November 6, 2024

The Honorable Paul Tonko
2369 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Turner
2183 Rayburn House Office Building
Washington, DC 20515

RE: Barriers to Accessing Medications for Opioid Use Disorder Post MAT Act

Dear Representatives Tonko and Turner:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to share our organization's actions and plans to eliminate barriers for accessing medications for opioid use disorder (MOUD). We laud your commitment to seeking solutions to ensure those who seek services and treatment for substance use are able to. We also appreciate your continued leadership in the Addiction, Treatment and Recovery Caucus.

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use disorders (SUDs), receive safe, appropriate, and effective treatment. Pharmacist members specialize in psychiatry, substance use disorders (SUD), and psychopharmacology and most are residency trained and Board certified in psychiatric pharmacy holding the BCPP credential (Board Certified Psychiatric Pharmacist). With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric disorders and SUDs.

Role of Psychiatric Pharmacists in SUD Care and Treatment

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy, have advanced training and expertise to provide direct patient care and medication management for the complete range of psychiatric disorders and SUDs across the lifespan.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) that extends beyond that of most other health care providers. When included in the provision of MOUD services through a collaborative practice arrangement, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders; reduce per patient dosage of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs. Furthermore, given the insufficient number of providers in addiction medicine, psychiatric pharmacists increase access to SUD treatment by providing medication management, education, monitoring, and follow-up care.

There are 13 states that allow pharmacists to prescribe buprenorphine for patients with opioid use disorder, pursuant to varying collaborative practice agreements and practice settings within each state. These states include: California, Colorado, Idaho, Iowa, Massachusetts, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Utah and Washington. In addition, federal pharmacists, including those at the VA, may prescribe controlled substances with corresponding licensure in one of the 11 states and active DEA registration.

Responses to Questions

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

Through our listserv and weekly newsletter, AAPP sends routine updates to its membership notifying them about changes in policy and guidelines including changes in federal law impacting psychiatric pharmacist practice. We informed our members about the passage of both the MAT Act and the MATE Act. AAPP prioritizes SUD topics for presentation at both annual meetings and summits that are widely attended by our members.

AAPP members are also aware of the required eight hours of training on treating and managing patients with SUDs. While not provided by AAPP, our members are aware of national pharmacist organizations that are providing training to pharmacists.

AAPP has a multitude of resources including legislative fact sheets available on our website. These cover key changes and promote removing additional barriers to access to MOUD for patients. These policy briefs and fact sheets are available here Letters and Statements | aapp.org and are also included in email briefs to the membership.

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

AAPP devotes significant effort to education on SUD and reducing stigma in various formats. We have a dedicated committee, the Substance Use Disorders Committee, focused on these efforts. The SUD Committee has three primary goals: education on SUDs, developing resources for treatment of SUD and related conditions, and advocacy to improve the care for those with SUD. This committee has developed several toolkits and additional resources that are open access, several of which are found here: Substance Use Disorders | aapp.org. In addition, ad hoc task forces are developed when unique initiatives arise. A recent task force worked together to promote harm reduction services by pharmacists and the publication may be found here: Exploring the harm reduction paradigm: the role of Board-Certified Psychiatric Pharmacists | Mental Health Clinician (allenpress.com).

AAPP members also educate federal and state policymakers to provide their perspective on the unique needs of patients with SUD and how psychiatric pharmacists participate on health care teams to manage and treat these conditions that are often cooccurring with mental health disorders. We support access to low-threshold services so that we can meet people where they are in terms of seeking SUD services and support.

AAPP members are often sought out for their expertise and often provide feedback on important statements and guidelines, including the recently published PhARM-OUD Guideline developed by the

National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA) available here: PhARM-OUD-Guidance.pdf (nabp.pharmacy). In addition, AAPP was invited by NABP and NCPA to attend an expert panel to provide formal comments before publication of the guidelines.

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

AAPP does not have a formal method for tracking buprenorphine inventory at specific pharmacies. However, we are aware that there are access challenges at some pharmacies in refusing to carry or fill buprenorphine prescriptions. There are a variety of factors that have led to these challenges, including concerns by pharmacists on the validity of the prescription and perceived limitations on how much buprenorphine they can dispense without raising concerns with the DEA and the state attorneys general. These challenges have been raised with the DEA in a March 15, 2023 consultation that AAPP participated in. Guidance from DEA to pharmacists and their field staff would be helpful in mitigating some of these barriers. In addition, state opioid settlement agreements with distributors of controlled substances must be altered to ensure that pharmacies are not deterred from stocking buprenorphine.

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

AAPP would like clinical pharmacists that are board certified and residency trained recognized as qualified health providers under Medicare so that access to MOUD can be expanded. It will take an act of Congress as CMS does not have the authority to do so. Congress, in recent years has added marriage and family therapists and mental health counselors as eligible providers which we applaud. More providers, including clinical pharmacists, should be added to increase access to MOUD and other behavioral health services.

AAPP members would like to see the *Modernizing Opioid Treatment Access Act* or MOTAA (H.R. 1359/S.644) become law. As you are aware, the legislation would allow addiction physicians/psychiatrist to prescribe methadone for treatment of an OUD as they currently can prescribe methadone to treat pain. This would increase access to methadone at community pharmacies, which remains the only FDA-approved MOUD that is not accessible outside an OTP.

AAPP also supports your *Reentry Act* (H.R. 2400/S.1165) to allow states to restore access to healthcare, including addiction and mental health treatment, through Medicaid for incarcerated individuals up to 30 days before their release. Access to MOUD is critical for optimizing transition back into the community.

AAPP also supports *Substance Use Prevention and Pharmacy Oriented Recovery Treatment Prescription Act or SUPPORT Rx Act* (S. 4429) that creates a pharmacy-based addiction care demonstration program along the lines of the Rhode Island model.

AAPP members would also like to see legislation passed that allows the telehealth flexibilities for buprenorphine to remain permanent, including teleprescribing. Telemedicine has proven to be an effective tool in reducing barriers to care and bridging the gap between patients and providers.

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

Scope of practice for pharmacists is determined at the state level. Psychiatric pharmacists provide broader patient care than just dispensing and can prescribe in select states as well as treat patients with MOUD. AAPP supports state model legislation authored by the American Society of Health-System Pharmacists that would:

Provide clear authority for pharmacists to initiate MOUD. The model legislation establishes clear authority for physicians and institutions to establish agreements with pharmacists to manage medication therapy to treat OUD. It should provide flexibility for these agreements to include a statewide protocol, collaborative practice agreement, or institutional protocol.

Establish a timeline for board of pharmacy action on buprenorphine. The elimination of the X-waiver was intended to expand access to buprenorphine. Legislation should direct the board of pharmacy to establish a statewide model protocol for pharmacist initiation and management of buprenorphine therapy for OUD.

Ensure pharmacists comply with federal registration and training requirements. Federal law requires that pharmacists register with the DEA and complete certain training requirements prior to prescribing controlled substances to treat OUD. State law should align with these federal prescribing requirements.

Remove any pre-existing state barriers to MOUD prescribing. Most MOUD, including buprenorphine, are controlled substances. Some state Controlled Substances Acts or Pharmacy Practice Acts may contain legacy prohibitions against pharmacists prescribing controlled substances. These must be removed to allow prescribing of MOUD.

Create a mechanism for Medicaid to pay for these pharmacist services. If the state does not have an existing Medicaid payment mechanism for clinical services provided by pharmacists, add this authority to the Medicaid statute to allow reimbursement of pharmacist services related to MOUD management.

6. Should prior authorization be eliminated for MOUD?

Yes, AAPP would be in favor of eliminating prior authorizations for MOUD. There are only 3 FDA-approved medications for OUD and these are all standard of care with methadone and buprenorphine having the most efficacy data. Removal of prior authorization should include all available buprenorphine formulations (generic, brand, transmucosal, long-acting injection, etc.) for treatment of OUD. We should provide low barrier access to OUD treatment.

7. We are aware that there continues to be uncertainty as to 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?

AAPP would like to see the DEA take a stronger stance on this and recommend that quotas /limitations for MOUD be avoided. In addition, AAPP supports the *Broadening Utilization of Proven and Effective*

Treatment for Recovery Act or the BUPE for Recovery Act (H.R. 9886/S.5271) to exempt buprenorphine from the SORS during the opioid PHE. In addition, as stated above we also support efforts to urge the state attorneys general to modify their settlement agreement with distributors to exclude buprenorphine ordering from suspicious order thresholds, monitoring, and reporting.

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

Pharmacists have prescriptive authority in a limited number of states. Additionally, state laws vary greatly in pharmacists' ability to collaboratively manage patients with OUD. AAPP members would like to see all states allow pharmacists to provide comprehensive medication management services within their scope of practice for patients being treated with MOUD including buprenorphine.

Another barrier in access to MOUD is the FDA Risk Evaluation and Mitigation Strategies (REMS) for Sublocade (long-acting injection) that hinders patient access to this live-saving medication. Overall, we strongly support the goal of the REMS program to mitigate the risk of serious harm or death that could result from intravenous self-administration. However, the requirements of the REMS program go far beyond the measures needed to mitigate the risk of self-administration. The REMS specifies that Sublocade be dispensed from REMS certified pharmacies. This creates an access barrier as it does not allow for utilization of a patient's pharmacy insurance benefits to cover the medication, and thus is cost prohibitive. We understand that addressing the access challenges of the Sublocade REMS may require changes in DEA policy and hope that your offices can work with the DEA and the FDA to mitigate these barriers.

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

As mentioned above, AAPP would like to see Congress pass the following pieces of legislation:

- *Modernizing Opioid Treatment Access Act* or MOTAA (H.R. 1359/S.644)
- *Reentry Act* (H.R. 2400/S.1165)
- *BUPE for Recovery Act* (H.R. 9886/S.5271)
- *Substance Use Prevention and Pharmacy Oriented Recovery Treatment Prescription Act or SUPPORT Rx Act* (S. 4429)

Further, APPP recommends Congress take action to:

- Allow HHS to use its authority under the PREP Act to authorize pharmacists, as part of physician led care teams, in every state to initiate and administer MOUDs, such as buprenorphine, and taper and discontinue use of opioids.
- Provide temporary authority permitting prescribers to initiate treatment of OUD with schedule II-V controlled substances via telehealth and remote supervision of pharmacists be made permanent.
- Direct HHS to recognize fentanyl test strips as a covered countermeasure under the Public Readiness and Emergency Preparedness Act, thereby allowing health care providers, including pharmacists, to distribute them in every state.

- Allow Medicare to reimburse physicians and health systems for medication management services related to treatment of OUD, provided incident to a physician, by pharmacists on their care team.
- Direct CMS to make clinical pharmacists qualified health providers under Medicare to expand the pool of providers that can provide MOUD.

Thank you again for the opportunity to respond to your inquiry. If you have any questions, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,

Brenda Schimenti

Brenda K. Schimenti
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