July 2, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, NW
Washington, DC 20201

Re: HHS Request for Comment on Chronic Disease of Addiction

Dear Secretary Kennedy:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to provide feedback on the Request for Information (RFI) regarding substance research, policy, and strategies to improve the prevention, treatment, recovery of chronic disease of addiction and mental illness and how to promote the Great American Recovery Initiative. We applaud HHS in seeking to improve strategies and programs to address mental health and substance use disorders.

We also want to thank the Department, through CMS, ACF, and SAMHSA, for issuing a Dear Colleague and Advisory on Expanding Access to Medications for Opioid Use Disorder: The Role of Pharmacists and the Settings in Which They Work. While the focus of the Advisory is primarily pharmacists in the retail setting, clinical pharmacists, including psychiatric pharmacists, working in health care settings also expand access to mental health and substance use services. Access to psychiatric pharmacists is limited due to barriers as outlined below in our comments.

About AAPP

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). Given the 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

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 specialized training in providing direct patient care and medication management for the complete range of psychiatric disorders and SUDs. Psychiatric pharmacists are not only integral to interprofessional treatment teams but also for decision-making and leadership roles in health care organizations, state and federal organizations, academia, and industry.

8055 O Street, Ste S113 ■ Lincoln, NE 68510
www.aapp.org ■ info@aapp.org
402-476-1677 (phone)

Psychiatric pharmacists are important members of the health care team working directly with patients and in collaboration with other health care providers including, but not limited to, psychiatrists, other physicians, therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase the capacity of the health care team to provide care and psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs. As medication experts, psychiatric pharmacists are uniquely positioned to facilitate medication access and adherence by identifying and helping to address potential treatment barriers, including prior authorizations and high out-of-pocket patient costs.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) and Medications for Alcohol Use Disorder (MAUD) 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, improve monitoring and titration; and reduce overall costs. Psychiatric pharmacists with their education and advanced training are uniquely positioned to provide education to raise awareness, reduce stigma and address SUD treatment barriers to mitigate the underuse of effective, evidence-based SUD pharmacotherapy. Furthermore, given the insufficient number of providers in addiction medicine, psychiatric pharmacists increase access to SUD treatment by providing systematic screening, medication initiation and management, monitoring, care coordination, and follow-up care.

AAPP Comments to RFI

1. **Programs or interventions that have rigorous, empirical evidence of effectiveness in improving outcomes**

   i. ***Psychotropic Stewardship as Standard of Care for mental health and substance use disorders for adults and youth***

The ultimate goal of psychotropic stewardship is that every patient with a psychiatric disorder, including substance use disorders, will have their medication therapy reviewed, optimized, and managed by a psychiatric pharmacist as part of a stewardship team. In short, intentional efforts to have a Board-Certified Psychiatric Pharmacist (BCPP) provide Comprehensive Medication Management (CMM) services to patients with psychiatric disorders will improve access, outcomes, and cost. A 2024 systematic literature review of the impact of psychiatric pharmacists found 202 articles where psychiatric clinical pharmacists impacted patient clinical outcomes for people experiencing a psychiatric disorder. Patient outcomes associated with a psychiatric clinical pharmacist included reduction in depression symptoms scores, increased psychiatric medication adherence and increased smoking cessation. The addition of a psychiatric pharmacist on the team improved health system operational outcomes such increased number of patients seen, number of hours of care provided and reduced rehospitalization rates.

The Veterans Affairs (VA) model identifies psychiatric pharmacists as integral providers in the delivery of CMM in mental health and substance use disorder care. There are more than 600 psychiatric pharmacists in the VA providing care for patients with mental health and substance use disorders which

improves quality, safety and access to care for Veterans. Most psychiatric pharmacists operate under a scope of practice which allows for independent prescribing and significant impact on access to care. During FY23, there were 484,975 patient care visits delivered by psychiatric pharmacists. Additionally, close to 200 psychiatric pharmacists have controlled substance prescribing authority and this number continues to grow. Controlled substance prescribing streamlines care for many Veterans including deprescribing initiatives. A variety of outcomes have been published regarding the improvement in care when utilizing psychiatric pharmacists in various VA sites including: decrease in utilization of psychiatric emergency services, improved medication adherence, increases in treatment response or remission compared to usual care, increase in treatment retention and decreased time to mental health provider follow-up post hospital discharge, improved suicide risk identification and evaluation, among others.

Patient outcomes improve when pharmacists are integrated at the system level. Programs that have similarly leveraged pharmacist expertise for systematic medication management consistently show:

- Improved medication safety and prescriber and patient satisfaction
- Reduced adverse drug events and polypharmacy
- Decreased annual health care cost, emergency department visits and hospitalizations

2. Policies or changes to federal programs might improve outcomes

i. Remove CMS regulatory barriers to incident-to billing for evaluation and management (E/M) services provided by clinical pharmacists on the health care team

Medicare allows physicians to bill Medicare Part B for services provided by pharmacists when supervised by a physician, known as billing “incident-to” the physician. However, pharmacist patient care services provided incident-to a physician or nonphysician practitioner are limited to reimbursement for the lowest level E/M code (99211), eliminating the ability for care teams to bill incident-to for complex services that would generally be reimbursed under the higher level E/M codes (99212 – 99215) and which pharmacists are licensed by states to provide within their scope of practice, either independently or through collaborative practice. Psychiatric pharmacists are not ancillary staff performing tasks delegated by physicians; but rather act as direct patient care providers on interdisciplinary care teams. Like other specialists such as psychologists, dietitians, or physical therapists, psychiatric pharmacists often manage patients’ complex conditions. This interferes with team-based care by restricting physicians’ ability to bill for the full scope of services across all levels of medical decision-making provided by members of the care team incident-to the physician.

Limiting coding for incident-to E/M services ignores the essential role pharmacists play in caring for patients in their communities and the value and expertise they provide to their interprofessional care teams. CMS should encourage and incentivize team-based care delivery models, supported by incident-to payment, that fully engage and utilize all clinicians on the health care team, rather than maintaining limitations on E/M incident-to billing that are inconsistent with pharmacists’ licensure. This limitation is misaligned with how states are advancing care delivery through pharmacists on the care team.

As such, we urge CMS to clarify that physicians and health care facilities have the authority to bill for all levels of E/M services provided by a psychiatric pharmacist practicing within their scope of practice while under supervision of such a physician. This will support scalability of psychiatric pharmacist services which will increase access to specialized care for our most vulnerable and complex patients.

ii. Remove the CMS regulatory barriers that prevent pharmacists from enrolling in PECOS and obtaining provider identification numbers when providing state-authorized services to Medicare beneficiaries

While clinical pharmacists, including psychiatric pharmacists, are not qualified health professionals (QHPs) under Medicare Part B, they can and do provide state-authorized patient care services to Medicare beneficiaries. This care is often disrupted because CMS does not provide a clear mechanism for pharmacists to enroll in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Pharmacists are not on the list of eligible professionals or nonphysician specialty types that use Form 855i to enroll in PECOS. This fails to account for the patient care role that pharmacists play in ambulatory clinical settings and results in care disruptions for Medicare beneficiaries.

For example, because Medicare Part B only covers prescription claims issued by providers enrolled in PECOS, Medicare beneficiaries with a valid prescription initiated by pharmacists, as authorized by their state license, experience rejection of their prescription claims. Beneficiaries are then forced to go to a second, medically unnecessary appointment simply to have these same medications prescribed by a PECOS-enrolled prescriber. This is particularly common for medications initiated by pharmacists, as explicitly allowed by CMS, during office visits, including during Medicare Annual Wellness Visits. Beneficiaries experience similar coverage barriers for laboratory testing ordered by pharmacists acting within their state scope of practice.

Enrolling in PECOS is also required for a pharmacist to receive a Provider Transaction Access Number (PTAN), necessary for internal processing and communication with Medicare. A PTAN is obtained after enrolling in PECOS and is used to communicate with Medicare Administrative Contractors and Medicare Advantage (MA) plans. Without a mechanism to obtain a PTAN, pharmacists are often unable to enroll as a provider of supplemental services for MA plans, even though they meet CMS' own definition of a provider under MA in all 50 states (42 CFR 422.2, CMS defines "provider" for the purposes of the MA program as including "any individual who is engaged in the delivery of health care services in a state and is licensed or certified to engage in that activity in the state)."[i]

CMS should provide an administrative mechanism for pharmacists to enroll as a prescriber in PECOS and obtain a PTAN. No legislation is needed for CMS to address this bureaucratic barrier that prevents pharmacists from providing care to beneficiaries as authorized under state law and CMS regulations.

We believe the most effective way to elevate pharmacists to increase patient access to care is by recognizing their services in the Medicare Part B benefit and classifying them as QHPs.

However, in the interim, states continue to expand patient access to pharmacist-provided services, creating a growing gap between the services Medicare beneficiaries can receive from pharmacists and those available to non-Medicare patients. All 50 states now allow pharmacists and physicians to enter collaborative practice arrangements, which allows physicians to fully utilize the specialized skills and expertise of pharmacists on the care team. Payers routinely recognize pharmacists for clinical services in ambulatory care settings, improving medication-related outcomes and reducing hospital readmissions. Currently, 44 states authorize reimbursement of pharmacist services provided within their scope of practice from commercial payers and/or Medicaid. We urge CMS to expand access to pharmacists' services for Medicare beneficiaries by taking the immediate steps outlined above to remove regulatory barriers to ensure that Medicare patients have equitable access to pharmacist services.

3. Federal policies and programs that can be improved to mitigate the stigma against Americans seeking addiction treatment and recovery

Psychiatric pharmacists support federal policies and programs that reduce stigma and barriers to evidence-based treatment for substance use disorders by promoting person-centered, recovery-oriented care. Federal agencies can continue to advance these efforts by encouraging the use of non-stigmatizing language, supporting harm reduction as a component of care, and expanding interdisciplinary models that integrate behavioral health, pharmacy, and primary care services.

Policies that recognize substance use disorder as a chronic, treatable medical condition and promote timely access to treatment, medications, and recovery can improve patient engagement and outcomes while reducing the stigma that often prevents individuals from seeking care. SAMHSA's Harm Reduction Framework provides a useful foundation for these efforts by emphasizing practical strategies to meet individuals where they are and connect them with appropriate treatment and recovery services.

4. Federal policies and programs that can be improved to address the practitioner supply issue

i. Expand Utilization of Clinical Pharmacists' Patient Care Services

Clinical pharmacists' medication expertise is invaluable, and their education prepares them for patient care that extends far beyond simply dispensing medications. Nevertheless, clinical pharmacists, including psychiatric pharmacists, continue to face both regulatory and reimbursement barriers to practicing at the top of their scopes of practice. As a result, our health care system fails to use resources effectively, squandering both human and financial capital.

AAPP encourages HHS to focus its efforts on engaging clinical pharmacists to ensure that patients receive the full value of a drug through adherence and effective management of comorbid chronic conditions. Even the most innovative, groundbreaking, lifesaving medication works only if a patient takes it correctly.

As described above, studies indicate that the inclusion of psychiatric pharmacists on the health care team demonstrates a significant return on investment in both patient outcomes and real dollars.

Despite this evidence, psychiatric pharmacists are neither eligible to participate in Medicare Part B, nor are they required providers within accountable care organizations (ACOs). As a result, psychiatric pharmacists are not directly reimbursed for patient care, making it more difficult for them to fully integrate into certain practice settings. To address this, we urge HHS to call on CMS and Congress to recognize psychiatric pharmacists as qualified health care professionals (QHPs) so they may bill independently for the care they are uniquely positioned and trained to provide. The Veterans Health Administration, the Bureau of Prisons, the Indian Health Service and tribal health authorities utilize and pay for psychiatric pharmacists as part of the care team to treat patients with mental health and substance use disorders. Medicare is long overdue in expanding the list of mental health and SUD providers to include psychiatric pharmacists, which will expand access to care for our most vulnerable and complex patients. Furthermore, recognition of psychiatric pharmacists as billing providers will enable growth and sustainability of ambulatory clinic-based psychiatric pharmacist services.

ii. Allow psychiatric pharmacists to serve as a psychiatric consultant in the Behavioral Health Integration/Collaborative Care Model (CoCM)

The Collaborative Care Model (CoCM)[i] is an evidence-based model for integrating physical and mental health and substance use services in a primary care setting, while maximizing the impact of a limited mental health and substance use workforce. The model integrates two team members into the primary care team, typically a mental health/substance use care manager and a psychiatric/addiction medicine consultant. The behavioral health care manager must have formal training in mental health/substance use. The psychiatric consultant must be trained in psychiatry and qualified to prescribe medications. These members expand the team's capability to identify and treat people with mental health and/or SUDs. The model promotes systematic communication among team members during and outside of face-to-face patient encounters. The model includes care management and evidence-based treatments, including psychotherapy and medications, regular/proactive monitoring and treatment to a targeted outcome using validated clinical rating scales, and regular, systematic psychiatric caseload reviews.

Psychiatric pharmacists are integral members of interprofessional health care teams that care for patients with mental health and substance use disorders. Psychiatric pharmacists practicing at the top of their license work with primary care teams daily to evaluate and manage patients who suffer not only from psychiatric and mental health illness but also comorbid chronic medical conditions. Thus, psychiatric pharmacists' knowledge of both physical and mental illnesses and the medications used to treat them make them an ideal fit for such an integration into the primary care setting. These models are reflected in primary care practices, including federally qualified health centers. In addition, the Veteran's Administration employs numerous behavioral health clinical pharmacy specialists on their primary care-mental health integration teams, co-located in primary care clinics. BCPPs are highly trained specifically to consult, evaluate, recommend, and manage depression and anxiety, as well as other mental health and medical disorders.

Under the CoCM model, the "psychiatric consultant" is defined as a medical professional, trained in psychiatry and qualified to prescribe the full range of medications. Additionally, the "psychiatric consultant" advises and makes recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies and medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services that are communicated to the treating physician or other qualified health care professional. Unfortunately, CMS does not allow psychiatric pharmacists to serve as the psychiatric consultant in the model. Psychiatric pharmacists, working as team members and often under collaborative practice agreements (CPAs), not only prescribe medications but provide comprehensive medication management (CMM) to optimize outcomes, improve medication safety, manage side effects and drug interactions, and promote adherence to appropriate, evidence-based pharmacotherapy. In many states under a CPA, pharmacists have full prescribing privileges including a DEA license in order to prescribe controlled substances. In some states, pharmacists are able to prescribe all medications except for controlled substances. However, when working in a team-based model of care the primary care physician can prescribe controlled substances.

Although psychiatric pharmacists are not trained to diagnose, they are trained to perform mental status exams and identify symptoms of mental illnesses that respond to, or are poorly responsive to, psychiatric medications. In addition, psychiatric pharmacists often collaborate with integrated behavioral health providers on the health care team who perform diagnostic assessments. Therefore, we believe that allowing psychiatric pharmacists to serve as the "psychiatric consultant" in the CoCM

will increase much needed access to this model of care in the primary care setting, especially in areas where there is a shortage of psychiatrists.

We urge CMS to allow psychiatric pharmacists to serve as a psychiatric consultant in the CoCM to help increase access to this successful model of care. Making it easier for primary care providers to deliver BHI and CoCM services will improve access to mental health care, including substance use treatment.

iii. Include Pharmacists in the National Health Service Corps (NHSC)

Currently, with the exception of the Substance Use Disorder Workforce Loan Repayment Program, pharmacists are not eligible to participate in most of the NHSC student loan repayment programs, which are open to primary care clinicians in a Health Resources and Services (HRSA)-approved service site in a Health Professionals Shortage Area (HSPA). Given that many psychiatric pharmacists practice in HPSA and their potential to bridge gaps in care by contributing valuable CMM services in the behavioral health and primary care settings, we recommend that pharmacists be added to the list of eligible disciplines for participation in all NHSC loan repayment programs.

iv. Safeguard the 340B Drug Pricing Program

The federal 340B drug pricing program helps underserved clinics and hospitals maximize federal resources while providing access to lifesaving medications and supporting patient services that might otherwise be unavailable. These 340B eligible clinics and hospitals reinvest cost savings from the 340B program to help expand access to mental health and SUD services for the most vulnerable patients through the following:

- Training the health care workforce (including psychiatric pharmacists) needed to care for complex patients including those with mental health and substance use disorders.
- Providing medications for the treatment of mental health and substance use disorders at no cost to patients who are otherwise unable to afford them.
- Providing clinical pharmacy services through innovative, integrated models of care to improve patient outcomes and reduce overall health costs.
- Providing uncompensated or charity care for patients who are uninsured or underinsured.

v. Fund Psychiatric Pharmacist Training to Increase Pool of Mental Health and SUD Providers

The nation's need for quality health care services includes the services provided through pharmacy residency training programs, which prepare pharmacists to work effectively as an integral part of an interdisciplinary health care team. Residency-trained pharmacists participate directly in clinical decisions regarding the use of medications and are leaders in improving patient outcomes. There continues to be a need for more pharmacy residency programs, and it is in the public's best interest that such programs be adequately funded. Due to scientific advancements and the evolution of care delivery models, pharmacy residencies are now essential to performing certain patient care services. AAPP specifically urges Congress to direct CMS to allow pass-through funds that are currently used to fund PGY1 pharmacy residencies to also fund ASHP-accredited PGY2 psychiatric pharmacy residency programs. Recent CMS audits have created uncertainty; therefore, providing a clear path for PGY2 psychiatric pharmacy residency training programs to receive federal funding will allow for expansion of specialized residency programs to increase the number of psychiatric pharmacists that are trained and entering the workforce each year.

5. **Ways to strengthen program evaluation and performance measurement, including through the use of AI, data modernization, and advanced analytics**

i. Identification of complex patients benefiting from a psychiatric pharmacist assessment

Medication safety in psychiatric settings is already complex. Caution is necessary with human oversight to avoid new artificial intelligence tools introducing failure modes of misinformation from large language models. Tools that are intended to improve efficiency to optimize the care of patients will allow clinicians to maintain compassionate, patient-centered care.

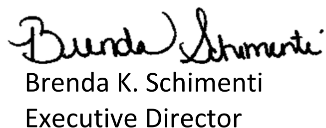
AI tools that augment the psychiatric pharmacist's ability to implement psychiatric stewardship services to provide a prospective psychotropic audit with intervention and feedback in an efficient manner should be prioritized. Examples of stewardship services to be prioritized include:

- Provision of Comprehensive Medication Management including:
  - Assessing the appropriateness of medications
  - Counseling patients/caregivers
  - Evaluating adherence
  - Medication monitoring
- Medication management in older adults
- Medication management for high-risk combinations such as opioids and benzodiazepines
- Medication management in narrow therapeutic spectrum medications with high risk of adverse drug reactions (ADRs)

As behavioral health workforce shortages continue to limit timely access to needed care for many Americans, individuals are increasingly turning to artificial intelligence (AI)-enabled tools, digital mental health applications, and online platforms for information and support. Psychiatric pharmacists are uniquely positioned to help patients navigate these technologies by promoting digital health literacy, evaluating the quality and safety of AI-generated information, identifying misinformation, and helping patients interpret recommendations within the context of evidence-based care. By integrating AI and digital tools into comprehensive medication management, psychiatric pharmacists can empower patients to make informed decisions, improve treatment adherence and self-management, and ensure that technology complements—rather than replaces—the therapeutic relationship and human connection needed to provide empathetic, individualized care.

Thank you again for the opportunity to comment on the Chronic Disease of Addiction RFI. If you have any questions, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at lahanen@venable.com. We look forward to working with you.

Sincerely,



Brenda K. Schimenti
Executive Director

Resources:

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9. Jonathan F. Lister et al., *Board-Certified Psychiatric Pharmacists in Substance Use Disorder Care: A Narrative Review of Roles and Outcomes*, *Annals of Behavioral Health & Clinical Pharmacy* (2025), https://doi.org/10.1177/29767342251352994
10. Maha Abdalla et al., *Responsible Use of Artificial Intelligence in Health Care: Evidence, Challenges, and Best Practices: An Opinion of the Drug Information Practice and Research Network of the American College of Clinical Pharmacy*, 8 J. Am. Coll. Clinical Pharmacy 1333 (2025), https://doi.org/10.1002/jac5.70131.
11. Robert J. Haight et al., *Psychotropic Stewardship: Advancing Patient Care*, Mental Health Clinician 36 (2023), DOI**:** 10.9740/mhc.2023.04.036

[i] 42 CFR 422.2 "Provider." Available at: https://www.ecfr.gov/current/title-42/part-422#p-422.2