

September 27, 2019

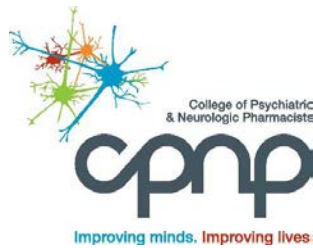
Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2020 [CMS-1715-P]

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) Proposed Rule [CMS-1715-P], *Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.*

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.

While approaches to prevention, intervention, and treatment have improved with the work of the Administration and passage of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT ACT), gaps in the health system continue to persist for the treatment of those with substance use, including opioid use, and mental health disorders. Psychiatric pharmacists are medication experts who stand to play a significant role in helping to ensure proper use of medication assisted treatment (MAT) for those dealing with opioid use disorders (OUDs). Still, we continue to see them omitted from solutions to address the opioid epidemic, despite their ability to serve alongside physicians and psychiatrists in various healthcare settings to address provider shortages, prevent medication related treatment errors, and improve overall care for OUDs. While we have seen a steady growth and recognition among states and various healthcare systems expanding the use of psychiatric pharmacists to provide treatment for vulnerable populations, we believe an underlying lack of awareness has contributed to the severe delay and under-utilization of these key healthcare providers at the federal level.



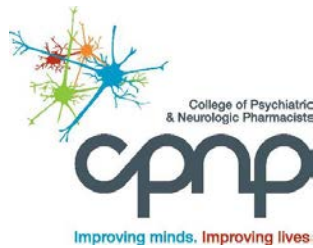
The following comments seek to highlight the qualifications, expertise, role and benefits of a psychiatric pharmacist and provide recommendations to CMS on how psychiatric pharmacists can and should be used to improve treatment and services for OUDs offered by an opioid treatment program (OTP) as well as in the physician office and primary care settings for the broader treatment of substance use disorders (SUDs) and mental health.

Comments on the Proposed Rule

We commend Congress and CMS for their expedited work in seeking to improve treatment for those suffering from opioid use disorders. However, as brought to light by the recent crisis, opioids as well as the medications used to treat OUDs and SUDs are powerful substances that must be used with the utmost care, monitoring, and supervision to ensure effective treatment and avoid medication related adverse events.

Successful treatment of SUDs, including OUDs, requires frequent and careful monitoring of medication use by qualified healthcare providers – care that can sometimes exceed or excessively burden a physician or psychiatrist’s already stretched capacity to serve their patients, particularly for those living in designated rural or health shortage areas. In addition, many patients struggling with SUDs have underlying or coexisting medical conditions that, whether treated or untreated, can significantly affect their response to medications used to treat their addiction. While psychiatrists, physicians, and non-physician providers such as physician assistants and nurse practitioners are familiar with these medications, they do not always have the recommended expertise to address patients’ unique needs and responses to treatment. This lack of time and expertise can often lead to preventable medication related adverse events resulting in patient relapse, hospitalizations, and even death. However, with proper care coordination and use of multidisciplinary teams that include psychiatric pharmacists, these events could be avoided.

Pharmacists today graduate with a Doctorate of Pharmacy degree, a required 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 pharmacotherapy for the complete range of psychiatric and substance use disorders. 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 healthcare team, with primary care providers (PCPs) or psychiatrists, to make recommendations on initial prescribing and dosing, to identify medication-related problems, and to increase the number of patients who can be treated by providing medication management and counseling, monitoring, and routine follow-up visits for individuals receiving medication assisted treatment (MAT) and other similar treatments for SUDs and mental health disorders.



Therefore, in order to prevent medication related adverse events and to ensure proper treatment and management of those dealing with OUDs, SUDs, and mental health disorders, ***CPNP strongly recommends that CMS recognize psychiatric pharmacists and the services they provide as an integral part of the care delivery team and include appropriate payment to incentivize their utilization in OTPs and the physician office setting.***

I. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTP)

We appreciate the efforts underway to provide Medicare coverage for treatment services furnished by OTPs as required by section 2005 of the SUPPORT Act. Consistent with the comments CMS received in response to the Request for Information (RFI) included in the CY 2019 PFS final rule (83 FR 59497), CPNP agrees that the bundled payments should not only recognize the intensity of services furnished, but also the costs associated with care coordination among the beneficiary's practitioners. Specifically, we urge CMS to include the use of psychiatric pharmacists as a necessary element to provide effective prescribing of MAT including the need for continued medication management, monitoring, and counseling for successful treatment. We understand Medicare's reliance on existing coverage policies provided by commercial insurers, Medicaid and Tricare for OTPs, but highlight that current bundled payments are generally viewed as inadequate to support the use of psychiatric pharmacists by OTPs. While federal guidelines support the use of psychiatric pharmacists to provide MAT services consistent with their licensing and state scope of practice acts,¹ the fact remains that OTPs are often minimally staffed with only a physician, licensed practical nurse (LPN) and counselor on the care team.

Inclusion of Psychiatric Pharmacists Services in the Bundled Payment for OUD Treatment Services Furnished by an OTP

The SUPPORT Act requires CMS coverage of OUD treatment services furnished by an OTP, defined by the statute to include: (1) opioid agonist and antagonist treatment medication; (2) dispensing and administration of such medications, if applicable; (3) substance use counseling; (4) individual and group therapy; (5) toxicology testing; and (6) other items and services that the Secretary determines are appropriate. While psychiatric pharmacists are included under the federal guidelines as a recommended practitioner to dispense and administer opioid agonist and antagonist treatment medications, their expertise and value extends far beyond their dispensing and administration capabilities. In fact, psychiatric pharmacists working in collaboration with physicians to the fullest extent of their license and scope of practice acts is a proven method to increase access to treatment, optimize patient care, improve

¹ Substance Abuse and Mental Health Services Administration. Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015. Available at: <https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf>



medication adherence and reduce treatment costs.² As a result, we believe the list of services defined in the SUPPORT Act is not sufficient to ensure patients receive effective care for OUDs when furnished by an OTP. **We urge CMS to use the authority granted to it under the SUPPORT Act to include the following services performed by psychiatric pharmacists: (1) prescribing of or consultation on proper medication use and dosing;³ (2) patient evaluations and follow-up for medication response and adherence; (3) medication management including modifications to avoid adverse reactions and drug interactions; and (4) medication education or counseling for patients and their caregivers. Each of these services is an integral part of ensuring patients receive proper MAT for OUDs.**

We note that CMS has also requested feedback on whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD services. CPNP believes that inclusion of these elements is important to fully capture the intensity of services provided for the treatment of OUDs and to ensure the bundled payment amount is adequate for patients to receive the necessary level of care. In addition, we would include psychiatric pharmacists as an individual who is well qualified to perform initial assessments and preparation of a treatment plan and recommend that the definition of “additional periodic assessments” include psychiatric pharmacists’ evaluation of patients’ medication response and adherence as well as other medication management services. **Therefore, we support CMS including the above services with clarification that these also include services to monitor patients’ medication response and adherence. In addition, we encourage CMS to revisit the proposed payment rates for the non-drug component of the bundle to ensure adequate payment.**

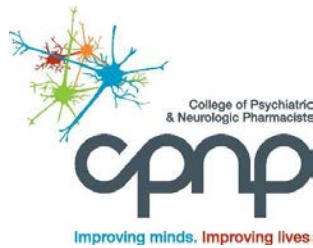
While CPNP has long held that psychiatric pharmacists should be a recognized provider under Medicare and permitted to bill directly for their services, federal law currently provides reimbursement for these services under the Part B program when furnished by a psychiatric pharmacist incident to a supervising physician in the physician office or other non-hospital based outpatient settings. As a result, we believe these services qualify for inclusion in the definition of OUD services provided by an OTP.

Adjustment to Bundled Payment Rate for Psychiatric Pharmacists Services or Additional Services

If CMS chooses not to finalize the addition of these services or if additional evaluation or medication management services are needed, CPNP recommends that the agency consider an adjustment similar to that proposed for additional counseling or therapy services with an add-on code for psychiatric pharmacists’ periodic evaluations of patients’ medication response and other medication management services. In the proposed rule, CMS provides examples of when additional therapy could be needed justifying the use of an add-on code such as weeks when a patient has a relapse warranting additional services that were not foreseen at the time the treatment plan was developed. We can foresee similar

² DiPaula, Bethany A. Menachery, Elizabeth et al. *Physician–pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients*. Journal of the American Pharmacists Association, Volume 55, Issue 2, 187 - 192

³ Psychiatric pharmacists may prescribe where permitted by their state licensing and scope of practice laws.



instances where ineffective medication or other medication related adverse events require an unplanned evaluation with a psychiatric pharmacist to modify and appropriately address the patients' needs. In addition, the use of an add-on code would allow OTPs to use psychiatric pharmacists for certain patients with complex cases to address medication selection, dosing, side effect management, adherence, drug-drug interactions, or level of care considerations when effective treatment requires services that exceed the typical case provided for under the non-drug component of the OTP bundle. Ultimately, we believe the necessity of an add-on code for services provided by a psychiatric pharmacist is dependent on whether CMS decides to expand the current list of services included in the OTP bundle.

Inclusion of Psychiatric Pharmacists Services via Telemedicine

CMS is proposing to allow OTPs to furnish services included in the bundled via two-way interactive audio-video communication technology to increase access to care. We support this proposal and similar to our above comments, recommend CMS extend this to include evaluation and medication management services when provided by psychiatric pharmacists as part of an OTP.

II. Bundled Payments Under the PFS for Substance Use Disorders

In response to CMS's request for comments in the CY 2019 PFS proposed rule, CPNP supported consideration of a separate payment for bundled episode of care for components of MAT and non-MAT associated management and counseling of SUDs and we recommended psychiatric pharmacists be included among the types of practitioners eligible to participate in the provision of these services. In addition, we were pleased to see CMS considering an episode of care that included medication management and supportive services in addition to initial assessments, treatment planning, counseling, care coordination and support services for individuals and families. In turn, we were disappointed to see that CMS's CY 2020 proposal for a bundled payment under the PFS no longer includes medication management and supportive services. CMS states that by creating a separate bundled payment for OUD treatment under the PFS, it hopes to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting. However, CPNP fears that without clear inclusion of services such as the evaluation and management of patients' medication response, CMS is sending a message that these are elective or unnecessary for adequate treatment of OUDs and we would strongly disagree.

Improving Primary Care Treatment for SUDs and Mental Health with Psychiatric Pharmacists

At present, more and more physician offices are working to expand services to include the use of a psychiatric pharmacist to address SUDs and mental health disorders treated in the primary care setting. Having a psychiatric pharmacist on site gives other providers more confidence in approaching medically complex patients, increases their comfort level in using MAT for OUDs, and improves overall access to care.⁴

⁴ <https://cpnp.org/psychpharm/profile?view=link-0-1471880668&.pdf>



Ideally, when included as an integrated member of the healthcare team, psychiatric pharmacists are able to (1) provide direct patient care, including treatment assessment and planning, optimization of medication regimens, dosing and prescribing; (2) monitor patients for potential adverse drug reactions and interactions; (3) educate providers, patients, and families on psychiatric and addiction medications as well as psychiatric and substance use disorders and other related conditions; and (4) work to reduce medication costs and demonstrate cost savings to healthcare systems.

As an example, for each patient that is considered for opioid therapy, pharmacists 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 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. This scenario is similarly applicable to the care of all patients struggling with mental or substance use disorders as well.

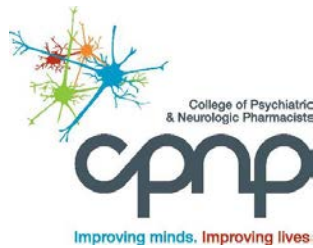
As mentioned previously in our comments related to the OTP bundle, psychiatric pharmacists also have a deep understanding of MAT that extends beyond that of most other healthcare providers. When included in providing MAT services, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for OUD; reduce per patient dosing of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs for treating patients with SUDs by relieving providers from services including medication management, counseling, monitoring and follow-ups.⁵

As with MAT, more general studies of non-MAT related programs have shown that when psychiatric or clinical pharmacists are able to provide the services described in collaboration with healthcare providers, including psychiatrists, they increase the rates of medication adherence, reduce the rates of over prescribing, improve patient satisfaction, increase patient knowledge, and reduce costs.⁶

Despite these overwhelming benefits, sufficient reimbursement continues to stand in the way of many practices seeking to include a psychiatric pharmacist on the care team. Due to federal limitations on reimbursement, pharmacists are generally seen as a non-revenue generating cost-center for the facilities.

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 *Id.*



Billing for Psychiatric Pharmacists Services

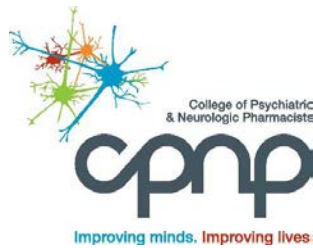
As previously mentioned, psychiatric pharmacists are not recognized providers under Medicare and are therefore unable to directly bill for their services. As a result, services provided by psychiatric pharmacists are billed incident to a supervising physician using CPT codes 99211 – 92115. However, despite psychiatric pharmacists' evaluations often meeting the criteria for higher-level visits, their services are often not reimbursed above the 99211 level. As addressed below in our comments, we are hopeful that the changes CMS has proposed in Section P of the proposed rule will improve reimbursement for these services when provided by a psychiatric pharmacist incident to a supervising physician. Still, inadequate reimbursement remains a significant barrier to ensuring patients have access to the most appropriate level of care required for the treatment of SUDs and mental health in the primary care settings.

For this reason, we are extremely concerned that the bundled payment for OUD omits invaluable services provided by psychiatric pharmacists in the physician office setting. ***We urge CMS to clarify that the services covered in the bundle include evaluation and medication management by a psychiatric pharmacist and to revisit the rate to ensure adequate reimbursement under the bundle for the use of psychiatric pharmacists. If not included, we request CMS clarify that psychiatric pharmacists services related to MAT and non-MAT treatment for SUDs, including OUDs, continue to be provided incident to a supervising physician with adequate reimbursement provided for the level of complexity billed and appropriately documented for the encounter.***

III. Payment for Evaluation and Management (E/M) Visits

CPNP is pleased to see CMS's continued review and response to stakeholder feedback received as a result of the policies proposed for CY 2021 for office/outpatient E/M visits and we support CMS's proposal to adopt the framework issued by the AMA/CPT. We agree that this framework will lead to a greater burden reduction and allow more flexibility for complex patients. In addition, by simplifying documentation requirements we hope this will yield more consistent reimbursement for psychiatric pharmacists' services across MAC regions.

While CPNP continues to advocate for psychiatric pharmacists to be a recognized provider under Medicare, we have also sought to improve reimbursement provided for psychiatric pharmacists' services billed incident to a supervising physician using codes 99211 – 92115. At present, psychiatric pharmacists are recognized by Medicare to provide services incident to a physician consistent with their licensing and states' scope of practice laws. In many cases, the level of services provided by psychiatric pharmacists meet the incident to requirements for higher levels of complexity. Still, many of our members have reported being denied reimbursement for billing E/M services using the higher level codes and stated that Medicare Administrative Contractors (MACs) have indicated that only the lowest level (99211) can be billed for pharmacists' services. We are optimistic that CMS's proposal to simplify documentation requirements and allow providers flexibility to choose "Medical Decision Making" (MDM) or "time" will improve reimbursement for psychiatric pharmacists' services. **However, we also request that CMS**



provide guidance to all local MACs clarifying psychiatric and clinical pharmacists' ability to bill across the range of CPT codes 99211-99215 when incident to requirements are met.

Conclusion

CPNP appreciates the opportunity to provide comments to CMS on proposals that seek to expand and improve access to treatment for SUDs in the PFS. CPNP hopes our comments demonstrate the important role of psychiatric pharmacists and the potential for them, when fully integrated into the interprofessional healthcare team, to increase access and improve quality and costs of care for the treatment of SUDs. Psychiatric pharmacists are a vital resource that should be recognized and utilized in 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, Sarah Mills at sarah.mills@dbi.com / 202-230-5182.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lisa Goldstone', is positioned above the printed name.

Lisa Goldstone, MS, PharmD, BCPS, BCPP
President

A handwritten signature in black ink, appearing to read 'Brenda K. Schimenti', is positioned above the printed name.

Brenda K. Schimenti
Executive Director