September 13, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies [CMS–1751–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–1751–P], *Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.*

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 provides our comments on the proposed rule as follows:

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

The COVID-19 public health emergency (PHE) prompted a transformation in the delivery of mental and behavioral health services. Without the current Medicare telehealth coverage flexibilities, many beneficiaries would have lost access to mental and behavioral health services at time of extreme stress and vulnerability.

CPNP thanks CMS for the current Medicare coverage flexibilities concerning telehealth, including but not limited to allowing individuals to receive services from their own homes, allowing more services to be

furnished via telehealth, and allowing patients to use audio-only devices. Given the long-term mental health impact of the COVID-19 pandemic, CPNP believes CMS must ensure that flexibility remains available to Medicare beneficiaries after the formal end of the COVID-19 PHE.

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

CPNP supports CMS' proposal to retain telehealth services in Category 3 until the end of 2023. This will allow for the continuation of coverage of those services that are temporarily covered until the expiration of the Public Health Emergency (PHE) rather than an abrupt end mid-way through the year. CPNP appreciates that the proposal provides additional time to collect more information regarding utilization of Category 3 services and to develop supporting evidence to retain and make permanent the telehealth flexibilities extended during the COVID-19 pandemic.

Implementation of Provisions of the Consolidated Appropriations (CAA) Act, 2021

The CAA removed the geographic restriction for Medicare telehealth services for the diagnosis, evaluation or treatment of a mental health disorder and adds the patent's home as a permissible originating site for these telehealth services. Payment is prohibited unless a physician or practitioner has furnished an item or service in-person within 6 months of the first telehealth visit. Additionally, the statute leaves it up to the Secretary as to the appropriate interval for in-person visits for subsequent telehealth visits. This effectively creates a new, arbitrary requirement for the patient to have an in-person mental health visit every 6 months should the patient plan to seek telehealth services with that provider. CPNP believes that barriers to telehealth for mental health and substance use services should be minimal. Some people with mental health conditions have symptoms that interfere with their ability to attend in-person appointments, such as anxiety or agoraphobia, such that they may prefer telehealth visits for all of their visits. In response to CMS's request for comment on this new policy, CPNP recommends CMS remove the continual 6-month in-person visit requirement and leave it to the treating clinician to determine the best interval for their patients if needed. The CAA gives CMS ample flexibility to expand that time period or eliminate it altogether. With the COVID-19 pandemic both exacerbating and highlighting the vast unmet need for mental and behavioral health services and the lack of access to providers in rural and underserved areas, CPNP urges CMS to facilitate broader access to care for all patients in need of care.

CMS is also seeking comments regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition, for both telehealth (with a 6 month in-person requirement) and in-person services. The rule also notes that there are circumstances under which CMS has historically treated the billing practitioner and other practitioners of the same specialty or subspecialty as if they were the same individual. CPNP appreciates CMS' provision of flexibility in the delivery of mental health services.

Pharmacists may provide services "incident to" the services of the billing physician or non-physician practitioner under § 410.26. Accordingly, CPNP respectfully asks CMS to clarify that this alternative policy will also be applied to clinical pharmacist members of patient care teams providing in-person incident to mental health services, at six (6) months or any other time-periods required by the agency, within the same group to all physicians or practitioners.

Psychiatric pharmacists are an important member of the health care team working in collaboration with the patient and other health care providers including psychiatrists, other physicians, therapists, social

workers, and nurses. Psychiatric pharmacists provide expert, evidence base Comprehensive Medication Management (CMM) services for the most complex patients with mental health and substance use disorders. Psychiatric pharmacists increase capacity of the health care team to care, provide psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs. Specifically psychiatric pharmacist services, whether provided via telehealth or in person, include:

- Initial consult appointment thought direct patient care via telemedicine, face-to-face over video conference, typically lasting 60 minutes
- Provide comprehensive medication management to include:
    - Assess all a patient's medications– prescription, nonprescription, vitamins, and supplements
    - Assess each medication to ensure that it is appropriate, effective, safe, and can be taken as intended
    - Identify and address medication-related problems
    - Develop individualized care plans with therapy goals and personalized interventions
    - Prescribe medications and order laboratory or other diagnostic tests (varies by state)
    - Follow up appointments at regular intervals (e.g., weekly, biweekly or monthly) to evaluate response, adverse effects, progress toward treatment goals, and to adjust medications as needed; typically lasting 30 minutes
    - Educate patient and family about medications and lifestyle modifications
    - Refer to other providers and specialists for services such as diagnostic clarification, psychotherapy, and dietary counseling
- Collaborating closely with other mental health team members to clarify diagnoses and discuss complex medication regimens

We also note the 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 in-person and 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. 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.

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

CPNP supports the provision allowing payment for mental health services to established patients via audio-only telephone calls when the originating site is the patient's home. In 2019, the Federal Communications Commission reported that between 21.3 and 42 million Americans lack access to broadband. Audio-only visits will ensure that those in areas with limited or no broadband, older adults and younger individuals with disabilities who rely on Medicare for essential behavioral health care won't lose access to critically needed services. Given the increase in utilization and reliance on audio-only services, a modifier is necessary so providers can appropriately code and bill for their services. Further,

In addition, CPNP urges CMS to consider other services outside of mental health, such as behavioral health services, that could be appropriately furnished through audio-only telephones. Specifically, audio-only services should be available for the treatment of substance use disorders particularly in light

of recent CDC research showing that over 40 states saw a rise in opioid-related overdose deaths since the start of the pandemic.

In response to CMS's question about the need for additional documentation in the patient's medical record to support the clinical appropriateness of audio-only telehealth, CPNP urges CMS to avoid creating new paperwork burdens on providers that could unnecessarily detract from the provider's ability to care for a patient. Further, the CPNP believes that audio-only telehealth should not be limited to only certain services such as level 4 or 5 Evaluation and Management (E/M) visit codes or psychotherapy with crisis as proposed. Instead, audio-only should be available, at a minimum, to all Medicare beneficiaries needing mental health services regardless whether the patient is "established" or not.

Expiration of PHE Flexibilities for Direct Supervision Requirements

CPNP supports revising the definition of ''direct supervision'' at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation after the PHE for COVID–19. 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 provision of in-person and telehealth services. If CMS limits which services can be furnished with virtual direct supervision and thus requiring in-person supervision only, CPNP would urge CMS not to include mental health and substance use services.

Reimbursement

One payment issue not directly addressed by CMS in the proposed rule is whether the agency will continue to pay for telehealth services at the same rate as in-person visits once the PHE ends. For mental and behavioral health providers, whose patients rely heavily on telehealth services, it would be a costly reduction if payment for these services returns to pre-pandemic reimbursement levels. Given the significant investments required of providers to offer and maintain telehealth services, this change could discourage many providers from continuing to offer telehealth services and thereby jeopardize access to mental and behavioral health services for many beneficiaries. CPNP urges CMS to continue reimbursement of telehealth and audio-only services at the non-facility rate.

<u>Valuation of Specific Codes</u>

Chronic Pain Management

CPNP supports CMS proposal to address the fact that there are no existing codes that specifically describe the work of clinicians in performing the tasks necessary to perform pain management care. As CMS recognizes, it is critically important that chronic pain management services be appropriately valued and reimbursed to ensure these services are available and provided to Medicare beneficiaries.
CPNP believes that clinical pharmacists, including psychiatric, pain management and palliative care pharmacists, can and do play a role in providing chronic pain management services. Psychiatric pharmacists are specifically trained to provide medication management, patient education and self-management, assessment and monitoring, and administration of a validated rating scale. As CMS notes, there are 50 million Americans with chronic daily pain that results in substantial medical expenditures.

However, there is a trend in clinical practice of health care professionals declining to provide pain management care for patients, both in rural and in urban areas. Clinical pharmacists are a growing and essential part of the comprehensive treatment of pain and an integral part of the multidisciplinary team, utilizing collaborative relationships with providers.

Evaluation and Management Visits

CPNP urges CMS to reverse the policy change in the CY 2021 final rule limiting physicians to billing only the lowest-level evaluation and management (E/M) code for pharmacist-provided incident-to services, regardless of the duration and complexity of the E/M services provided. This policy shift undermines health system care models that leverage care team members, including clinical pharmacists to support physicians, thereby threatening patient access to critical services, including comprehensive medication management. The CMS E/M policy change is fundamentally at odds with efforts to implement care models that include clinical pharmacists. Many commercial payers as well as states consider pharmacists to be qualified health professionals whose services can be billed incident-to a physician using the higher-level E/M codes. Barring a full reversal of the policy change, we urge CMS to adopt either a clinical pharmacist modifier for existing E/M codes or a new clinical pharmacist-specific code set that corresponds to the higher-level E/M codes and accounts for the duration and complexity of pharmacist-provided incident-to services.

Revising the Definition of RHC and FQHC Mental Health Visit

CPNP supports the proposal by CMS to revise the definition of a mental health visit provided by clinicians serving in Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) to include telehealth and audio-only services. This change would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. This would ensure that Medicare beneficiaries receiving services through these facilities would have the same access to mental and behavioral health services as those treated by providers practicing independently.

In the proposed rule, CMS specifically requests feedback on whether the agency should further align FQHC and RHC telemental health services with telemental care that is covered under the PFS by replicating the problematic in-person requirement that is statutorily required for PFS services. CPNP urges CMS to avoid adding an unnecessary in-person requirement to remote services for these patients.

CPNP also believes outpatient behavioral therapy services offered by Critical Access Hospitals (CAHs) are part of a comprehensive rural behavioral health strategy. Without action to ensure these hospitals can bill behavioral health services via telehealth as they do in-person services, access to these CAH-provided outpatient services will be lost for thousands of Americans in rural areas.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Proposed OTP Coding and Payment for New Nasal Naloxone Product

The Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities or SUPPORT 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

2022, CMS is proposing to add the newly FDA approved 8 mg naloxone product and establishing a reimbursement rate for a take-home supply of a box containing two 8mg nasal sprays. CPNP supports providing OTPs with the flexibility to utilize all FDA-approved naloxone products to help treat individuals with OUD, thus increasing access to this lifesaving, emergency treatment for all who need it.

Counseling and Therapy Furnished via Audio-Only Telephone

CPNP supports CMS' proposal permanently allowing OTPs to furnish certain OUD services, including therapy and counseling portions of the weekly bundles, using audio-only telephone calls. We support removing barriers for patients in receiving these services.

Many pharmacists are actively caring for patients with OUD at OTPs, yet many barriers prevent patients from receiving care. CPNP believes psychiatric pharmacists can help meet treatment demands but their ability to do so is dependent, in part, on coverage frameworks that encourage better optimization of resources, such as pharmacists. CMS should take action to acknowledge and attribute clinical pharmacist provided-patient care services that can be provided using audio-only telephone calls provided through OTP programs. 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. Services performed by psychiatric pharmacists include: (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.

As CMS is aware, patients receiving care in an OTP may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners outside of the OTP. CPNP encourages CMS to specifically consider how psychiatric pharmacists' time devoted to treatment planning and revision, and care coordination can be included among the services covered by Medicare Part B. Psychiatric pharmacists providing mental health and SUD services should receive attribution, recognition and compensation by CMS for providing these services.

<u>Electronic Prescribing for Controlled Substances (ECPS) for a Covered Part D Drug</u>

Proposed Timeframe for ECPS Adoption

The SUPPORT Act mandated that controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program with an effective date of January 1, 2021. To allow time for implementation, CMS originally established a compliance date of January 1, 2022 and is proposing, in part due to the strains of the COVID-19 pandemic to push the compliance date of January 1, 2023. CPNP supports this proposal to allow prescribing clinicians additional time to come into compliance.

[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

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