

February 11, 2025

The Honorable Paul Tonko 2269 Rayburn HOB Washington, DC 20510 The Honorable Mike Turner 2183 Rayburn HOB Washington, DC 20510

Re: Existing actions and plans to eliminate barriers to accessing medications for opioid use disorder (MOUD)

Dear Representative Tonko and Turner:

The American Pharmacists Association (APhA) is pleased to provide the following responses to your October 2024 inquiry on efforts APhA is undertaking and asks for your continued assistance in removing barriers and increasing access to effective addiction medication treatments for opioid use disorder (MOUD).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists, scientists, 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.

Please find responses to your specific questions (below):

1. What are you doing to educate your members about the change in the law after the MAT Act?

APhA thanks you for your leadership in passing the Medication Access and Training Expansion Act ("MAT Act") and the Mainstreaming Addiction Treatment Act ("MATE Act") that removed the DEA's burdensome "X waiver" requirement, making it easier for pharmacists and other providers to prescribe buprenorphine. However, Congress and the Substance Abuse and Mental Health Services Administration (SAMHSA) omitted the ability of the Accreditation Council for Pharmacy Education (ACPE) to provide the now-required continuing professional; education (CE) training for pharmacists to prescribe buprenorphine—requiring a fix.

APhA's government affairs team worked with your offices and other congressional champions to successfully secure this legislative fix, permitting both APhA and ACPE to provide this required training for prescribing pharmacists in the previous 2024 end-of-year package. This "fix" has already passed the full U.S. House of Representatives in the text of the reauthorization of the SUPPORT Act, was passed by the Senate, Health, Education, Labor, and Pensions (HELP) Committee, and included as a consensus item in the recent bipartisan, bicameral 2024 health care end-of-year package. However, as you know, unfortunately, this package and several other vital health care authorizations were removed from the final package.

Thirteen states now permit pharmacist-prescription of buprenorphine. APhA looks forward to working with you and Congress to pass this fix into law, allowing new and renewing DEA-licensed pharmacists in these states to educate and permit pharmacists to continue prescribing buprenorphine to save patients' lives.

APhA has provided several opportunities for our members to learn about the changes after the MAT Act, including:

- Hosted a Pulse on Practice and Policy webinar entitled Medications for Opioid Use Disorder (MOUD) Access after the MAT Act; a link to a webinar may be found here.
- Offered APhA's Initiating Buprenorphine Certificate Training Program, which is a
 comprehensive, webinar-based training program designed to meet the SAMHSA
 training requirements for the MATE Act. Pharmacists and physicians initiating
 medications for opioid use disorder will learn about screening, non-pharmacologic and
 pharmacologic management and communication, and addressing barriers related to the
 management of pain and substance use disorders.

2. What are you doing to reduce stigma around MOUD and increase access?

APhA has passed policy resolutions supporting access to MOUD and advocated for pharmacists' independent prescriptive authority for MOUD, showing our members' support. Tangible items include hosting webinars on MOUD, recommending pharmacists' authority to prescribe MOUD therapy, and producing educational products on MOUD. The pharmacists' authority to prescribe MOUD therapy, and producing educational products on MOUD. The pharmacists' role in reducing stigma surrounding opioid use disorder resources is available to all our members.

3. We also have heard concerns that some pharmacies are not stocking buprenorphine. Do you have information on which pharmacies are stocking buprenorphine?

APhA encourages pharmacies to maintain an inventory of medications used to treat MOUD to ensure patient access. This is a current policy statement enacted by the consensus of members. APhA supports pharmacies in maintaining a stock of buprenorphine according to their community's needs. APhA also promoted a call to action that urged the distributor community to act swiftly to realign thresholds for buprenorphine, provide transparency so pharmacies know what those thresholds are, and provide expedited appeals processes if access to

buprenorphine, or controlled substances generally, is cut off. Therefore, encouraging DEA not to punish distributors who are increasing their stock of buprenorphine according to demand. Patients should check with their local pharmacies to determine the stock of buprenorphine products.

4. What would you like to see changed to better allow access to MOUD?

Please see the answer to Question #1 regarding the ACPE and APhA training fix included in the SUPPORT Act's reauthorization.

As one of the most accessible and trusted health care providers in their communities, ¹ pharmacists have a significant role in initiating access to MOUD and providing culturally competent and culturally sensitive care. Nearly 90% of the U.S. population lives within five miles of a community pharmacy, and this high level of accessibility allows pharmacists to serve a unique role as another point of entrance for patients to integrate into receiving MOUD and other harm reduction services. Programs allowing pharmacists to prescribe MOUD and other harm reduction services have expanded nationwide in the past ten years.

The establishment and success of such programs depend on overcoming two primary policy barriers: pharmacists' state scope of practice and coverage for pharmacists' patient care services by Medicare Part B, Medicaid, and commercial health plans.

Pharmacists' scope of practice has grown substantially across the country over the last 25 years, unlocking new opportunities for pharmacists to provide added services and value to patients while working as equal members of an interprofessional and collaborative healthcare team. The foundational scope of practice of pharmacists has traditionally been limited to making medication therapy recommendations that require prescriber approval to make medication changes. Through expanded authorities, pharmacists can use their medication expertise to autonomously prescribe medications through various mechanisms.

Pharmacists' prescriptive authority is variable from state to state and falls on a spectrum of how independently they may prescribe. This is often completed through collaborative arrangements with physicians, nurse practitioners, physician assistants, or other prescribing practitioners. In recent years, there has been an expansion in pharmacists' ability to provide services in response to public health needs and disease states (examples include HIV PrEP/PEP, hormonal contraceptives, tobacco cessation, and opioid antagonists). Many of these services are provided by pharmacists under statewide protocols or standing orders. At the time of writing,

¹ Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I, Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, Journal of the American Pharmacists Association (2022), doi: https://doi.org/10.1016/j.japh.2022.07.003.

pharmacists have the authority to prescribe MOUD in 13 states² via a statewide protocol, standing order, or independent prescriptive authority. Pharmacists also have the authority to prescribe opioid antagonists in every state and the District of Columbia via collaborative practice agreements, statewide protocols, standing orders, or independent prescriptive authority.

As the National Academies of Sciences, Engineering, and Medicine (NASEM) report states, "The greatest challenge to integrating the role of the pharmacist in primary care relates to financing barriers..." Pharmacists and their services are not currently recognized in Medicare Part B, and coverage is variable in state Medicaid and private sector plans, indicating inequitable access to coverage of pharmacist-provided patient care services. Lack of payment to cover the pharmacist's time to deliver professional services is a significant barrier that must be addressed to fully utilize pharmacists as medication experts. Another barrier related to sustainable models for pharmacists' services is in value-based payment models. While APhA supports these models, many are still dependent on fee-for-service (FFS) payment as a component, and the lack of FFS payment for pharmacists further complicates their involvement. In addition, pharmacists' documentation of patient care data is often not accepted or attributed in quality metric calculations, preventing their contributions to care from being fully recognized in these models.

The Equitable Community Access to Pharmacists Services (ECAPS) Act, introduced as H.R. 1770 / S. 2477 in the last Congress, cosponsored by Rep. Tonko, and set for reintroduction in mid-March if 2025 would amend title XVIII of the Social Security Act to provide coverage of certain services by pharmacists under Medicare Part B.⁴ Additionally, there are numerous efforts at the state level to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of their services under the medical benefit through the submission of a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) by state medical assistance programs. Finally, many private payers are adding pharmacists as a provider type and covering their patient care services independent of state policy changes. There are also examples of states passing legislation mandating that all private payers in a state must cover services within the pharmacists' scope of practice.

5. What resources would help your members feel confident in dispensing MOUD?

 APhA has multiple resources to make members feel more confident in dispensing MOUD, including:

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² California, Colorado, Idaho, Massachusetts, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Tennessee, Utah, Washington

³ National Academies of Sciences, Engineering, and Medicine. 2021. Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/25983.

⁴ https://www.congress.gov/bill/118th-congress/house-bill/1770/text

- A comprehensive pain management certificate training program that includes a section on understanding medications for opioid use disorder.
- An initiating buprenorphine certificate training program that educates pharmacists about screening, non-pharmacologic and pharmacologic management, communication, and addressing barriers related to the management of pain and substance use disorders.
- An Annual Institute on Substance Use Disorders provides continuing education opportunities on MOUD.
- Continuing education on how physicians and community pharmacists can collaborate to improve access to medication-assisted treatment.
- Continuing education on pharmacists' roles in medication-centered addiction treatment.
- o A test your knowledge quiz on medications for opioid use disorder treatment.
- Cosponsored <u>Buprenorphine 101:</u> Physicians and Community Pharmacists
 Collaborating to Improve Access to Medication-Assisted Treatment discussion
 guide along with the American Society of Addiction Medicine.
- o Sponsored affinity group for pain, palliative care, and addiction professionals.

6. Should prior authorization be eliminated for MOUD?

Prior authorizations hinder timely access to MOUD. Eliminating prior authorizations will improve health outcomes, increase treatment engagement, reduce overdose risk, and result in fewer emergency department visits. ^{5,6} APhA supports methods that reduce the burdens of patients obtaining needed medications.

7. We are aware that there continues to be uncertainty about how the Drug Enforcement Administration (DEA) uses the Suspicious Orders Report System (SORS) and interprets other DEA rules for enforcement actions. Have your members struggled with quotas or perceived limitations from distributors or the DEA? If yes, what clarification would allow pharmacies to properly stock buprenorphine?

Pharmacists will not identify locations that do not stock buprenorphine to avoid being flagged as suspicious activity by the DEA. Buprenorphine should not be included in the list of

⁵ Nguemeni Tiako MJ, Dolan A, Abrams M, Oyekanmi K, Meisel Z, Aronowitz SV. Thematic Analysis of State Medicaid Buprenorphine Prior Authorization Requirements. *JAMA Netw Open.* 2023;6(6):e2318487. doi:10.1001/jamanetworkopen.2023.18487

⁶ Keshwani S, Maguire M, Goodin A, Lo-Ciganic WH, Wilson DL, Hincapie-Castillo JM. Buprenorphine Use Trends Following Removal of Prior Authorization Policies for the Treatment of Opioid Use Disorder in 2 State Medicaid Programs. JAMA Health Forum. 2022 Jun 24;3(6):e221757. doi: 10.1001/jamahealthforum.2022.1757. PMID: 35977240; PMCID: PMC9233239.

medications in the SORS, which would allow pharmacists to stock it without fear of being flagged for inappropriate ordering and promote access to patients who need the treatment.

8. Are there existing barriers you think we should be aware of that impact your ability to increase patient access to MOUD?

As discussed above, pharmacists' scope of practice has recently changed in several states, allowing pharmacists to prescribe controlled substances and receive a controlled substance license from their State Board of Pharmacy. However, the DEA has not yet updated the online DEA application and Mid-Level Practitioners Authorization by State to reflect these changes and allow pharmacists to apply for a DEA registration successfully. Under the "RPH" column of the Mid-Level Practitioners Authorization by State table, the following states need to be updated:

Colorado

3, 3N, 4, 5 Administer, Prescribe & Dispense (pursuant to a collaborative agreement with prescriber or statewide protocol)

Explanation: HB 1045 expands pharmacists' authority to prescribe medications for opioid use disorder (MOUD) pursuant to a collaborative practice agreement or a statewide protocol and requires coverage of these services by health plans in the state.⁷

Idaho

2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Dispense

Explanation: Idaho recently removed the requirement that controlled substances be prescribed under collaborative practice agreements. Pharmacists can now independently prescribe controlled substances.^{8,9}

Nevada

2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Dispense (pursuant to a statewide protocol)

Explanation: AB 156 expands pharmacists' scope of practice to assess, prescribe, and dispense drugs for medication assisted treatment. 10, 11, 12

⁷ C.R.S. 12-280-604. Collaborative pharmacy practice agreement statewide drug therapy protocol for medication-assisted treatment for opioid use disorder - rules - definition

 $^{^{8}}$ Idaho Code § 54-1705. Practice of pharmacy — General approach.

⁹ IDAPA 24.36.01.350 PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.

¹⁰ Nev. Rev. Stat. Ann. § 639.0124 "Practice of pharmacy" defined.

¹¹ Nev. Rev. Stat. Ann. § 639.28079 Medication-assisted treatment of opioid use disorder: Conditions under which pharmacist registered with Board is authorized to assess and counsel patient and prescribe and dispense drug; regulations regarding registration and establishment of protocol.

 $^{^{12}}https://bop.nv.gov/uploadedFiles/bopnvgov/content/board/ALL/2023 \\ \underline{Meetings/Workshop\%20D\%20WS\%20Proposed\%20Amendment\%20to\%20NAC\%20MOUD\%20-\%20AB\%20156\%20-\%20FINAL.pdf$

Oregon

2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Dispense

Explanation: HB 4002 expands pharmacists' authority to prescribe and dispense an early refill of a medication for the treatment of OUD to a patient.¹³

9. Are there actions you need Congress to take that would in turn allow you to expand access to MOUD?

Congress must pass the SUPPORT Act reauthorization and the ECAPS bill and expand coverage under Medicare Part B under subsequent actions to MOUD and other harm reduction services pharmacists provide.

Additionally, APhA believes it would benefit state Medicaid programs to have guidance from CMS to the state Medicaid programs encouraging submission of state plan amendments (SPAs) to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of services with the pharmacists' state scope of practice. APhA believes guidance and SPA templates and instructions would be very beneficial to support expanded, streamlined, and consistent implementation of these programs in the states. Congress should encourage CMS to provide such guidance and SPA templates and instructions to the states.

Thank you for the opportunity to comment on APhA's efforts to increase access to MOUD. We look forward to continuing to work with you on ways our nation's pharmacists can help eliminate barriers to treatments that help save patients' lives.

Sincerely,

Michael Baxter

Vice President, Government Affairs

Michael Baxter

¹³ https://olis.oregonlegislature.gov/liz/2024R1/Downloads/MeasureDocument/HB4002/Enrolled