October 5, 2020

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 2021 [CMS-1734-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-1734-P], *Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP).*

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.

Pharmacists today graduate with a Doctor 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 medication management for the complete range of psychiatric and substance use disorders. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

CPNP respectfully provide our comments on the proposed rule are as follows:

<u>Telehealth and Other Services Involving Communications Technology</u>

CPNP generally supports CMS' efforts to retain and make permanent the telehealth flexibilities extended during the COVID-19 pandemic.

Direct Supervision By Interactive Telecommunications Technology
For the duration of the Public Health Emergency (PHE) due to the COVID-19 pandemic and for purposes of limiting exposure to COVID-19, CMS adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245).

CPNP requests CMS make permanent the current temporary regulatory flexibility allowing physicians to provide direct supervision of clinical staff virtually, using real-time audio/video technology. Physicians should be empowered to supervise clinical staff virtually (and via audio in rural and underserved areas), at their discretion, regardless of whether there is a declared PHE. By allowing physicians and auxiliary personnel, including psychiatric pharmacists, to provide services from two separate locations, this flexibility supports the expansion of telehealth services and protects frontline workers by allowing appropriate social distancing. The rapid shift to telehealth services during COVID-19 has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. Therefore, **CPNP asks that CMS permanently allow direct supervision to be provided virtually in order to meet the growing demand for telehealth services, which will likely extend beyond the COVID-19 pandemic.**

It should be noted that lack of sufficient reimbursement continues to stand in the way of many practices seeking to include a psychiatric pharmacist on the care team and as part of their provision of telehealth services. Medicare does not recognize clinical psychiatric pharmacists as providers and as such will not reimburse health care systems or providers who employ them for their services. In many states, this means that they also are not recognized by private insurers or Medicaid, and many health systems and providers are reluctant to add psychiatric pharmacists to their teams without the ability to be reimbursed for the services that they provide. This is to the detriment of those health systems successfully employing psychiatric pharmacists to reach rural patients in particular. With the increase in stressors related to COVID-19 there has been an increased demand for psychiatric services in which psychiatric pharmacists could help fill that gap if there was payment for their services.

Audio-Only
During the COVID-19 PHE, CMS recognized the need to perform E/M services remotely, including using telephones and cell phones for audio-only services. While some types of services will still be permitted to be done using audio-only, **CPNP urges CMS to expand Medicare-covered behavioral health services provided through telehealth on a permanent basis to match the new flexibilities it allowed during the current PHE**. **CPNP strongly supports having Medicare continue to pay for a broad range of mental and behavioral health services furnished through audio-only telephones.** Older adults and younger individuals with disabilities who rely on Medicare for essential behavioral health care will lose access to critically needed services if they are limited to using devices with both audio and visual communication technology.

Requiring dual audio-video communication is particularly a problem in rural and underserved areas of the country that lack sufficient broadband coverage, among sizeable groups of older adults and people with disabilities who may lack the ability or comfort level to use these devices due to cognitive or visual impairments, and among racial/ethnic and lower income communities, who may not even own such devices. In 2019, the Federal Communications Commission reported that between 21.3 and 42 million Americans lack access to broadband. The ability to communicate between patients and behavioral health providers according to individuals' own needs is crucial to eliminating artificial barriers to care. CPNP further believes that CMS has the authority to proceed with this change in Medicare policy

without specific congressional authorization. We believe that the current statutory authority under Section 1834m of the Social Security Act allows CMS to make this change now without further direction from or action by Congress.

Originating Sites

CPNP urges CMS to support the elimination of Medicare's originating and geographic site restrictions so that patients can receive essential behavioral health services regardless where they are located including at home. Eliminating these restrictions is key to meeting individuals and families where they are. Although the pandemic has so clearly demonstrated the tremendous value of providing telehealth to individuals and families in their homes during this crisis, the benefits transcend the goal of reducing the spread of COVID-19. Allowing telehealth from homes is enabling millions of people to receive care who, due to barriers to care such as transportation and scheduling difficulties, previously were unable to access services.

Psychiatric Collaborative Care Model

CPNP urges CMS to allow psychiatric pharmacists to be considered a "psychiatric consultant" under the Psychiatric Collaborative Care Model (CoCM). Clinical psychiatric pharmacists practicing at the top of their license work with primary care teams daily to evaluate and manage these patients who suffer not only from psychiatric and mental health illness, but co-occurring chronic medical conditions. 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 a 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" involved in incident to care 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. Likewise, with the exception of diagnoses, many psychiatric pharmacists, working as team members, often under collaborative practice agreements, do all levels of care and are not only prescribing medications but are also managing all medications to optimize outcomes, manage drug interactions, and promote adherence to therapies. 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.

Pharmacists Providing Services Incident to Physicians Services

Pharmacists who dispense medications screen for potential drug therapy problems such as "therapeutic duplication, contraindications, over-utilization, under-utilization, and drug-drug interactions" which is considered part of the dispensing fee under Part D.

Services paid for under the incident to benefit are an incidental part of the physicians' services in which auxiliary personnel assist them in rendering services to the patient such as changing bandages, setting casts, administering injections, or, as in the example provided collect specimens and report results of COVID tests. These are tasks typically performed by community pharmacists. Another example is if a physician started a patient on a blood pressure medication and asked them to come back in 2 weeks to see the pharmacist. In the chart the plan would be for the pharmacist to increase the dose of the medication if the patient was not at a specified blood pressure goal. That is an incident to service as the auxiliary personnel (pharmacist) carries out a physician's order.

However, we believe that often psychiatric pharmacists do not fall under these categorizations as dispensing medications nor incidental work done to implement a physician's plan. Psychiatric pharmacists are specialists who provide direct patient care as part of the healthcare team. They are experts uniquely trained and qualified to provide a service that is considered specialty care. Physicians routinely refer patients to specialists such as psychologists, dieticians, and physical therapists to provide their patient with the care that they need that the physician them self is not an expert in providing. Psychiatric pharmacists are another example of a specialist to whom physicians refer their patients. They are experts focused on optimizing treatment response and minimizing adverse events associated with medications for people living with serious mental illnesses and other chronic conditions that often co-occur in this patient population.

Many psychiatric pharmacists see patients in appointments within medical practices as part of collaborative practice agreements with physicians, within the scope of practice in their state. They assess patients' presenting symptoms and select, adjust, and/or discontinue medications per evidence-based guidelines. They follow-up with patients to assess response to treatment based on objective rating scales, patient self-report, observations of family and friends, and physical exam to assess for antipsychotic-induced movement disorders, and then adjust doses or change medications as indicated. They complete a thorough assessment of adherence to medications via rating scales, laboratory results, patient report, pharmacy refills, and/or payer claims data to determine the underlying causes of decreased adherence. They use shared decision-making, motivational interviewing and problem-solving skills to help patients identify solutions to improve adherence to their medication regimens. They order and interpret vital signs, drug levels, and laboratory data to identify medication-related adverse effects and adjust medications as needed to minimize adverse outcomes and optimize response. Psychiatric pharmacists document their assessments and plans in the medical record like other patient care providers. In these cases psychiatric pharmacists are determining and implementing the plan of care for patients, therefore it does not meet the incident to requirements.

CPNP requests that psychiatric pharmacists be recognized as patient care providers and be paid using E&M codes commensurate with the service provided and documented like all other providers.

In the absence of recognition as a patient care provider, CPNP urges CMS to clarify the ability for an eligible practitioner to bill for pharmacists' services incident to a physician at any level including levels 2-5, provided that the service provided is within the pharmacist's state scope of practice and meets all other billing requirements. Currently, it is primarily the case that when billing incident to for psychiatric pharmacists' services, and their documentation meets the criteria for higher-level visits, 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 and improve patient outcomes. Until billing and reimbursement are addressed, health care

systems and providers who want to employ psychiatric pharmacists cannot afford to bring them on-board.

Bundled Payments for Substance Use Disorders

CMS proposes to expand the bundled payments to be inclusive of other Substance Use Disorders (SUDs), not just Opioid Use Disorders (OUDs). To accomplish this, CMS has proposed revising the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder.'' **CPNP supports this change to support clinicians in treating various substance use disorders, including alcohol.**

CMS is also seeking information on whether there are differences in the resource costs associated with furnishing services for the various SUDs, and accordingly whether there is a need for more stratified coding to describe these services.

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 primary care providers, psychiatrists, and other health care professionals. They make recommendations on initial prescribing and dosing, identify and resolve medication-related problems, and increase the number of patients who can be treated by providing medication management and counseling, monitoring, and routine follow-up visits for individuals with mental health and SUDs, including MAT. Psychiatric pharmacists also promote preventive health care, medication adherence, and lifestyle modification. Value provided by psychiatric pharmacists includes improvements in patient symptoms, increased medication adherence rates, increased patient satisfaction, and the potential to reduce health care costs.

As to SUDs, psychiatric pharmacists have a deep understanding of MAT that extends beyond that of most other healthcare providers. When included in the provision of MAT services, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders; 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 delivering services including medication management, counseling, monitoring and follow-ups.

CPNP is concerned that the bundled payment for SUD, particularly OUDs, 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, CPNP requests 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.**

Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Definition of OUD Treatment Services

The SUPPORT for Patients and Communities Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care, beginning on or after January 1, 2020. For CY 2021, CMS is proposing to add opioid antagonist medications, such as naloxone, that are

approved by the FDA for the emergency treatment of known or suspected opioid overdose to the list of covered OUD treatment services. CMS proposes to do so through two add-on G codes (for nasal and auto-injector), and proposes to apply a limit on the frequency of the add-on payment for opioid antagonists dispensed by OTPs to one add-on code every 30 days to the extent that it is medically reasonable and necessary.

CPNP supports CMS' proposal to include opioid antagonist medications, such as naloxone, to the list of covered OUD treatment services. As CMS notes in the proposed rule, naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose. FDA-approved naloxone products for overdose reversal have been shown to be effective in reversing opioid overdoses. CPNP therefore supports providing OTPs with the flexibility to utilize naloxone to help treat individuals with OUD, thus increasing access to this lifesaving, emergency treatment for all who need it.

CPNP also supports the proposal to include overdose education into the currently established payment bundles as this education is crucial to every bundle and can greatly benefit the patient.

Billing and Payment Policies

In the rule, CMS states it welcomes comments on how the agency might better account for differences in resource costs among patients over the course of treatment and that the agency will consider the comments received in developing any proposed refinements to coding policies in future rulemaking. As such, CPNP reiterates our request from our CY 2020 PFS comment letter that the bundled payment for episodes of care for the treatment of OUD furnished by OTPs recognize 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 Medication Assisted Therapy (MAT) including the need for continued medication management, monitoring, and counseling for successful treatment.

While psychiatric pharmacists are included under the federal guidelines as a recommended practitioner to dispense and administer opioid agonist and antagonist treatment medications,[1] their expertise and value extends far beyond their dispensing and administration capabilities. 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 medication adherence and reduce treatment costs.[2] **CPNP urges 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; (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.

In the CY 2020 PFS final rule (84 FR 62645), CMS finalized an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished, HCPCS code G2080.

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[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/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP

[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

This add-on code may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. **In the absence of inclusion in the bundled payment, CPNP recommends that the agency consider an add-on code for psychiatric pharmacists' periodic evaluations of patients' medication response and other medication management services.** In the proposed rule, CMS notes that patients' needs for service may fluctuate over time, depending on a variety of factors and circumstances. We can foresee 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.

Payment for Office/Outpatient Evaluation and Management (E/M) Visits

E/M services are a vital component of the Medicare program, comprising 40 percent of all Physician Fee Schedule (PFS) allowed charges; additionally, office or outpatient E/M visits comprise approximately 20 percent of all PFS fee for service allowed charges. In the CY 2020 PFS Final Rule, CMS finalized its proposal to increase payments starting in CY 2021 for E/M services, per recommendations from the American Medical Association Relative Value Scale Update Committee.

Consequently, the proposed CY 2021 conversion factor is now $32.26 and a significant drop from the CY 2020 conversion factor of $36.09. The conversion factor update will result in a 10.61 percent cut reflecting a budget neutrality adjustment for reductions in relative values for individual services in 2021. Cuts of this magnitude will have a significant impact and should not be implemented in the final rule.

While CPNP supports the E/M modifications that implement significant increases to payment for office visits, we urge CMS to work with Congress to let the increases in payment go forward while mitigating such significant losses that will be compounded by the challenges and financial impact of the on-going COVID-19 pandemic. While we appreciate the legal requirement of budget neutrality of changes in payment under the PFS, cuts of this magnitude all in one year will have a significant impact on practitioners in rural and underserved areas and most importantly patient's access to care. The COVID-19 pandemic has significantly increased the need for mental health services and now is not the time to cut payments that will only exacerbate the challenge in getting access to these critical services and potentially worsen an already high suicide rate, most particularly in rural areas.

In closing, 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. For their contributions to be fully realized and utilized, sufficient reimbursement is necessary. If you have any questions or require any additional information, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at laura.hanen@faegredrinker.com.

Sincerely,

Brenda Schimenti

Brenda K. Schimenti
Executive Director