appropriate rationale for the inclusion of additional substances to the monitoring list.

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[41] *Id.* at 6558. Available at: https://www.federalregister.gov/d/2025-01099/p-246.
[42] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-246.
[43]Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability, 89 Fed. Reg. 63616-17 (Aug. 5, 2024). Available at: https://www.federalregister.gov/d/2024-14975/p-1507.
[44] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6558 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01099/p-251.
[45] *Id.* at 6559. Available at: https://www.federalregister.gov/d/2025-01099/p-251.
[46] *Id.* at 6584. Available at: https://www.federalregister.gov/d/2025-01099/p-482.

DEA states that the aggregated data from pharmacies will allow them "to make more informed, evidence-based policy decisions."[47] A specific example of how this information could be utilized involves implementing quotas to prevent or mitigate medication shortages.[48] DEA also provides that it could use this "data to evaluate: patient outcomes associated with special registration prescriptions; the impact of the proposed Special Registrant regulations on patient access to controlled substances (especially in remote or rural areas); the efficacy of the proposed Special Registration regulations on preventing and detecting diversion associated with remote prescribing; and trends or changes to telemedicine prescription practices that might necessitate regulatory reforms."[49] APhA acknowledges the importance of DEA's efforts to combat the opioid crisis and minimize polysubstance abuse and the value that this data may have in its efforts. However, APhA is concerned that this aggregated data could be used to penalize pharmacies that are in good standing for filling legitimate prescriptions. As such, APhA reiterates its previous recommendation that DEA remove this additional reporting requirement for pharmacies.

Annual Special Registrant Reporting of Special Registrant Prescription Data (FR 6560)

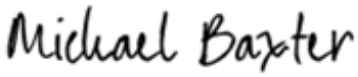
Individual special registrants and platform special registrants, under proposed 21 CFR 1304.61, would be required to "report annual data on the total number of new patients in each state for which they issued at least one special registration prescription for a Schedule II controlled substance or certain Schedule III-V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine; the total number of special registration prescriptions for Schedule II controlled substances issued by the special registrant, in aggregate across all states; and the total number of special registration prescriptions for certain Schedule III-V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepines (including their salts, isomers, and salt of isomers), which were issued by the special registrant, in aggregate and across all states."[50] DEA again notes in this section of the proposed rule that "Schedule III-V controlled substances subject to this proposed requirement under 21 CFR 1304.61 are limited to those specifically identified" and adds that "additional Schedule III-V controlled substances may be included in the future via regulation based on trends in diversion and misuse."[51] APhA reiterates the above points regarding adding Schedule III-V medications to a reporting list and the importance of DEA establishing clear guidelines on which drugs should be reported and processes for communicating any changes to pharmacists and entities employing pharmacists registered as clinician special registrants.

APhA appreciates the opportunity to provide feedback on the "Special Registrations for Telemedicine and Limited State Telemedicine Registrations" NPRM. APhA supports

[47] *Id.* at 6559. Available at: https://www.federalregister.gov/d/2025-01099/p-268.
[48] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-268.
[49] *Id.* at 6560. Available at: https://www.federalregister.gov/d/2025-01099/p-268.
[50] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-271.
[51] *Id.* Available at: https://www.federalregister.gov/d/2025-01099/p-251.

regulations that permit health care providers, including pharmacists, who are qualified to prescribe controlled substances to do so via telemedicine to increase access to care when certain conditions are met. APhA requests DEA rework certain provisions of this NPRM to explicitly state that pharmacists are eligible to become clinician special registrants and eliminate provisions that will make filling special registration prescriptions unnecessarily difficult and jeopardize patient access to care. If you have any questions, want to arrange a meeting with APhA, or need any additional information, please contact Corey Whetzel, Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,
Michael Baxter



Vice President, Government Affairs