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September 6, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Hubert H. Humphrey Building, Room 445–G 200 Independence Avenue, SW Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Notice of Proposed Rule Making (NPRM) on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2023.

According to a recent study, approximately 1.7 million Medicare beneficiaries had a substance use disorder (SUD) in the last year. However, only 11% of these beneficiaries received any treatment for their SUD. While there are many reasons a patient may not pursue treatment, this staggering statistic underscores the importance that Medicare plans be comprehensive and reflective of the complexity of the disease of addiction to ensure that all beneficiaries have access to care.

ASAM is encouraged by the proposals set forth in this proposed rule to expand access to addiction treatment. We appreciate the agency's response to the COVID-19 public health emergency (PHE) by modifying federal regulations to permit expanded access to care via telehealth and for extending these flexibilities for a certain time beyond the PHE to ensure that access is not abruptly upended. Additionally, ASAM is supportive of the agency's proposals in response to stakeholder feedback regarding opioid treatment programs (OTPs) and the need to ensure appropriate valuation of these service components. We also applaud the proposal to add new coding and payment for chronic pain management (CPM) services and look forward to working with CMS to ensure that this proposed bundle is appropriately defined and valued.

Finally, ASAM welcomes the request for information (RFI) within this NPRM on intensive outpatient (IOP) services. These are critical services for patients who need additional care beyond the outpatient setting, but who do not require residential or inpatient care. ASAM has provided CMS with several potential options below for addressing the current coverage gap for IOP services in the Medicare program.

In comments further detailed below, ASAM recommends that CMS:

- Adopt its proposal to revalue the therapy component of the OTP bundle and clarify whether this revision would prohibit OTPs from billing for the OTP bundle for therapy sessions less than 45 minutes in duration;
- Finalize its proposal to allow OTP intake activities to be provided through audio-video telehealth for the
 initiation of treatment with buprenorphine to the extent allowed by the appropriate federal agencies and to
 permit the use of audio-only communication technology for such activities when audio-video technology is
 not available to the beneficiary;
- Allow OTP periodic assessments to continue to be furnished using audio-only communication technology following the end of the COVID-19 PHE and to extend similar flexibility to patients receiving treatment with methadone or naltrexone;
- Proceed with its proposal to pay for treatment services provided by OTP mobile units;
- Consider an exception to electronic prescribing requirements and penalties for prescribers who treat patients with buprenorphine for treatment of opioid use disorder (OUD);
- Adopt its proposals to revise the code descriptors for alcohol misuse screenings (G0442) and (G0443)
 behavioral counseling for alcohol misuse and revise its policy to include Addiction Specialist Physicians (ASPs)
 as providers who may bill for (G0442) alcohol misuse screenings and (G0443) behavioral counseling for
 alcohol misuse;
- Review its coverage and payment policy for G0442 (alcohol misuse screening) to ensure it reflects the latest US Preventive Services Task Force (USPSTF) recommendations on unhealthy alcohol use;
- Finalize its proposal regarding CPM services after incorporating some changes, ensure these services are available via telehealth under certain conditions, and establish separate coding and payment for management of acute pain;
- Adopt its proposals to add CPM and behavioral health integration services to the services offered by Federally
 Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs), and its proposal to implement the
 telehealth provisions of the Consolidated Appropriations Act (CAA) of 2022;
- Finalize its proposal to allow some behavioral health services to be provided via general supervision;
- Establish a bundled payment for the provision of ASAM Level 2.1 (IOP) services to a Medicare beneficiary, similar to the payment methodology established for OTP services, which include both drug and non-drug components;
- Consider whether the agency has regulatory authority to extend coverage of any new IOP billing codes to OTP and FQHC/RHC settings to ensure that patients in these settings have access to these critical services;
- Review state Medicaid policies to determine whether there are payment and coverage policies that could be implemented in the Medicare program; and
- Examine whether it has any regulatory flexibility to amend regulations or issue clarifying, sub-regulatory guidance to permit IOP services to be provided to patients with a primary diagnosis of SUD.

ASAM looks forward to continued collaboration with CMS to address the challenges of the overdose epidemic through these proposals and other actions. We hope that you find our comments below helpful in that endeavor. If you have any questions or need further clarification, please do not hesitate to contact Corey Barton, Associate Director, Advocacy and Government Relations at cbarton@asam.org.

Sincerely,

William F. Haning, III, MD, DLFAPA, DFASAM President, American Society of Addiction Medicine

Conversion Factor

CMS proposes a CY 2023 Medicare conversion factor (CF) of \$33.0775, a decrease of \$1.53 or 4.42 percent from the 2022 CF rate of \$34.6062. The proposed CF is largely a result of an expiring 3 percent increase funded to the CF at the end of CY 2022 as required by law. The additional approximate 1.5 percent decrease to the CF is a result of a budget neutrality adjustment primarily from increases to payment for hospital, nursing facility, home health and emergency medicine visits.

ASAM is concerned that if finalized, the proposed CF would have significant consequences for physicians treating addiction. The toll of the COVID-19 pandemic placed on physician practices plus the numerous other challenges facing clinics would be exacerbated should this proposed CF be finalized. While ASAM understands CMS' statutory obligations in regard to the CF, we look forward to working with Congress to avoid the consequences of this financial harm to physicians, especially those treating addiction.

Medicare Coverage for OUD Treatment Services Furnished by OTPs

OTP Bundle - Therapy

In response to feedback from interested parties, including associations and groups that represent OTPs, CMS proposes to modify the payment rate for the non-drug component of the bundled payment for an episode of care to base the rate for individual therapy on a crosswalk to CPT code 90834 (Psychotherapy, 45 minutes with patient), instead of 90832 (Psychotherapy, 30 minutes with patient). Beginning with CY 2023, CMS would apply the Medicare Economic Index (MEI) from 2021-23 to update the 2023 payment rate for the non-drug components of the bundle. While ASAM supports CMS' proposal to revise this component of the OTP bundle in response to stakeholder feedback, we request that CMS clarify whether this revision would prohibit OTPs from billing for the OTP bundle for therapy sessions less than 45 minutes in duration. ASAM is supportive of appropriately valued services that reflect a typical use case, but we also recognize that there will be some patients who may require less than 45 minutes of service for psychotherapy. We urge that CMS clarify that this change in valuation would not prohibit OTPs for billing for services when less than 45 minutes of the service is provided.

G2076 - OTP Intake Activities

CMS is proposing to allow G2076 to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) at the time the service is furnished. CMS is also proposing to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. CMS interprets the requirement that audio/video technology is "not available to the beneficiary" to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction. **ASAM supports this proposal and encourages CMS to finalize it.**

G2077 - OTP Periodic Assessments

CMS is seeking comment on whether to allow periodic assessments (G2077) to continue to be furnished using audioonly communication technology following the end of the PHE for COVID-19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. ASAM currently supports the furnishing of such services through audio- or telephone-only technologies in the case where a physician or practitioner has already conducted (or conducts shortly thereafter in the context of buprenorphine treatment) an in-person medical evaluation or a telehealth evaluation that utilizes both audio and visual capabilities with the eligible telehealth individual. ASAM encourages CMS to make such services available via audio-only following the end of the PHE and to extend similar flexibility to patients receiving treatment with methadone or naltrexone as described.

Mobile Units

CMS is clarifying that OTPs can bill Medicare for medically reasonable and necessary services furnished via mobile units in accordance with SAMHSA and DEA guidance. The agency is proposing that locality adjustments for services furnished via mobile units would be applied as if the service were furnished at the physical location of the OTP registered with the DEA and certified by SAMHSA.

Mobile units are an important avenue for expanding access to treatment. Given that access to methadone is restricted to regulated OTPs, the potential for expansion of this treatment modality has been limited. Unfortunately, the number of OTPs in the US (1,754 in 2020) increased by about 42% over the prior 11 years, much more slowly than the growth of the prevalence of OUD.² Further, most US counties have no OTPs. Inadequate public funding and unfavorable local and state zoning regulations have historically resulted in waitlists at some OTPs. These factors have culminated such that OTPs have established only a limited number of mobile units and a limited number of satellite medication units in locations such as free-standing dispensaries, pharmacies, jails, prisons, FQHCs, and residential treatment facilities, resulting in limited geographic reach. ASAM believes this proposal will provide additional clarity and guidance to OTPs operating mobile units and we encourage CMS to finalize it.

Requirement for Electronic Prescribing for Controlled Substances (EPCS)

CMS is proposing to extend the existing non-compliance action of sending letters to non-compliant prescribers for the EPCS program from 2023 into 2024. These letters would consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver.

CMS notes that the agency plans to increase the severity of penalties beginning in CY 2025. CMS is considering the following non-exhaustive list of penalties for non-compliant prescribers beginning in CY 2025:

- Requiring a non-compliant prescriber to enter into a corrective action plan, which would require the noncompliant prescriber to comply with the EPCS requirement within 2 years prior to applying other potential actions outlined below;
- Posting a non-compliant prescriber's name on the CMS website and identifying the prescriber as noncompliant;
- Public reporting of EPCS compliance status, including that a prescriber is noncompliant, on the Care Compare website;
- Referral of non-compliant prescribers to the DEA to support potential investigations;
- Sharing the list of EPCS non-compliant prescribers with the States; and/or
- Referral for potential fraud, waste and abuse review.

CMS is interested in comments on whether these proposed penalties would be appropriate/effective, whether the penalties should be phased-in, and compliance enforcement among Medicare participating and non-participating providers.

In previous comments to CMS, ASAM has noted that EPCS is an important tool to assure quality and reduce errors and fraud in the transmission of prescriptions from the prescribing healthcare practitioner to the dispensing pharmacist. EPCS eliminates the possibility that a patient loses, or a pharmacist misreads a physical prescription note. EPCS can also facilitate reporting of prescriptions to prescription drug monitoring programs (PDMPs).

While ASAM generally supports EPCS, we reiterate our concern that small practices may find it financially difficult to implement the required technology. ASAM continues to recommend that CMS consider the financial impact of this requirement on small practices that have not yet adopted electronic systems allowing for EPCS, and accordingly provide additional resources or incentives for these practices to adopt such technology. **ASAM welcomes the agency's proposal to extend the start date for compliance actions to 2024.**

Additionally, ASAM advises CMS that over 160 prescribers in more than 19 states have alerted ASAM that they have encountered repeated declinations from pharmacists to fill legitimate prescriptions for buprenorphine to treat a patient's OUD. The reasons cited stem from pharmacists outright refusal to fill due to corporate policy, insurance coverage, to pharmacists noting that the pharmacy did not have the medication in stock due to distributor refusal to ship the medication. Recent studies have found that pharmacies in metropolitan counties were more likely to have buprenorphine available than pharmacies in non-metropolitan counties.³ This is compounded by the fact that studies have also shown that despite having a high need for services, many rural areas have a low to no capacity for treatment with buprenorphine.⁴ There are many reasons for the aforementioned disparities, including a lack of trained prescribers, stigma, and insurance barriers to name a few. However, these factors when added together with the agency's proposed penalties for failing to abide by EPCS are especially concerning to ASAM at a time when it has received reports of considerable delays in patients' ability to attain their buprenorphine prescriptions. ASAM is concerned that these penalties may only add to the complex landscape that small and rural practices already have to contend with when prescribing this life-saving medication. Accordingly, ASAM again strongly encourages CMS to consider an exception to this requirement for prescribers who treat patients with OUD with buprenorphine, as well as small practices.

Annual Alcohol Misuse and Depression Screenings

CMS notes in the proposed rule that the agency has received feedback that the 15-minute threshold in the code descriptors for G0442 and G0444 is too high and limits providers' ability to bill the codes. As a result, CMS is proposing to revise the code descriptors for each code from 15 minutes to 5-15 minutes in hopes that more providers can bill for the services.

ASAM supports a wide variety of measures to prevent alcohol and other drug related problems, understanding that carefully thought-out prevention measures have demonstrably reduced the early onset of alcohol, nicotine, and other drug use in some populations. This has contributed to a reduction in deaths and serious injuries resulting from drug related injuries and illnesses. These and other identifiable results have major economic implications. ASAM also supports insurer policies that provide coverage of services that target early detection of and intervention for substance use, such as the utilization of Screening, Brief Intervention, and Referral to Treatment (SBIRT) approaches for unhealthy and harmful alcohol use and evidence-informed prevention interventions offered by healthcare providers.⁵

While ASAM supports this CMS proposal, ASAM also calls on CMS to initiate a review of existing Medicare policy and claims guidance on this subject which has not been updated since 2012.⁶ This policy and billing guidance currently excludes ASPs from coverage of their professional claims, despite recognition that these physicians hold certifications that attest to their knowledge to identify, through screening, the risk for, or early warning signs of, addiction and perform early interventions; and prescribe a comprehensive range of prevention services.⁷ ASAM recommends that CMS revise its policy to include Medicare provider specialties 5, 8, 11, 79, 84, 86 (Addiction Medicine & Psychiatry) under its professional billing requirements as providers who may bill for (G0442) alcohol misuse screenings and (G0443) behavioral counseling for alcohol misuse. Since 2012, the US Preventive Services Task Force (USPSTF) has made updated recommendations about unhealthy alcohol use in adults and the use of screening and behavioral counseling interventions.⁸ We encourage CMS to review the latest USPSTF recommendations on unhealthy alcohol use and consider working with stakeholders to ensure that Medicare policy reflects the latest scientific consensus.

Chronic Pain Management (CPM) Services

CMS is proposing to create two bundled codes to describe chronic pain management and treatment. These two new proposed codes would be defined as following:

GYYY1: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician

or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)

GYYY2: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)

The agency is proposing to define chronic pain as "persistent or recurrent pain lasting longer than three months" and is seeking comments on various aspects of the proposed bundle.

According to the American Medical Association's (AMA) Pain Care Task Force (PCTF), "pain continues to be the one of the most common reasons many patients seek medical care in the United States. This care costs an estimated \$250 to \$300 billion in health care resources nationally per year since 2008." Yet, current payment systems have several problems that create barriers to the successful treatment of patients with chronic pain. These include existing coding and payment that:

- Favors imaging and subsequent interventional procedures significantly more than counseling, cognitive therapies, therapeutic exercise, and nutritional education leading to episodic, fragmented care that incentivizes performance of procedures often with limited evidence of benefit;
- Incentivizes prescription medication management and less face-to-face time compared to longer counseling visits;
- Encourages outpatient treatment and discourages inpatient interventions (like spinal cord stimulators or regional neurolytic procedures), even in cases where unmanaged chronic pain prolongs a hospitalization; and
- Provides inadequate reimbursement for services to home-limited patients, as these patients can require more time and care coordination services.

Given the challenges of treating patients with chronic pain, the Department of Health and Human Service's Pain Management Best Practices Inter-Agency Task Force recommended that payers reimburse for pain management using a chronic disease management model. ASAM commends CMS for recognizing the disease burden of chronic pain by proposing new coding and payment for chronic pain management services and recommends that CMS finalize its proposal, with some changes.

ASAM offers several comments below in response to the agency's request for information on certain aspects of the proposal.

First, CMS seeks comments on the definition of chronic pain. Surveyed ASAM physicians define chronic pain as "persistent or recurrent pain without a serious progression or exacerbation of an underlying pathologic condition and without tolerability over time (generally three months)," generally in line with the proposed CMS definition.

CMS is also seeking comments on a typical episode of care for patients with chronic pain.

Surveyed ASAM physicians note that the following aspects are typically part of an episode of care for chronic pain:

- Assessment: including obtaining and reviewing past records related to the condition causing pain (often past
 cancer treatment, procedures/surgeries, imaging reports, or pain intervention notes) and reassessment of
 response to treatment plan;
- Screening for mood disorder/suicidality, substance use and medication misuse;
- Medication management, including medication counseling and monitoring;
- Providing education to patients on pain, including resources for self-help if multiple appointments to other clinicians are not feasible;
- Ordering and follow-up of additional tests or imaging, as needed;
- Referral and care coordination with physical therapy, occupational therapy, skilled nursing like home health or wound care, podiatry, interventional pain, pain psychology, integrative medicine, neurology, behavioral health; and

Ordering of durable medical equipment (DME).

While most of these services appear to be included in the proposed code GYYY1, ASAM recommends that CMS also include screening services to identify, reduce, and prevent hazardous or harmful alcohol and drug use within this bundle. ASAM also encourages CMS to ensure that practitioners' time spent ordering tests and DME, obtaining prior authorizations and peer review for all referrals, medications, and communication with pharmacies are also included within this bundle. Separately, surveyed ASAM physicians are concerned that including "chronic pain-related crisis care" within this proposed bundle does not recognize the individualized needs of each patient who may need this kind of care, nor does it consider the time spent by practitioners arranging to provide this care. Therefore, ASAM urges CMS to exclude this component from the bundle and pay separately for the provision of chronic pain-related crisis care.

While ASAM considers 30 minutes a proper threshold for billing CPM services for the initial patient visit, ASAM is concerned that the proposed 30-minute threshold for billing GYYY1 may be too high for billing this code for patient visits beyond the initial visit. This threshold may discourage subsequent billing for these services, especially in circumstances where billing practitioners spend less than 30 minutes in a month providing these services. Instead, CMS should finalize a separate code with a 15-minute threshold for billing for these services beyond the initial visit. Furthermore, the use of validated pain assessment tools should be excluded and be a separately billable service, as utilization of clinically useful (i.e. low patient burden) assessment tools is still limited, inconsistent, and early in adoption. Failure to use these tools should not be a barrier for practitioners to use these codes. Multidimensional assessments should be incentivized with an overall focus on physical, social, and emotional functioning and a shift away from an isolated focus on pain intensity. ASAM encourages CMS to finalize a separate add-on code for assessment tools that should include both administration of the measures and required discussion with the patient.

ASAM offers the following edits and proposals to CMS in response:

- GYYY1: Chronic pain management and treatment, monthly initial bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)
- GYYY2: Chronic pain management and treatment, monthly bundle including any of the following: diagnosis; assessment and monitoring; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. First 15 minutes personally provided by physician or other qualified health care professional, per calendar month; used in subsequent months after initial visit. (When using GYYY2, 15 minutes must be met or exceeded.)
- GYYY23: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1 or GYYY2). (When using GYYY2 GYYY3, 15 minutes must be met or exceeded.)
- GYYY4: Administration of a validated pain rating measures; requires use of at least 2 domains in addition to pain intensity; requires discussion of validated measures with the patient by physician or other qualified healthcare professional. (add-on code to GYYY1 or GYYY2

These revisions should appropriately incentive a more complete initial visit and encourage subsequent follow-up

interactions between coordinating practitioners. Lowering the threshold for subsequent visits would incentive ongoing collaboration and communication between disciplines as a 15-minute interaction is likely more realistic than requiring 30 minutes in subsequent months. CMS should use half of the resource inputs of GYYY1 for the valuation of the proposed GYYY2 above. The proposed GYYY3 code above should be valued the same as CMS has proposed to value GYYY2 as written in the proposed rule. CMS should study state Medicaid programs to determine the appropriate value for the proposed GYYY4 above.

ASAM encourages CMS to ensure that these new codes are available for billing in primary care and specialty clinics, in the patient's home, in FQHCs/RHCs, skilled nursing facilities, long term care, acute care hospitals, and mental health and substance use treatment facilities. CMS should also encourage practitioners billing for these services to consider continuing medical education in pain and addiction, as well as non-pharmacologic treatment of pain.

ASAM also recognizes that some patients may be limited in their ability to seek in-person care due to their health conditions or proximity to physicians specializing in the treatment of chronic pain. Hence, ASAM recommends that CPM services be available via telehealth (including audio-only for mental health services), with some qualifications. The initial visit described by GYYY1 should be allowed via telehealth, so long as an in-person, face-to-face visit occurs shortly after CPM initiation and prior to the prescribing of controlled medications for pain. This specification is important to allow initiation of referrals to home health services and telehealth behavioral health services as part of CPM for people who are home-limited.

Finally, CMS seeks comment on whether the payment for services for the management of acute pain should be included within this proposed bundle. Just as the Pain Management Best Practices Inter-Agency Task Force recognized in its report, acute pain may result in response to a number of factors and is often interlinked with chronic pain. It is equally important that practitioners have the tools and resources to provide patients care for acute pain. While CMS has recognized the burden of acute pain, it does not propose to include the treatment of acute pain within this bundle. ASAM notes that the evaluation of acute pain may lead to vastly different plans of care, depending on the etiology, that may differ with managing the care of a patient with chronic pain. At the same time, ASAM recognizes that management of acute pain in patients with chronic pain, especially those treated with long-term opioid therapy, may involve additional considerations and effort compared to the management of acute pain outside of chronic pain or long-term opioid treatment. Therefore, ASAM recommends that CMS considers this aspect as the agency finalizes the relative resource costs for these new codes. While ASAM does support coding and payment for the management of acute pain by a practitioner, ASAM recommends that CMS establish separate payment and coding for the management of acute pain that considers and recognizes the differential resources and components involved with furnishing and managing the treatment of patients with acute pain.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS proposes to add the CPM and behavioral health integration services to the all-inclusive RHC/FQHC payment for general care management (G0511).

CMS maintains that since the requirements for the new chronic pain management and behavioral health integration services are similar to the requirements for the general care management services furnished by RHCs and FQHCs, the payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC and FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) and PCM codes (CPT codes 99424 and 99425).

CMS is also proposing to implement the telehealth provisions in the CAA, 2022 via program instruction or other sub-regulatory guidance to ensure a smooth transition after the end of the PHE. These policies extend certain flexibilities in place during the PHE for 151 days after the PHE ends, including allowing payment for RHCs and FQHCs for furnishing telehealth services (other than mental health visits that can be furnished virtually on a permanent basis) under the payment methodology established for the PHE. The CAA, 2022 also delays the in-person visit requirements for mental health visits furnished by RHCs and FQHCs via telecommunications technology until 152 days after the end of the PHE. ASAM supports and encourages the adoption of the CMS proposal to add CPM and behavioral health integration services to the services offered by FQHCs and RHCs, as well as the proposal to implement the telehealth provisions of

the CAA, 2022.

Supervision Requirements for Behavioral Health Services

CMS is proposing to amend the direct supervision requirement under the agency's "incident to" regulation at § 410.26 to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. Access to behavioral health services continues to be a major challenge for people with a SUD. Additionally, existing provider workforce shortages are complicated further when a limited number of physicians are already available to provide direct supervision. ASAM applauds this proposal by CMS that will enable physicians to provide the necessary supervision without compromising patient safety and encourages CMS to finalize this proposal as it will have a positive impact in not only the Medicare program, but in commercial insurance lines of business with similar access issues.

Comment Solicitation on IOP Mental Health Treatment, including IOP SUD Treatment

ASAM commends CMS for examining whether the current coding and payment mechanisms under the PFS adequately account for IOP services that are part of the SUD continuum of care. Patients in the IOP level of SUD care (ASAM Level 2.1) may have a greater intensity of SUD-related symptoms/unable to stabilize at a lower level of care and require close monitoring and more structure to promote treatment progress and prevent further deterioration. Patients in this setting require at least 9 hours of skilled treatment services per week, including individual and group counseling, medication management, family therapy, education groups, occupational and recreational therapy, and other therapies. While these services may be offered in any setting that meets state licensure and standards, they are most often provided in free-standing specialty settings that are not covered Medicare providers.

Importantly, *The ASAM Criteria* provides that programs delivering IOP services should be "staffed by an interdisciplinary team of appropriately credentialed addiction treatment professionals," and any "physicians treating patients in this level should have specialty training and/or experience in addiction medicine or addiction psychiatry." ¹¹ Practitioners in the IOP setting typically include appropriately credentialed addiction treatment professionals including addiction counselors, psychologists, social workers, and ASPs who assess and treat SUD and other addictive disorders. These teams also include generalist physicians who may be involved in providing general medical evaluations (physical exams) and concurrent/integrated general medical care (services for hepatitis, HIV, tuberculosis, or other co-occurring infectious diseases).

Unfortunately, existing federal statutes, Medicare payment policy, and administrative rules governing participation in the Medicare program taken together mean that the program is neither comprehensive nor exhaustive in covering all ASAM Levels of Care, and effectively limit coverage of comprehensive IOP services. As the Legal Action Center has documented extensively, coverage limitations such as the requirement for patients to have a primary mental health diagnosis and the exclusion of free-standing SUD treatment facilities from coverage mean that these services are very restricted for Medicare beneficiaries who need them.¹²

The points above underscore the current coding gaps in the Medicare program. While practitioners not working in Medicare-covered settings could theoretically provide IOP services through separate claims for each service, there are potential actions that CMS could take to remedy these gaps and ensure that Medicare beneficiaries have access to a more comprehensive continuum of care. First, CMS could establish a bundled payment for the provision of ASAM Level 2.1 services to a Medicare beneficiary, similar to the payment methodology established for OTP services, which include both drug and non-drug components. This bundle would include the services prescribed by ASAM Level 2.1 and include the evaluation and management of the patient, as well as any medical, psychiatric, and therapy (individual, group, family, occupational), medication management, needs of the patient. In the past, CMS has used a building block methodology to determine the payment for these bundles (e.g. OTP services). CMS could use the same approach here, while excluding more resource-intensive costs such as drug testing and biopsychosocial assessments from the bundle (these could be covered as separate add-on codes).

There are many existing CPT and Medicare G codes that CMS could use as building blocks to create coding and

payment for IOP services. For example, CMS could include office evaluation and management (E/M) codes (CPT 99202-99205 and 99212-99215), chronic care management (CPT 99424-99427, 99437-39, 99487, and 99489-91), psychotherapy (90832) and group psychotherapy (90853), alcohol and drug assessment (H0001), care management services for behavioral health (99484), and psychiatric collaborative care (99492-93) as reference services for these new codes for IOP services. ASAM recommends that CMS also consider whether the agency has regulatory authority to extend coverage of any new IOP billing codes to OTP and FQHC/RHC settings to ensure that patients in these settings have access to these critical services.

At the same time, several state Medicaid programs have established standalone payment and coverage policies for ASAM Level 2.1 services. ASAM encourages CMS to review state Medicaid policies to determine whether there are payment and coverage policies that could be implemented in the Medicare program.

Furthermore, ASAM recommends that CMS examine whether it has any regulatory flexibility to amend regulations or issue clarifying, sub-regulatory guidance to permit IOP services to be provided to patients with a primary diagnosis of SUD. As referenced above, current rules render this benefit unavailable to Medicare beneficiaries, unless they have a primary mental health diagnosis.

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