

November 20, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: The Centers for Medicare and Medicaid Services Request for Information: Innovation Center New Direction

On behalf of the College of Psychiatric and Neurologic Pharmacists (CPNP), we appreciate the opportunity to provide feedback on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) regarding the CMS Innovation Center (Innovation Center) and new directions to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs and improve outcomes. In general, we agree with the fundamentals of the new guiding principles that incentivize choice and align incentives based on the value of services delivered to beneficiaries. We believe that products such as prescription medications and services such as team-based care should be tested to assess their value in improving outcomes and reducing overall healthcare costs. CPNP is specifically interested in testing new models that improve the quality of care for people with behavioral health (BH) disorders.

CPNP is a professional association of more than 2,300 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. Most members are specialty pharmacists and Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorder, psychopharmacology, and neurology.

Psychiatric pharmacists are residency-trained, board certified pharmacists who are experts in the safe, effective, and well-informed use of medications in the treatment of substance abuse and mental health disorders. As experts employed across numerous government, private and community health care settings psychiatric pharmacists work collaboratively with other members of the inter-professional team to (1) optimize drug therapy; (2) provide direct patient care, including treatment assessment and optimization of medication regimens and dosing; (3) monitor patients for potential adverse drug reactions and interactions; (4) educate patients and families on psychiatric and addiction medications as well as psychiatric and substance use disorders and other related conditions; (5) engage in patient advocacy efforts both independently and with consumer groups; (6) teach pharmacy students and trainees as well as other health care practitioners; (7) conduct original research and publish in peer-reviewed journals and texts; (8) develop medication and formulary policies for state Medicaid programs; and (9) work to reduce medication costs and demonstrate cost savings to health care systems. Given the extent of their



capabilities and clinical services, psychiatric pharmacists should be more widely and effectively utilized throughout the health care system to address mental health and substance use disorders.

Value of Psychiatric Pharmacists in Treating Patients with Mental Health and Substance Use Disorders

CPNP believes that all individuals deserve access to affordable, meaningful health care coverage. While approaches to prevention, intervention, and treatment have improved, gaps in the health system continue to persist for the treatment of those with substance use or mental health disorders. However, there is demonstrated value in incorporating psychiatric pharmacists in the delivery of their health care.

Psychiatric pharmacists have the knowledge and expertise to provide direct patient care for the complete range of psychiatric and substance use disorders. While the clinical contribution of pharmacists has not been universally accepted or defined, pharmacists play a critical role in addressing the public health challenges associated with mental health and substance use disorders, including opioid addiction. As experts in pharmacotherapy, pharmacists have a unique skill set that complements other members of the interprofessional team, including physicians, social workers, and nurses. Further, studies have shown that when psychiatric pharmacists work in collaboration with primary care physicians and psychiatrists, they can help to increase the rates of medication adherence, improve patient satisfaction, increase patient knowledge, and reduce costs, by limiting the number of necessary primary care visits.¹

Given their education and training, psychiatric pharmacists are effective in treating mental and behavioral health disorders, often more so than a primary care physician who receives little instruction in clinical pharmacology. Primary care physicians are not trained in managing the additional complexities associated in diagnosing and treating medical problems of patients who suffer from psychiatric or substance use disorders. Moreover, psychiatric pharmacists possess the expertise that allows them to engage patients in their treatment plan by providing information regarding the benefits of treatment and any expected adverse effects, which promote the appropriate use of medications.²

In this regard, psychiatric pharmacists can help fill a need unmet by primary care providers across the health care system, improving patient care and reducing overall costs. Fifteen minute office visits in primary care do not allow the appropriate time to provide the care and counseling that is necessary to adequately help patients struggling with psychiatric and substance use disorders. For each patient that is considered for opioid therapy, pharmacists within advanced practice settings can help perform the necessary tasks which include evaluating past and current therapies, counseling and initiating a consent for long-term opioid therapy, identifying and recommending non-pharmacological and non-opioids that might be more appropriate for their disorder, ordering and evaluating baseline urine toxicology screens, providing and interpreting validated risk assessment tools for opioid abuse and misuse, assessing percent

¹ Goldstone LW, DiPaula BA, Caballero J, Park SH, Price C, Slater MZ. Improving medication-related outcomes for patients with psychiatric and neurologic disorders: value of psychiatric pharmacists as part of the health care team. *Ment Health Clin* [Internet]. 2015;5(1):1-28. DOI: 10.9740/mhc.2015.01.001.

² *Id.*



risk of opioid-induced respiratory depression, prescribing and counseling about naloxone therapy to prevent overdose, ordering and interpreting pharmacogenetic testing that can affect response and toxicity to opioid and other medications, and more. It is not realistic to expect any primary care provider to accomplish these tasks in a fifteen minute office visit and this scenario is applicable to all patients struggling with mental or behavioral health disorders. Pharmacists involved in the daily care of a mental health patient add significant value with regard to safety and appropriate therapies.

Similarly, psychiatric pharmacists also play a significant role in clinical activities in the inpatient setting, which directly contributes to the improvement of care for patients with psychiatric or neurologic disorders. Psychiatric pharmacists employed in the inpatient setting engage in multidisciplinary team rounds, reconciliation of medications, and patient discharge education. They also engage in patient interviews, review patients' medical records, and analyze medication use in an effort to provide recommendations for patients.³ Studies also have shown that pharmacist-led medication education groups are effective in reducing psychiatric hospital readmissions due to medication non-adherence.⁴

CPNP Comments on Innovation Center Mental and Behavioral Health Models

We are pleased to see the Innovation Center soliciting stakeholder feedback on expanding or establishing mental and behavioral health models to enhance care integration and address opioid use, substance use disorders, dementia, and the need for improved provider participation across the Medicare, Medicaid, and CHIP programs. As mentioned above, we believe psychiatric pharmacists can play a larger role in improving quality and costs of care for patients with mental health and substance use disorders. To date, psychiatric pharmacists have been an underutilized resource, despite being expertly qualified to address the increasing demand for mental health services. The Innovation Center can better meet the demands of the mental health care system by utilizing psychiatric pharmacists as: (1) members of the treatment team in managing medications for patients with psychiatric and substance use disorders; (2) the authoritative experts on the optimal use of medications and patient care; and (3) resources to increase provider choice and patient centered care for patients, physicians, and non-physician health care professionals in both inpatient and outpatient settings.

In many states throughout the U.S. and within the Department of Veterans Affairs (VA) and the Department of Defense (DOD), psychiatric pharmacists are being used more effectively in collaboration with other health care professionals to reduce costs and improve patient care. Though BCPPs are not typically allowed to make an initial diagnosis or change a diagnosis, collaborative practice agreements with the VA and DOD allow BCPPs to prescribe and manage patient medications, credentialed to the same level as nurse practitioners. BCPPs are particularly important for complex patients and in team based care where they are uniquely qualified in these instances to manage multiple medications and prevent adverse drug reactions or interactions. Currently, there are approximately 955 BCPPs who practice in the U.S. and

³ *Id.*

⁴ Arterbury, A., Bushway, A., Goldstone, L., Effect of a Pharmacist Led Medication Education Group on Hospital Readmissions due to Medication Non-Adherence for Patients with Previous Inpatient Psychiatric Admissions.



estimates suggest there will be more than 2,400 by 2025. The increased use of and integration of BCPPs into the health care team is an important step in addressing psychiatric shortages and access to mental and behavioral health services.

In 2015, CPNP published position paper⁵ that explored current practice models using complex medication management (CMM)⁶ to determine the impact psychiatric pharmacists on the provision of mental health services. The following are findings and examples of practice models as summarized in the paper.

In Montana, a psychiatric medication management private practice group provided CMM for patients with psychiatric or neurologic disorders, including depression, anxiety, and bipolar disorder. Data demonstrated cost savings of \$586 per patient, a 2.8:1 return on investment, and favorable patient outcomes, such as improvement in clinical status and patient satisfaction.⁷

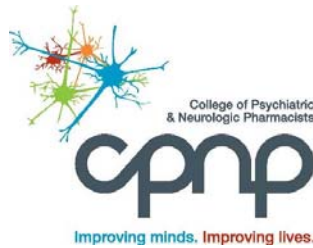
As mentioned earlier, the Veterans Health Administration began a joint initiative between the Veterans Affairs (VA) Offices of Mental Health Services and Primary Care Services in 2007. The goal was to integrate evidence-based mental health services into the primary care setting under the Patient Aligned Care Team model. This initiative focused on the 7 foundational principles of (1) creating patient-driven services; (2) offering team-based care; (3) increasing the efficiency of care; (4) providing comprehensive care, including access to specialists; (5) developing continuous service across time; (6) improving communication; and (7) developing seamless coordination of care. Pharmacists served on care teams, and patients were referred to them for specialty services, including CMM. In 2013, approximately 2,640 pharmacists were working in the VA system under advanced scopes of practice, as members of a clinical treatment team and with prescribing privileges. These pharmacists have been working as non-physician providers in nearly 40 subspecialty settings, including pain management and mental health. The value that clinical pharmacists can provide has been recognized, and the role of the clinical pharmacist in the VA system is being standardized. During a 6-month period from April to September, more than 35,000 pharmacy interventions were made and documented by pharmacists across 9 pilot sites. This initiative will continue to be deployed across the country as pharmacists, including psychiatric pharmacists, continue to bridge the gap between primary care and specialty care.⁸

⁵ Goldstone LW, DiPaula BA, Caballero J, Park SH, Price C, Slater MZ. Improving medication-related outcomes for patients with psychiatric and neurologic disorders: value of psychiatric pharmacists as part of the health care team. *Ment Health Clin* [Internet]. 2015;5(1):1-28. DOI: 10.9740/mhc.2015.01.001.

⁶ In 2012, the Patient-Centered Primary Care Collaborative (PCPCC) developed guidelines for CMM to ensure that each medication, including nonpsychiatric medications, is individually assessed to determine its appropriateness for the individual patient. CMM is a distinct service from Medication Therapy Management (MTM), which was adopted in 2003 by CMS and must by law be offered to high-risk patients enrolled in Medicare Part D plans. The main difference is that CMM is a well-defined, patient-centered care practice under which the pharmacist provides direct patient care services as a member of the health care team, not as an independent practitioner. CMM is also an ongoing service, rather than a one-time intervention, which allows patients to develop a relationship with their pharmacists. CPNP has endorsed CMM because it is a clearly defined, evidence based model for ongoing direct patient care provided by pharmacists, and it focuses on the pharmacist as an integrated part of a treatment team rather than as an independent provider. For more information see, *Id.*

⁷ *Id.*

⁸ *Id.*



In addition to looking primarily at the role of psychiatric pharmacists in mental health services, CPNP also expanded their examination to include models based on the use of specialty pharmacists across the health care system.

Fairview Health Services of Minneapolis–St Paul is a nonprofit health care system at which more than 2.7 million patients are seen annually. A 1-year prospective study of medication management services was performed from August 2001 to July 2002 at 6 clinics in this system. This study found that 637 medication therapy problems were resolved by 285 interventions. Medication management services were provided by pharmacists in conjunction with PCPs. Patient outcomes from 6 outpatient clinics offering medication management services (the intervention group) were compared with patient outcomes from 1 of 9 Fairview clinics that did not offer such services. The percentage of patients who met the goals of therapy was higher in the intervention group than in the control group for hypertension (71% versus 59%) and cholesterol management (52% versus 30%). Total health expenditures declined from \$11,965 to \$8,197 per person ($n=186$, $P<.0001$). The reduction in total annual health expenditures exceeded the cost of providing CMM services by more than 12:1.⁹

During the past several years, Fairview's care model innovation (CMI) initiative was organized to decrease reliance on fee-for-service payment systems. To accomplish this goal, CMI clinics relied on team-based care, and the Fairview system was categorized as a level 2 Accountable Care Organization. Treatment teams consisted of PCPs, pharmacists, nurses, certified diabetes educators, dietitians, and health coaches. Pharmacists' roles on the treatment team included face-to-face medication therapy management consultations, home visits, telephone visits, telehealth (Internet-based video) visits, and covisits with other providers on the team. They also developed collaborative practice agreements allowing them to help manage medication therapy for patients with diabetes and other chronic conditions. In 2008, outcomes from the 4 CMI team-based outpatient clinics were compared with outcomes from the other 38 non-CMI clinics. From December 2008 to March 2010, per-patient per-month spending increased by 3.7% in the team-based CMI group but by 14.7% in the standard clinics. A total of 40% of patients with diabetes met all 5 benchmark care goals in the team-based clinics, whereas only 17.5% of patients with diabetes met these goals statewide. Pharmacists provided CMM services for 823 patients in the CMI clinics during that period, with an average of 2.13 visits per patient. Pharmacists were able to resolve a total of 4135 drug therapy problems, more than 2 per visit. This finding is important, because patients with psychiatric and neuropsychiatric disorders often have chronic medical conditions, such as hypertension and hyperlipidemia, and would therefore benefit from services such as those provided by a psychiatric pharmacist who is familiar with both the patient's psychiatric or neurologic disorders and the patient's other medical comorbid conditions.¹⁰

In a 1-year pilot project carried out in 2009 and 2010, pharmacists in Connecticut initiated a pharmacist network to contract independently for medication management services. The pharmacists met individually with patients and provided medication management services at 4 health centers in

⁹ *Id.*

¹⁰ *Id.*



Connecticut. Pharmacists had access to the patients, their electronic health record, and pharmacy claims data. For 88 patients with chronic disorders, including pain, lipid disorders, hypertension, asthma, chronic obstructive pulmonary disease, diabetes, and depression, the pharmacists documented 3248 medication discrepancies between data sources. Of these, 917 constituted medication therapy problems, and only 26% of these problems were attributed to a lack of adherence to medication regimens. Most of the problems involved the need for an additional medication (30%), an adverse medication event (16%), the need to switch medications (7%), the need to discontinue an unnecessary medication (7%), an ineffective dose (7%), or the need to reduce a potentially toxic dose (5%). Pharmacist interventions resulted in estimated annual savings of \$1,123 per patient in medication claims and \$472 per patient in medical, hospital, and emergency department expenses. The estimated total savings were approximately 2.5 times the cost of the fees for the pharmacists and network administration.¹¹

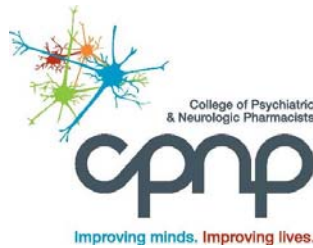
CPNP also found patients who benefit most from CMM are likely those who are undergoing a transition in care (admission or discharge from a hospital or nursing home), taking multiple chronic medications, suffering from chronic diseases, being seen by multiple providers, taking medications that require frequent monitoring (eg, clozapine, lithium, antipsychotics), or exhibiting poor medication adherence. For example, patients who are admitted to or discharged from the hospital are at higher risk of an adverse drug event (ADE). As many as 20% of patients may have an adverse event after discharge, and adverse medication events are the most preventable type. By focusing on these transition points of care, pharmacists working in inpatient hospitals and performing CMM can help to reduce costs to the patient and the institution. In a medical home model, patients who received medication management services at discharge had lower readmission rates than other patients at 7, 14, and 30 days after discharge; these lower rates translated to a cost savings of \$1.5 million annually. This finding is important as future reimbursements trend away from a fee-for service model and toward a pay-for-performance model. By providing CMM, psychiatric pharmacists can work with and develop relationships with these high-risk patients who may otherwise use emergency services for their care.¹²

As demonstrated in the studies and practice models described above, psychiatric pharmacists can have a positive impact on medication-related outcomes for patients with various psychiatric or neurologic disorders across multiple practice settings. Numerous studies have demonstrated substantial increases in clinical (therapeutic and safety), humanistic, and economic outcomes when psychiatric pharmacists are part of the care of patients. There are multiple other examples of practice models in which psychiatric pharmacists are involved with direct patient care as part of the multidisciplinary team. Adding a psychiatric pharmacist to the team not only improves patient outcomes and reduces costs, but it allows increases in the number of patients that physicians can see in a practice or in a patient-centered medical home (PCMH).¹³

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*



We urge the CMS Innovation Center to take from these existing practice models and collaborative practice agreements to expand or establish mental and behavioral health models. Whether in a primary care or a mental health setting, it is clear patients can benefit from psychiatric pharmacists' expertise in pharmacotherapy and their experience in educating patients about the risks and benefits of treatment. In fact, if the patient is to be treated as a whole person, primary care and mental health outcomes cannot be divided into separate domains. Integrated care requires the recognition that the use of psychiatric medications, such as antidepressants and antipsychotics, can result in other medical problems. In addition, patients with severe mental illness may be at a higher risk of cardiovascular problems regardless of whether medication is prescribed. Because of their specialized training in pharmacology, pharmacokinetics, and drug-drug and drug-disease interactions, psychiatric pharmacists are well positioned to partner, as a member of the health care team, with patients, families, nurses, social workers, and PCPs or psychiatrists, and to identify medication-related problems, increase the number of patients who can be treated, and optimize care.

Feedback on Specific Questions in the RFI

Prescription Drug Models

We encourage research into the role of new medications or drug delivery systems such as long-acting injectable antipsychotics (LAIs) in the treatment of serious psychiatric disorders. We are particularly interested in the results of programs that increase access to LAIs. One such proposal would be to allow pharmacists to administer LAIs in community pharmacies. Pharmacist-administered immunizations has been shown to significantly increase population access to immunizations. We could then assess the impact on LAI utilization on resources including inpatient hospitalization and rehospitalization rates. We also encourage the testing of value-based purchase agreements between manufacturers and Medicare and Medicaid.

State-Based and Local Innovation, including Medicaid-focused Models

States are struggling with adequate access to care for people with BH disorders. A paper entitled the "Psychiatric Shortage" was released by the National Council Medical Director Institute in March 2017 which outlines several solutions to the shortage.¹⁴ In response, some states such as Montana, have recently received Medicaid waivers to allow reimbursement for patient care services as part of a team approach to care provided by pharmacists with advanced training [Clinical Pharmacist Practitioners (CPPs)]¹⁵. Especially in rural or frontier areas these services are often provided in primary care clinics with

¹⁴ National Council Medical Director Institute. The psychiatric shortage: causes and solutions. March 28, 2017. www.thenationalcouncil.org/wp-content/uploads/2017/03/Psychiatric-Shortage_National-Council-.pdf Accessed 11/10/17

¹⁵ Montana Healthcare Programs Notice July 3, 2017 <https://medicaidprovider.mt.gov/Portals/68/docs/providernotices/2017/provnotice2744025556ClinicalPharmacistPractitioner07032017.pdf> Accessed 11/10/17



integrated BH programs. Allowing CPPs to provide direct patient care services should be assessed to determine the impact on access to care, outcomes, and cost of care.

Mental and Behavioral Health Models

As outlined above there is an increasing shift to integrating BH treatment into primary care settings due to the psychiatric shortage with BCPPs proposed as part of the solution. We encourage the Innovation Center to test various models of care that include a variety of providers on the team, including CPPs and BCPPs. Pharmacists are key partners for patients, families, and care teams in treating co-occurring chronic medical conditions which often account for high rates of morbidity and mortality in this population. We believe that having pharmacists on the team reduces drug interactions, decreases serious adverse reactions, and improves medication adherence which reduces overall healthcare costs. Pharmacists are currently not included as providers in the social security act so they have been excluded from fee-for-service and other team-based models of care in the past. We encourage the Innovation Center to test models that include BCPPs in BH models of care.

Response to Questions in Part C

Q3. One of the risks identified in testing models that include BCPPs is the small numbers of pharmacists who are BCPPs. CMS could encourage pharmacists to become BCPPs by allowing pass through funds for post-graduate psychiatry specialty training programs for pharmacists. This would increase the number of institutions providing training of psychiatric pharmacists. Some states have no psychiatric pharmacy training programs due to insufficient funding.

Q5. CMS can engage beneficiaries by assessing satisfaction with care received in these new models. Patients who have received care from BCPPs often express positive experiences and better understanding of their medications.¹⁶

Q6. CMS should consider a payment waiver to include payment for BCPPs to test new team-based models of care.

Conclusion

CPNP appreciates the opportunity to provide comments to the CMS Innovation Center on the exploration of new mental and behavioral health models and we look forward to working with CMS on the continued development of these models. CPNP hopes our comments provide new insight on the important role of psychiatric pharmacists and the potential for them, when fully integrated into the interprofessional health care team, to increase access and improve quality and costs of care for mental health services across the health care system. Psychiatric pharmacists are a vital resource that should be recognized and utilized in

¹⁶ Cobb C. Optimizing Medication Use with a Pharmacist-Provided Comprehensive Medication Management Service for Patients with Psychiatric Disorders. *Pharmacotherapy* 2014 doi: 10.1002/phar.1503



the multidisciplinary approach to addressing the need for an affordable, accessible healthcare system. If you have any questions or require any additional information, please do not hesitate to contact me or our Health Policy Consultant, Jeremy Scott at Jeremy.Scott@dbi.com / 202-230-5197.

Sincerely,

Deanna Kelly, PharmD, BCPP
President