August 1, 2022

Admiral Rachel Levine, MD
Assistant Secretary for Health

Re: HHS Initiative to Strengthen Primary Health Care RFI (87 FR 38168)

Dear Admiral Levine:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to submit comments on the Department of Health and Human Services' (HHS) request for information (RFI) on strengthening primary care.

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 and neurologic disorders, receive safe, appropriate, and effective treatment. Members are specialty pharmacists, and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorders (SUDs), psychopharmacology, and neurology. With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric and SUDs.

Pharmacists today 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 healthcare professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency-trained mental healthcare practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric and SUDs. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

Psychiatric pharmacists are positioned to be an important component of primary care transformation for improving access to care for people with mental health and SUDs. They are integrated into primary care teams to provide additional support and expertise to primary care and behavioral health providers. They are trained to optimize medications for patients with psychiatric disorders, including mental health conditions, SUDs, as well as those for non-psychiatric medical conditions common in the primary care setting. Psychiatric pharmacists can be invaluable in a primary care setting where most patients are prescribed medications for both mental and physical illnesses concurrently. As medication experts, they can enable more primary care physicians to provide services to their patients with mental health and SUDs.

Successful models of integrated care that provides primary health care with mental health and substance use services include the following:

1. <u>Comprehensive Medication Management</u>

Psychiatric pharmacists are well positioned to collaborate with primary care providers to conduct comprehensive medication management (CMM) for patients with mental health and SUDs. CMM is

a standardized, systematic process that includes an individualized care plan that achieves the intended goals of therapy with appropriate follow-up to determine actual patient outcomes.

CMM is an evidence-based process of care provided by psychiatric pharmacists that includes:

- Assessing all of a patient's medications– prescription, nonprescription, vitamins, and supplements;
- Assessing each medication to ensure that it is appropriate, effective, safe, and can be taken as intended; identifying and addressing medication-related problems, including medication interactions and adverse effects;
- Developing individualized care plans with therapy goals and personalized interventions;
- Prescribing medications and ordering laboratory or other diagnostic tests when permitted by state regulations;
- Following up with appointments at regular intervals to evaluate response, adverse effects, progress toward treatment goals, and to adjust medications as needed;
- Educating patients and families about medications and lifestyle modifications; and
- Referring to other providers and specialists for services such as diagnostic clarification, psychotherapy, and dietary counseling.

CMM services benefit patients:

- Needing complex care coordination among multiple providers;
- With multiple chronic conditions; on complex medication regimens;
- Who are not meeting treatment goals; who have serious medication adverse effects;
- Transitioning between health care settings;
- Taking specialty medications like clozapine or long-acting injectable antipsychotic medications;
- Who would benefit from genetic testing to optimize their medication regimen;
- With tobacco, alcohol, opioid, or other SUDs who may benefit from medication treatment; and
- Who have conditions that complicate psychiatric medication treatment such as pregnancy, advanced age, concomitant medical illness; and those receiving antipsychotic medications as children.

Barriers to implementing CMM:
Although CMM model is well accepted in some government funded health systems such as Veteran's Affairs and federally qualified health centers, it has not gained widespread acceptance. The primary cause for this lag is lack of recognition of psychiatric pharmacists as qualified healthcare providers by CMS and failure of Medicare to reimburse practices for CMM as a covered service.

Proposed HHS Action:
CMS should make comprehensive medication management a covered service to be provided by clinical pharmacy specialists, including psychiatric pharmacists. To ensure that clinical pharmacists are reimbursed for these time intensive services, CMS must also designate them as qualified healthcare providers for the provision of CMM under Medicare. This will allow for a level of reimbursement commensurate with the service provided, higher than a level 1 Evaluation and Management code. Currently it is the case that when billing "incident to" for psychiatric pharmacists' services, their documentation meets the criteria for higher-level visits, however their services are not reimbursed above a level one visit. Allowing higher levels of "incident to" billing under the supervision of a physician would make collaboration with a psychiatric pharmacist more financially feasible for practices and improve patient outcomes. Until billing and reimbursement are

addressed, primary care clinics and providers who want to employ psychiatric pharmacists cannot afford to bring them on-board and utilize their services.

2. Medicare Psychiatric Collaborative Care Model (CoCM)

CoCM 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.

Barriers to implementing CoCM:

Psychiatric pharmacists could be a valuable member of the team in collaborative care models (CoCM) however CMS does not allow psychiatric pharmacists to serve as the psychiatric consultant in the model. Clinical 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 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. With the exception of diagnosing, many psychiatric pharmacists, working as team members and often under collaborative practice agreements (CPAs), also provide all levels of care and not only prescribe medications but also manage all of their patients' medications to optimize outcomes, manage drug interactions, and promote adherence to therapies. In many states under a CPA, they have full prescribing privileges including a DEA license in order to prescribe controlled substances. There are some states where they 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 make diagnoses, 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 healthcare 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.

Proposed HHS Action:
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.

3. Patient-Centered Medical Home

The Patient-Centered Medical Home (PCMH) is an organizational model of primary care that delivers the core components of primary care with integrated specialty services. The PCMH is accountable for meeting the large majority of each patient's physical and mental health care needs. Clinical pharmacists, including psychiatric pharmacists, participate in the delivery of CMM under this model. Typically, these clinical pharmacists are salaried employees of the clinic or health care practice and their services are not reimbursed separately and therefore not recouped by the practice.

Proposed HHS Action: To increase psychiatric pharmacist participation in more primary care teams using PCMH, regulatory changes to payment and policy must be made.

4. CCMI's Primary Care First Model

The Primary Care First (PCF) model builds upon the previous Centers for Medicare and Medicaid Innovation model Comprehensive Primary Care Plus (CPC+) model design. The model provides a payment structure to support the delivery of advanced primary care services. The PCF model is designed to support practices caring for patients with complex chronic needs or serious illness. Some model sites are utilizing clinical pharmacists to provide CMM and collaborative management of certain conditions because of their expertise in medications to treat both physical and mental illnesses.

Proposed HHS Action:
Value-based care payment models function best when interprofessional teams are supported to deliver high-quality, comprehensive, person-centered services. We need immediate delivery system, payment, and policy transformation to enable successful interprofessional team implementation and dissemination of CMM by clinical pharmacists, including psychiatric pharmacists.

To reiterate, psychiatric pharmacists are an important component of primary care transformation for improving access to care for people with mental health and SUDs. Their cross-knowledge of all medications, drug interactions, and adverse effects would enhance the delivery of care and patient outcomes in the primary care setting. Regulatory changes to payment and policy must be addressed to allow for their participation in more primary care teams.

Thank you again for the opportunity to comment. 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
Executive Director