



OFFICERS

President
Brian Hurley, MD, MBA, FAPA, DFASAM
President-Elect
Stephen M. Taylor, MD, MPH, DFAPA, DFASAM
Vice-President
Aleksandra E. Zgierska, MD, PhD, DFASAM
Secretary
Anika Alvanzo, MD, MS, FACP, DFASAM
Treasurer
Timothy Wiegand, MD, FACMT, FAACT, DFASAM
Immediate Past-President
William F. Haning, III, MD, DLFAPA, DFASAM

BOARD OF DIRECTORS

Directors-at-Large
Alta DeRoo, MD, MBA, FACOG, DFASAM
Lori D. Karan, MD, FACP, DFASAM
Marla D. Kushner, DO, FACOFP, FAOAAM, FSAHM, DFASAM
Nicole Labor, DO, FASAM
Surita Rao, MD, FASAM
Michael F. Weaver, MD, DFASAM

REGIONAL DIRECTORS

Emily Brunner, MD, DFASAM
Megan Buresh, MD, DFASAM
Itai Danovitch, MD, MBA, FAPA, DFASAM
Keyghobad Farid Araki, MD, FRCPC, ABAM, FASAM
Teresa Jackson, MD, DFASAM
Christina E. Jones, MD
Audrey M. Kern, MD, DFASAM
James P. Murphy, MD, DFASAM
Kelly S. Ramsey, MD, MPH, MA, FACP, DFASAM
Shawn Ryan, MD, MBA, DFASAM

EX-OFFICIO

Nicholas Athanasiou, MD, MBA, DFASAM
Julia L. Chang, MS, MBA
Michael Fingerhood, MD, FACP, DFASAM
Kenneth I. Freedman, MD, MS, MBA, FACP, AGAF, DFASAM
Margaret A. E. Jarvis, MD, DFASAM
Cara A. Poland, MD, MEd, FACP, DFASAM

FOUNDING PRESIDENT

Ruth Fox, MD
1895-1989

September 8, 2023

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

**Re: ASAM's Comments on 2024 Medicare Hospital Outpatient
Prospective Payment Systems (OPPS) Proposed Rule**

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 Hospital Outpatient Prospective Payment Systems for calendar year (CY) 2024.

The proposals set forth in this proposed rule appear to set an important benchmark in the provision of care for people with substance use disorders (SUDs). As people across the United States continue to experience the crushing toll of the addiction and overdose crisis through the loss of family members, friends, and loved ones, ASAM welcomes the proposals in this rule which address numerous payment and coverage barriers for Americans and their families experiencing the devastating impacts of SUDs.

Specifically, ASAM is thrilled to see Medicare working to implement coverage and payment for intensive outpatient programs (IOP) for people with SUD in defined settings after fervent efforts over the years to close this Medicare coverage gap. While there are many more IOP settings to address and coverage gaps to close, this is a remarkable step in the right direction.

In the comments detailed below, ASAM recommends that CMS:

- **Finalize coverage and payment for IOP treatment in defined settings;**
- **Provide a mechanism for physicians to attest that IOPs have the capability of appropriately referring or providing necessary biomedical and psychiatric care;**
- **Clarify in its final rule that SUD treatment professionals would be included in the scope of benefits to minimize any uncertainty;**
- **Clarify whether certain medications to treat addiction are included within the scope of benefits;**
- **Revise patient eligibility criteria for IOP care to ensure that access to IOPs is not inappropriately denied to beneficiaries with SUDs;**
- **Add/create new billable services to the list of available treatments available in IOPs;**
- **Appropriately recognize the different level of service intensity between IOP and partial hospitalization programs (PHPs) by valuing the resource costs appropriately in subsequent program years; and**
- **Incentivize uptake of this new IOP benefit and minimize clinician burden by using the alternative approach identified in table 46 of the proposed rule to pay for PHPs and IOPs beginning in 2024 for at least one year until further data collection can refine the appropriate resource costs.**

ASAM looks forward to continued collaboration with CMS to address the challenges of the addiction and overdose crisis 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,

Brian Hurley, MD, MBA, FAPA, DFASAM
President, American Society of Addiction Medicine

Detailed Comments

Intensive Outpatient Program Treatment

Background & Elements

According to the *The ASAM Criteria*, 4th Edition (forthcoming Fall 2023), Level 2.1 programs provide intensive outpatient services, delivering 9 to 19 hours of structured programming per week consisting of psychotherapy, counseling, and psychoeducation regarding management of addiction and co-occurring mental health conditions. *The ASAM Criteria* emphasizes that IOP care for patients with SUD should be coordinated with biomedical providers and other mental health care providers who specialize in treating mental health diagnoses other than SUD, as needed. The specific services provided to a patient should depend on their individual needs and preferences, as determined through the Treatment Planning Assessment.

CMS Implementation of IOP Benefit

Following passage of the Consolidated Appropriations Act of 2023 that authorizes Medicare coverage and payment for IOP services in defined settings, CMS proposes several regulatory revisions to implement this new benefit.

Specifically, CMS proposes to define IOP services as “...a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.”

CMS also proposes to establish new regulation at § 410.44(c) to codify that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

CMS also explicitly notes that the term “mental health diagnosis” includes SUD and behavioral health diagnoses generally.

While ASAM appreciates the clarification that “mental health diagnosis” includes SUD and behavioral health diagnoses generally, ASAM is concerned about the proposed patient eligibility criteria for IOP at § 410.44(c), as well as the existing eligibility criteria for PHP at § 410.43(c), and how they might be used to exclude and deny treatment to patients with SUD.

To address these concerns, ASAM recommends that CMS:

- **Codify that these services are available for patients who “have a mental health or substance use disorder diagnosis.” §§ 410.43(c)(5), 410.44(c)(5);**

- Remove the requirement that patients have an adequate support system while not actively engaged in the program, as discussed below. §§ 410.43(c)(4), 410.44(c)(4); and
- Remove the requirement that patients are not judged to be dangerous to self or others, as discussed below. §§ 410.43(c)(6), 410.44(c)(6).

Other than the PHP benefit, there are no other Medicare services to our knowledge that require patients to “have an adequate support system while not actively engaged in the program.” §§ 410.43(c)(4), 410.44(c)(4). Beyond the inherent inequity in this eligibility criteria, the requirement to have an adequate support system contradicts *The ASAM Criteria* dimensional assessment, which identify the range of factors (identified as 6 dimensions) that must be considered when determining the appropriate level of care placement for a patient with a SUD.

Specifically, *The ASAM Criteria* identifies that one of the dimensional assessment criteria for IOP or PHP is whether the patient lacks supportive social contacts. Notwithstanding the patient’s need for supportive contacts, the correct placement is either the IOP or PHP level for patients with SUD. Individuals with SUD often gain those supportive social contacts in the IOP, who help them maintain their recovery. **We, therefore, recommend CMS remove the eligibility requirement that a patient have an adequate support system while not actively engaged in the program, both for IOP and PHP.**

Similarly, another ASAM Criteria dimensional assessment criteria for IOP and PHP is that the patient is assessed at a mild to moderate risk of danger to self or others, and thus we urge CMS to remove §§ 410.43(c)(6), 410.44(c)(6) from the eligibility criteria for IOP and PHP. At a minimum, CMS should amend the language at §§ 410.43(c)(6), 410.44(c)(6) to read, “Are not judged to be dangerous to self or others,” to prevent stigma and unfounded perceptions of people with SUDs from interfering with patient access to care.

We also note that the forthcoming 4th edition of *The ASAM Criteria* in fall 2023 will make some small revisions to ASAM Level 2.5 – PHP, including the name of this level of care. We urge CMS to use the opportunity of this new publication to revisit the PHP regulations in the CY 25 OPPTS to ensure that this benefit aligns with *The ASAM Criteria* and meets the needs of beneficiaries with SUDs who require this level of care and reflects how services are delivered.

Finally, ASAM supports CMS’s proposal to exclude IOP from the outpatient mental health treatment limitation.

Additionally, CMS proposes a new regulation at § 410.44(a) that defines IOP services as services that:

- (1) are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; (3) are furnished in accordance with a physician certification and plan of care as specified under new regulations at § 424.24(d); and include any of the services listed in § 410.44(a)(4).

Furthermore, CMS proposes a scope of benefits at § 410.44(a)(4) that includes:

- Individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law);
- Occupational therapy requiring the skills of a qualified occupational therapist;
- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients;
- Drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered);
- Individualized activity therapies that are not primarily recreational or diversionary;
- Family counseling (the primary purpose of which is treatment of the individual's condition);
- Patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment);
- Diagnostic services; and
- Such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement

Within *The ASAM Criteria*, its Universal Support System Standards outline the foundational support systems that should be available in all levels of care. These support systems enable addiction treatment programs to rapidly provide referrals for biomedical and psychiatric care when needed and facilitate effective transitions to more and less intensive levels of care as appropriate (based on the Dimensional Admission Criteria and the Transition and Continued Service Criteria). *The ASAM Criteria* recommends that all levels of care should establish formal relationships with practitioners appropriately licensed in the state of practice to provide the appropriate biomedical and psychiatric care by program referral when needed.

As CMS implements the new IOP benefit, ASAM recommends that the physician certification process provide a mechanism for physicians to attest that the program has the capability of appropriately referring or providing necessary biomedical and psychiatric care, including, but not limited to:

- physical examinations;
- medical assessments;
- withdrawal management;
- medications for the treatment of SUD;
- medications for the treatment of other mental health diagnoses;
- other prescribed medications, including those that are obtained from a specialty pharmacy;
- medication management services;
- laboratory testing; and
- toxicology services.

While these services generally should not be included within the IOP scope of benefits (see comments under "Addiction Medications" below) and should be billed separately, it is vital to ensure that patients have access to these items and services if needed.

Additionally, ASAM notes that state laws and regulations may separately define the scopes of practice for mental health and SUD treatment professionals. Thus, ASAM recommends that CMS clarify in its final rule that SUD treatment professionals are included in the scope of benefits listed above. To that end, ASAM recommends as follows:

- CMS revise § 410.44(a)(4)(iii) to read, “Services of social workers, mental health counselors including substance use disorder counselors, marriage and family therapists, trained psychiatric nurses, and other staff trained to work with psychiatric patients individuals with mental health or substance use disorder diagnoses.”
- CMS revise § 410.44(a)(4)(i) to read, “Individual and group therapy with physicians or psychologists or other mental health or substance use disorder professionals to the extent authorized under State law.”
- CMS add a new subsection: “Substance use counseling by a professional to the extent authorized under State law to furnish such services,” consistent with the regulations for Opioid Treatment Programs, and discussed. See § 410.67(b)(iii).

Addiction Medications

ASAM also notes that there are FDA-approved medications to treat opioid use disorder (OUD) that may be implicated by the proposed scope of benefits, which includes coverage of drugs and biologicals furnished for therapeutic purposes which cannot be self-administered. Specifically, extended release formulations of buprenorphine and naltrexone used to treat OUD are medications that are ordinarily administered by a clinician and cannot be self-administered. Additionally, *The ASAM Criteria* notes that biomedical care (including medications) are typically coordinated and provided outside of the IOP care. **ASAM requests that CMS provide clarification on whether it is expected that the service associated with the administration of these extended release formulations would be billed outside of the IOP benefit or whether the IOP should include the service of administering these medications within the benefit (and if so, whether CMS plans to add the appropriate HCPCS codes to report these services to the list of IOP services).**

Coding and Billing

In the proposed OPPTS rule, CMS provides on table 43 the list of proposed codes that IOP programs may choose from when billing for services.

While many services in the scope of benefits are listed, the proposed IOP benefit does not explicitly outline Medicare coverage for:

- Patient assessment and reassessment;
- Treatment planning;
- Care coordination; or
- Identification of and addressing SDOH needs.

While the proposed rule does add CPT codes 96130, 96131, 96132, 96133, 96136, 96137, 96138, and 96139 (psychological/neuropsychological testing and evaluation codes) to the list of HCPCS codes eligible for payment of IOP claims, **ASAM encourages CMS to codify in**

regulations whether the inclusion of these HCPCS codes can be used by practitioners to conduct level of care assessments/reassessments, as indicated by *The ASAM Criteria*.

Adding Additional Services

ASAM recommends that CMS also add HCPCS codes 99446-99449 (interprofessional telephone/internet/electronic health record consultation services) to the list of reportable IOP services to allow clinicians to report time spent on activities such as verifying that a patient has had a physical examination conducted by a physician or advanced practice practitioner within the past year.

ASAM also notes that psychoeducation is a critical component of IOP care for patients with SUD, along with psychotherapy and counseling services. According to *The ASAM Criteria*, psychoeducation includes interventions with systematic, structured, and didactic knowledge transfer for an illness and its treatment, integrating emotional and motivational aspects to enable patients to cope with their illness(es) and improve treatment adherence and efficacy. Counseling is defined as professional assistance in coping with SUD and co-occurring conditions using techniques such as active listening, guidance, discussion, and clarification. Counseling and psychoeducation should be provided by appropriately trained and supervised professionals acting within their state-regulated scopes of practice for the given service or, when appropriate, via evidence-based digital therapeutics.

Notably, the proposed list of primary services on table 44 does not include codes that describe psychoeducation or counseling services. **Given that these services comprise the bulk of IOP care for SUD, ASAM strongly recommends that CMS add HCPCS codes G0396 (Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes), G0397 (Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes), and G0177 (Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more)) to the primary list of services to allow clinicians to report counseling AND psychoeducation services.** CMS used HCPCS code G0396 to build the OTP weekly bundle to pay for substance use counseling when the bundle was developed in 2020.

At the same time, ASAM notes that while the above-referenced codes can be used to report psychoeducation and counseling services, there is a need for more granular coding to report the provision of these services. Existing coding does not appropriately capture the resource intensity and specificity of provision of IOP care for psychoeducation and counseling services provided in IOP settings for SUD.

For example, CMS recently revised HCPCS codes G0442 (Annual alcohol misuse screening, 5 to 15 minutes) and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) to allow clinicians to report a lower time threshold for providing these services. Similarly, clinicians in IOP settings provide less than 15 minutes and more than 30 minutes of counseling services per day to patients. Yet, G0396 does not provide the flexibility for reporting lower time thresholds. Additionally, while clinicians can report counseling provided for more than 30 minutes, the resources involved in providing 60 minutes of counseling are much greater than what clinicians can currently bill for under G0397.

Therefore, CMS should consider revising G0396 to allow clinicians to report counseling services of 5-15 minutes (similar to G0442) and G0397 to allow clinicians to report counseling services of 15-30 minutes. The revised valuation for G0396 could be crosswalked to G0442 while G0397 should have a value similar to existing G0396. CMS should create a new add-on code to allow clinicians to report each additional 30 minutes of counseling services with a valuation mirroring existing G0397. As noted above, CMS should also consider creating new codes to allow clinicians to report psychoeducation services with more specificity. Specifically, this code could follow the time reporting thresholds for G0396 and G0397 (and the proposed add-on) such that there are three codes for reporting psychoeducation:

- GPSE1 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; 5-15 minutes, in the following activities to address the care and treatment of a patient's mental health and/or substance use disorder condition:
 - Identifying and safely managing withdrawal symptoms;
 - Recognizing when to seek emergency care;
 - Differentiating between healthy and unhealthy withdrawal management strategies;
 - Learning healthy coping skills;
 - Adhering to medications;
 - Learning etiology of illness and treatment process;
 - Life skills training;
 - Communicating effectively with prescribers; and
 - Supporting wellness through healthy diet, hydration, exercise, and sleep hygiene.
- GPSE2 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; 15-30 minutes)

GPSE3 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; each additional 30 minutes (List separately in addition to GPSE2). Should CMS create new coding for counseling and psychoeducation services, they should be added to the primary list of IOP services.

CMS also seeks feedback on whether caregiver services should be added to the list of services available to IOPs. According to *The ASAM Criteria*, caregivers comprise an informal yet crucial component of ongoing recovery support. The caregiver burden has been well-established as a serious, yet oft-overlooked health concern that results from the demands of caring for an individual with chronic illness. Additionally, caregivers often serve a particularly important role in supporting patients during withdrawal management. Education and training for caregivers is critical in:

- Monitoring for withdrawal signs and symptoms;
- Supporting medication adherence;
- Supporting adequate hydration and nutrition;
- Creating a low stimulation environment; and
- Offering encouragement and reassurance.

Hence, ASAM recommends that CMS add the following HCPCS codes describing caregiver services to the list of reportable IOP services:

- 96202 multiple -family group behavior management/modification training for parents(s) guardians(s) caregivers(s) with a mental or physical health diagnosis, administered by a physician or other QHP without the patient present, face to face up to 60 minutes.
- 96203 (each additional 15 minutes)
- 96161 administration of caregiver -focused health risk assessment instrument (that is, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- 9X015 CAREGIVER TRAINING 1ST 30 MIN
- 9X016 CAREGIVER TRAINING EA ADDL 15
- 9X017 GROUP CAREGIVER TRAINING

Furthermore, ASAM encourages CMS to consider adding one or more HCPCS codes from CPT codes 99424-99427 (principal care management services), 99437, 99439 (chronic care management services), or 99487, 99489-99491 (complex chronic care management services) to the list of allowable HCPCS codes on table 43 to allow IOP programs to bill for treatment planning, care coordination/transitions, and discharge planning services. ASAM notes that these codes may also allow clinicians to manage care transitions between and among clinicians, settings, and other levels of care.

CMS also seeks feedback on whether peer support services should be added to the list of available services reportable by IOPs. According to *The ASAM Criteria*, all programs should provide recovery support services (RSS), either directly or through formal affiliations with external service providers, tailored to the needs of each individual as determined based on an ASAM Criteria assessment, treatment planning, and appropriate to the stage of treatment. These services may be provided by allied health staff (e.g., peer support specialists, patient navigators, health educators), and may serve a variety of roles at this level of care, including providing health education, helping patients get oriented to the community and/or milieu, supporting engagement in the program, and providing or facilitating access to RSS. **Accordingly, ASAM encourages CMS to add proposed HCPCS codes GXXX3 *Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month* and GXXX4 - *Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3)* to the list of eligible HCPCS codes available for billing to IOPs.**

ASAM also recommends that CMS add proposed code GXXX5 (Social determinants of health risk assessment) to the list of HCPCS codes eligible for payment in IOPs. As noted in our comments on the Medicare Physician Fee Schedule proposed rule included Appendix A, identifying and addressing SDOH needs is an integral part of addiction treatment.

These are all services that *The ASAM Criteria* identifies as integral to a patient's treatment in all levels of care, including IOP. Therefore, ASAM recommends that CMS use the authority delegated to the HHS Secretary under 42 USC § 1395x (ff)(2)(i) to include these services under the IOP scope of benefits.

Apart from these services, CMS should also consider whether it may be appropriate to create new G codes to describe existing services described by HCPCS H codes (state Medicaid mental health/SUD codes commonly used for IOP).

Payment Rates

Currently, CMS makes payment on a per diem base to hospital-based and Community Mental Health Centers (CMHC)-based PHP programs based on those programs offering at least 3 services from an approved list of procedures per day.

CMS is proposing that beginning in 2024, to qualify for payment, PHPs and IOPs (hospital or CMHC-based) would be required to provide at least 3 services from an approved list of services to bill for a per diem. Specifically, CMS proposes to establish 4 separate codes and payment rates for PHPs and IOPs beginning in 2024. Those would be described and valued as follows:

TABLE 45: PROPOSED CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2024 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	\$97.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$153.09
5853	Partial Hospitalization (3 services per day) for CMHCs	\$97.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$153.09
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$284.00
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$368.18
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	\$284.00
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$368.18

CMS states in the proposed rule that “since IOPs furnish the same types of services as PHP, just at a lower intensity, we believe it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024.”

CMS also notes that “we believe setting the IOP payment rates equal to the PHP payments would be appropriate because IOP is a newly established benefit, and we do not have definitive data on utilization. However, both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week depending on the program. Therefore, we believe it is appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.”

CMS also provided an alternative, simplified payment methodology that it is considering implementing for PHP/IOP services that does not take into account whether the service is furnished in a CMHC or hospital:

TABLE 46: ALTERNATIVE CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

<u>Group Title</u>	<u>Alternative PHP and IOP APC Geometric Mean Per Diem Costs</u>
Partial Hospitalization (three services per day)	\$281.48
Partial Hospitalization (four services per day)	\$316.63
Intensive Outpatient (three services per day)	\$281.48
Intensive Outpatient (four services per day)	\$316.63

ASAM appreciates the recognition by CMS that IOPs and PHPs provide the same types of services at differing levels of intensity. ASAM also recognizes that the IOP benefit is new and that CMS must continue to collect data to inform its approach to setting payment rates. At the same time, ASAM acknowledges that clinicians value simplicity and minimal burden, especially when billing for new benefits.

Therefore, ASAM concurs with the CMS approach to pay for IOPs and PHPs at the same rate for the first year while CMS tailors its payment approach with additional data. However, ASAM recommends that for year two and subsequent years that CMS appropriately recognize the differing level of service intensity between IOPs and PHPs by valuing the resource costs appropriately. Additionally, ASAM recommends that as a method to incentivize uptake of the new IOP benefit and minimize clinician burden, CMS should use the alternative approach identified in table 46 of the proposed rule to pay for PHPs and IOPs beginning in 2024 for at least one year until further data collection can refine the appropriate resource costs associated with providing these services.

OTPs

CMS proposes to define OTP intensive outpatient services as those services specified in proposed 42 CFR § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of opioid use disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting.

OTP intensive outpatient services would be services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care. CMS proposes that in order to qualify as "OTP intensive outpatient services," a physician must certify that the individual has a need for such services for a minimum of 9 hours per week and requires a higher level of care intensity compared to existing OTP services.

CMS proposed to establish a new HCPCS add-code that could be billed in addition to the HCPCS code for the primary weekly bundle. The proposed code would be *GOTP1 (Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent*

authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; List separately in addition to code for primary procedure.

CMS proposes to value HCPCS code GOTP1 based on an assumption of a typical case of three IOP services furnished per day for approximately 3 days per week. CMS proposes to use a crosswalk to APC 5861 (IOP services, hospital) to value a per diem. After adjustments for the primary OTP bundle which already includes individual and family psychotherapy, the proposed valuation for this code in 2024 would be \$719.67 per week.

ASAM is appreciative of CMS' recognition that IOP service are provided across settings, via the agency's proposal to establish coverage and payment for IOP treatment in OTPs. ASAM encourages CMS to finalize this proposal.

FQHCs/RHCs

CMS proposed to maintain the same patient eligibility, physician certification, and scope of benefits related to IOP services that are provided under the IOP benefit established by the CAA, 2023.

The CAA, 2023 required that IOP services provided in FQHCs/RHCs be the same rate as if they had been covered outpatient department services furnished by a hospital. Therefore, CMS proposes that the rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs): \$284 would be the payment rate for IOP services furnished in an RHC. For IOP services furnished in FQHCs, CMS proposes that that payment is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861.

ASAM is appreciative of CMS' recognition that IOP service are provided across settings, via the agency's proposal to establish coverage and payment for IOP treatment in FQHCs and RHCs. ASAM encourages CMS to finalize this proposal.

**Appendix A: ASAM Comments to CMS on 2024
Proposed Medicare Physician Fee Schedule Rule**



OFFICERS

President
Brian Hurley, MD, MBA, FAPA, DFASAM
President-Elect
Stephen M. Taylor, MD, MPH, DFAPA, DFASAM
Vice- President
Aleksandra E. Zgierska, MD, PhD, DFASAM
Secretary
Anika Alvanzo, MD, MS, FACP, DFASAM
Treasurer
Timothy Wiegand, MD, FACMT, FAACT, DFASAM
Immediate Past-President
William F. Haning, III, MD, DLFAPA, DFASAM

BOARD OF DIRECTORS

Directors-at-Large
Alta DeRoo, MD, MBA, FACOG, DFASAM
Lori D. Karan, MD, FACP, DFASAM
Marla D. Kushner, DO, FACOFP, FAOAAM, FSAHM, DFASAM
Nicole Labor, DO, FASAM
Surita Rao, MD, FASAM
Michael F. Weaver, MD, DFASAM

REGIONAL DIRECTORS

Emily Brunner, MD, DFASAM
Megan Buresh, MD, DFASAM
Itai Danovitch, MD, MBA, FAPA, DFASAM
Keyghobad Farid Araki, MD, FRCPC, ABAM, FASAM
Teresa Jackson, MD, DFASAM
Christina E. Jones, MD
Audrey M. Kern, MD, DFASAM
James P. Murphy, MD, DFASAM
Kelly S. Ramsey, MD, MPH, MA, FACP, DFASAM
Shawn Ryan, MD, MBA, DFASAM

EX-OFFICIO

Nicholas Athanasiou, MD, MBA, DFASAM
Julia L. Chang, MS, MBA
Michael Fingerhood, MD, FACP, DFASAM
Kenneth I. Freedman, MD, MS, MBA, FACP, AGAF, DFASAM
Margaret A. E. Jarvis, MD, DFASAM
Cara A. Poland, MD, MEd, FACP, DFASAM

FOUNDING PRESIDENT

Ruth Fox, MD
1895-1989

September 8, 2023

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

**Re: ASAM's Comments on 2024 Medicare Physician Fee
Schedule Proposed Rule**

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) 2024.

The proposals set forth in this proposed rule appear to set an important benchmark in the provision of care for people with substance use disorders (SUDs). As people across the United States continue to experience the crushing toll of the addiction and overdose crisis through the loss of family members, friends, and loved ones, ASAM welcomes the proposals in this rule which address numerous payment and coverage barriers, provider participation in the Medicare program, and critical shortages of mental health (MH) professionals, including SUD professionals.

ASAM also welcomes new coding and payment for services to identify and address social determinants of health (SDOH) needs of patients. Research has shown that SDOH are drivers of healthcare outcomes and the proposals in this rule are noteworthy and laudable. Finally, ASAM hopes that the comments offered below in the request for information on behavioral health will assist CMS in closing additional coverage gaps in the Medicare program.

In the comments detailed below, ASAM recommends that CMS:

- **Appropriately define and value, and provide information on the appropriate use of, G2211 (visit complexity);**
- **Finalize the proposed adjustments for timed behavioral health services;**
- **Finalize the proposal to reflect a greater intensity of psychotherapy service delivery for patients receiving treatment for a SUD through office-based care;**
- **Establish coverage and payment for intensive SUD outpatient treatment services using HCPCS G code(s) under the existing office-based SUD treatment billing code set (G2086-G2088);**
- **Explicitly codify the inclusion of Addiction Counselors who meet all the applicable requirements of a Mental Health Counselor to enroll in Medicare and bill for services;**
- **Finalize the proposed code descriptors and valuation for HCPCS code GXXX5 (social determinants risk assessment), with the modifications described below;**
- **Finalize the coding descriptors and valuation for proposed HCPCS codes GXXX1 and GXXX2 (community health integration services), with the modification described below;**
- **Finalize the proposed coding descriptors and valuation for HCPCS codes GXXX3 and GXXX4 (principal illness navigation services), with the modifications described below; Finalize the proposal to extend the audio-only flexibilities for periodic assessments in opioid treatment programs (OTPs);**
- **Finalize proposal to revise the reimbursement rate for behavioral health integration (BHI) services (CPT code 99484 and HCPCS code G0323) to more accurately value the work involved in the delivery of these services.**
- **Consider new coding to allow clinicians to report psychoeducation services with more specificity;**
- **Consider revisions to HCPCS codes for reporting counseling for substance use services;**
- **Use the terms “mental health” and “substance use disorder” rather than “behavioral health” in Medicare regulations;**
- **Support data integration from digital therapeutics into electronic health records with new billing codes or other meaningful incentives;**
- **Avail digital therapeutic services for billing for multiple conditions by multiple practitioners at shorter intervals to support patient care for conditions such as SUD;**
- **Establish more granular coding that appropriately recognizes the range of digital therapeutic treatment options, as well as the resources involved in furnishing them;**
- **Give appropriate attention to patient privacy protections and the need for important guardrails to ensure that clinicians providing digital therapeutics are acting in accordance with federal regulatory standards; and**
- **Consider regulatory flexibilities, as well as forthcoming clinical practice guidelines regarding the use of contingency management in conjunction with other therapies such as cognitive behavioral therapy (CBT) in the use of digital therapeutics.**

ASAM looks forward to continued collaboration with CMS to address the challenges of the addiction and overdose crisis 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,

Brian Hurley, MD

Brian Hurley, MD, MBA, FAPA, DFASAM
President, American Society of Addiction Medicine

Detailed Comments

Visit complexity inherent to evaluation and management (G2211)

CMS is proposing to implement the add-on code (G2211) designed to better recognize the resource costs associated with evaluation and management (E/M) visits for primary care and longitudinal care of complex patients. CMS proposes that this code would be used in outpatient office visits, recognizing the inherent costs practitioners may incur when longitudinally treating a patient's single, serious, or complex chronic condition.

While ASAM supports CMS' proposal to implement G2211, in 2024, ASAM also directs CMS to comments from the AMA RUC, which has previously outlined various concerns with CMS regarding implementing this code. Namely, ASAM would like to see CMS provide additional clarity surrounding the purpose, use, and reporting of this code in light of existing care management, collaborative, coordination, and add-on codes. We encourage CMS to define and value, appropriately, and provide information on the appropriate use of, this proposed code.

Adjustments to Payment for Timed Behavioral Health Services

CMS is proposing to adjust the work RVUs for the following services over a four-year transition period as part of the agency's effort to address distortions that may occur within the valuation process that may otherwise result in understated estimates of the relative resources involved in furnishing psychotherapy services. The work RVUs will be adjusted for psychotherapy CPT codes 90832, 90834, 90837, 90839, 90840, 90845, 90846, 90847, 90849, 90853, and HCPCS codes GPFC1 and GPFC2 (Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting)).

CMS proposes to adjust the work RVUs for these services by calculating the difference between the total RVUs for evaluation and management office visits (99202-99205 & 99211-99215) billed with the visit complexity code (G2211) and E/M office visits billed without the visit complexity code.

Psychotherapy is a vital component of treatment for a SUD. However, as recognized by CMS, there are inherent resource costs associated with providing psychotherapy that is not valued by the existing practice expense costs associated with these codes. **ASAM applauds CMS' proposal to value these important codes more appropriately, which represents a step in the right direction, and we encourage CMS to finalize this proposal.**

Updates to the Payment Rate for the PFS SUD bundle (HCPCS codes G2086-G2088)

In the FY 2023 MPFS, CMS finalized a change to the payment rate for the non-drug component of the bundled payment for episodes of care under the office-based treatment benefit to base the rate for individual therapy on a crosswalk to CPT code 90834 (Psychotherapy, 45 minutes with patient), which reflects a 45-minute psychotherapy session, instead of a crosswalk to CPT code 90832 (Psychotherapy, 30 minutes with patient), as was the policy at the time.

CMS notes in the proposed rule that they are persuaded by comments in previous rulemaking that noted that patients who are prescribed buprenorphine in non-OTP settings will have

similarly complex care needs requiring more intensive therapeutic care, and that CMS should recognize the appropriate complexity and intensity of the services in those settings.

In response, CMS is proposing to increase the payment made for HCPCS codes G2086 (Office-based treatment for a SUD, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month) and G2087 (Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month) to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (Psychotherapy, 45 minutes with patient), rather than CPT code 90832 (Psychotherapy, 30 minutes with patient).

ASAM strongly supports this revision to reflect a greater intensity of service delivery for patients receiving treatment for a substance use disorder through office-based care and encourages CMS to finalize this proposal.

General Behavioral Health Integration Care Management

ASAM supports CMS' proposal to revise the reimbursement rate for BHI services (CPT code 99484 and HCPCS code G0323) to more accurately value the work involved in the delivery of these services. Research demonstrates that the integration of MH and SUD treatment with medical care improves health outcomes, improves patient and provider experiences, and is cost effective. Integrated care also helps to address MH and SUD treatment barriers that disproportionately affect Black and brown individuals, rural communities, and people with lower incomes. Thus, increasing the reimbursement rate for BHI services will make progress towards CMS's dual goals of improving access to MH and SUD care and advancing health equity.

Coverage of Marriage and Family Therapists and Mental Health Counselors

ASAM supports CMS' proposal to create new regulations to define marriage and family therapists (MFTs) and mental health counselors (MHCs), and to specify the services these practitioners can provide. We also support CMS' proposals to add these providers to the list of practitioners eligible to provide BHI services, order diagnostic tests, deliver Medicare telehealth services, and be subjected to limited-risk screening.

ASAM strongly supports CMS' proposal to allow Addiction Counselors who meet all the applicable requirements of a MHC to enroll in Medicare as MHCs and bill Medicare for MHC services. However, ASAM urges CMS to explicitly codify this inclusion at § 410.54 to ensure that these providers and Medicare beneficiaries are aware of such coverage. As CMS has previously noted in its proposed Medicaid Managed Care Access Rule when amending its regulations to specify MH and SUD instead of behavioral health, "It is important to use clear, unambiguous terms in regulatory text." As such, we believe it is necessary to include "addiction counselor or alcohol and drug counselor" at §§ 410.54(a)(1) and (3); "addiction counseling" at § 410.54(a)(2); and "substance use disorders" at § 410.54(b)(1).

Behavioral Health Request for Information

Intensive Outpatient Services

In comments offered to CMS last year on the 2023 proposed MPFS rule, ASAM commended CMS for examining whether the current coding and payment mechanisms under the PFS adequately accounted for IOP and other services that are part of the SUD continuum of care. In response to Congressional action and years of advocacy by patients and advocates alike, ASAM is extremely pleased to see that the SUD care continuum continues to expand, now with the implementation of coverage and payment for IOP services provided in certain settings.

Although ASAM is encouraged by this expansion, we note that while these services may be offered in defined settings that meet state licensure and standards, IOP services for the treatment of SUDs are most often provided in free-standing addiction specialty settings that are not covered Medicare providers. Even with the latest Congressional action, IOP care as outlined in separate rulemaking will only be covered by Medicare when provided by a community mental health center (CMHC), a hospital outpatient department, a federally-qualified health centers (FQHC), a rural health center (RHC), or an OTP (and in an OTP, with respect to opioid use disorder treatment services only). This means a tremendous, continued coverage gap for intensive SUD outpatient treatment services that still will not be covered under this expansion.

Hence, ASAM encourages CMS to help remedy this gap by establishing coverage and payment for intensive SUD outpatient treatment services not covered by the treatment expansion authorized under the Consolidated Appropriations Act, 2023.

Notably, Title 42 U.S. Code § 1395k (a)(2)(B) authorizes Medicare Part B coverage of “medical and other health services.” Title 42 U.S. Code § 1395x (s)(1) defines “medical and other health services” as including “physician services,” and Title 42 U.S. Code § 1395x (s)(2)(K) and (L) define “medical and other health services” to also include qualifying services by a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Accordingly, ASAM encourages CMS to use the IOP framework proposed under its separate hospital Outpatient Prospective Payment Systems (OPPS) rulemaking to establish Medicare payment and coverage under the Medicare Physician Fee Schedule for IOP services certified by a physician and coordinated by a physician or non-physician practitioner which are not covered under the Consolidated Appropriations Act, 2023 (collectively, “Intensive SUD Outpatient Treatment Services”), i.e., exclusive of IOP coverage proposed for CMHCs, hospital outpatient departments, FQHCs, RHCs, and OTPs. Specifically, CMS should:

- **Similar to requirements proposed under separate OPPS rulemaking, require physician attestation that a patient needs IOP services;**
- **Define Intensive SUD Outpatient Treatment Services provided under the MPFS as those services described by proposed § 410.2 that are a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44;**
- **Establish a scope of benefits for Intensive SUD Outpatient Treatment Services provided under the MPFS that is analogous to the benefits described under proposed § 410.44(a)(4));**
- **Include additional services with Intensive SUD Outpatient Treatment Services as identified by ASAM below;**

- Establish coding for Intensive SUD Outpatient Treatment Services using an add-on HCPCS G code(s) under the existing office-based SUD treatment billing code set (G2086-G2088) that physicians and non-physician practitioners may bill for Intensive SUD Outpatient Treatment Services delivered to a patient following a physician certification that a patient needs Intensive SUD Outpatient Treatment Services;
- Establish bundled payment for Intensive SUD Outpatient Treatment Services under the existing office-based substance use disorder treatment billing code set (G2086-G2088) using a crosswalk to proposed *GOTP1 (Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; List separately in addition to code for primary procedure.*

Additionally, ASAM notes that state laws and regulations may separately define the scopes of practice for mental health and SUD treatment professionals. Thus, ASAM recommends that should CMS establish this benefit, that the agency also clarify that SUD treatment professionals are included in the scope of benefits listed above.

In addition to the areas noted above, CMS should also:

- Ensure that the physician certification process provides a mechanism for physicians to attest that the billing physician or non-physician practitioner has the capability of appropriately referring or providing necessary biomedical and psychiatric care, including, but not limited to:
 - physical examinations;
 - withdrawal management;
 - medical assessments;
 - medications for the treatment of SUD;
 - medications for the treatment of other mental health diagnoses;
 - other prescribed medications, including those that are obtained from a specialty pharmacy;
 - medication management services;
 - laboratory testing; and
 - toxicology services.
- Ensure that physicians and non-physician practitioners coordinating Intensive SUD Outpatient Treatment Services are able to bill for this level of care; assessments/reassessments, as indicated by The ASAM Criteria;
- Allow them also to report time spent on activities such as verifying that a patient has had a physical examination conducted by a physician or advanced practice practitioner within the past year; and
- Allow them also to bill for treatment planning, care coordination/transitions, and discharge planning services

In comments provided to CMS regarding the hospital OPPS proposed rule, ASAM encourages CMS to add a number of services to the list of eligible services available for billing within IOP programs. Should CMS add those services to the list of eligible services, ASAM assumes that this may change the proposed payment rate for IOPs billing in OTPs given the proposed method of calculating payment for IOP services in OTPs. **Therefore, ASAM strongly encourages CMS to crosswalk any payment for Intensive SUD Outpatient Treatment Services with the finalized payment for GOTP1, accounting for any adjustments made in response to feedback from stakeholders.** Given that some of the services that ASAM encourages to be added to the benefit would be eligible for separate billing outside of the **Intensive SUD Outpatient Treatment Service** billing under the MPFS, ASAM would expect that physicians and non-physician practitioners coordinating Intensive SUD Outpatient Treatment Services **and their** billing under the MPFS would not be able to bill for those services concurrently with any claims for an IOP service under the OPSS.

ASAM directs CMS to Appendix A where we have included our comments on the proposed 2024 OPSS rule for further information.

Additional Coding for Psychoeducation and Substance Use Counseling Services

The ASAM Criteria outlines the importance of psychoeducation, along with psychotherapy and counseling services in the care of patients with a SUD. According to *The ASAM Criteria*, psychoeducation includes interventions with systematic, structured, and didactic knowledge transfer for an illness and its treatment, integrating emotional and motivational aspects to enable patients to cope with their illness(es) and improve treatment adherence and efficacy. Counseling is defined as professional assistance in coping with SUD and co occurring conditions using techniques such as active listening, guidance, discussion, and clarification. Counseling and psychoeducation should be provided by appropriately trained and supervised professionals acting within their state-regulated scopes of practice for the given service or, when appropriate, via evidence-based digital therapeutics.

While existing coding theoretically allows these services to be reported under the MPFS, there is a need for more granular coding to report the provision of these services. Existing coding does not appropriately capture the resource intensity and specificity of the provision of psychoeducation and counseling services.

For example, CMS recently revised HCPCS codes G0442 (Annual alcohol misuse screening, 5 to 15 minutes) and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) to allow clinicians to report a lower time threshold for providing these services. Similarly, clinicians may provide less than 15 minutes and more than 30 minutes of counseling services per day to patients. Yet, G0396 (which is often used to report counseling services) does not provide the flexibility for reporting lower time thresholds (less than 15 minutes). Additionally, while clinicians can report counseling provided for more than 30 minutes, the resources involved in providing 60 minutes of counseling are much greater than what clinicians can currently bill for under G0397.

Therefore, CMS should consider revising G0396 to allow clinicians to report counseling services of 5-15 minutes (similar to G0442) and G0397 to allow clinicians to report counseling services of 15-30 minutes. The revised valuation for G0396 could be crosswalked to G0442 while G0397 should have a value similar to existing G0396. **CMS should create a new add-on code to allow**

clinicians to report each additional 30 minutes of counseling services with a valuation mirroring existing G0397.

Additionally, CMS should consider creating new codes to allow clinicians to report psychoeducation services with more specificity. Specifically, this code could follow the time reporting thresholds for G0396 and G0397 (and the proposed add-on) such that there are three codes for reporting psychoeducation:

- GPSE1 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; 5-15 minutes, in the following activities to address the care and treatment of a patient's mental health and/or substance use disorder condition:
 - Identifying and safely managing withdrawal symptoms;
 - Recognizing when to seek emergency care;
 - Differentiating between healthy and unhealthy withdrawal management strategies;
 - Learning healthy coping skills;
 - Adhering to medications;
 - Communicating effectively with prescribers; and
 - Supporting wellness through healthy diet, hydration, exercise, and sleep hygiene.
- GPSE2 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; 15-30 minutes)
- GPSE3 (Psychoeducation services performed by certified or trained auxiliary personnel, under the direction of a physician or other practitioner; each additional 30 minutes (List separately in addition to GPSE2).

Apart from these services, CMS should also consider whether it may be appropriate to create new G codes to describe existing services described by HCPCS H codes (state Medicaid mental health/SUD codes commonly used for IOPs).

Use the terms “mental health” and “substance use disorder” rather than “behavioral health.”

In its recently proposed Medicaid Managed Care Access Rule (CMS-2439-P), CMS stated that, while it uses “behavioral health” to mean MH and SUD, “it is an imprecise term that does not fully capture the full array of conditions that are intended to be included...It is important to use clear, unambiguous terms in regulatory text.” Accordingly, CMS changed “behavioral health” throughout its regulations to clarify when it meant MH and SUD. **For consistency across federal programs, and for much needed clarity for Medicare providers and beneficiaries, ASAM urges CMS to make similar changes throughout the Medicare regulations.**

Digital Therapies

ASAM is encouraged by CMS' focus on potential coverage and reimbursement for digital therapeutics. It is imperative, however, that CMS build a reimbursement model that supports the involvement of physicians and other practitioners in patient care and is designed not just for the current landscape of digital therapeutics but one that will also serve future developments. As CMS considers these issues for rulemaking, it is important to foster innovation that recognizes universal standards, supports a continuum of evidence of effectiveness, avoids unintended consequences, coordinates policy objectives across federal agencies, and establishes appropriate

reimbursement models from the outset that recognize the importance of a clinician's involvement in patient care.

According to the Digital Therapeutics Alliance (DTA), "digital therapeutics deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes."¹ Additionally, there is some evidence (based on FDA-approvals) that some digital therapeutics for SUD treatment are safe, cost-effective, and can improve treatment engagement.

While ASAM does not have a formal definition of digital therapeutics, conversations with our physician members revealed that these therapeutics can be especially helpful for patients who:

- May have difficulty accessing traditional behavioral health treatment;
- Have impediments to accessing treatment due to geographic limitations;
- Value taking an active role in their care;
- Are seeking therapies as adjuncts to other, currently available care; or
- Are looking for therapeutics options that allow for personalization, are cost-effective, and improves patient engagement.

At the most basic level, ASAM members emphasized that patients should be enrolled in/engaged in SUD treatment, open to cognitive behavioral therapy, have access to a mobile device, and have access to the internet/wireless connection for uploading information to/receiving information from their clinicians. Many patients may also have medication needs that have an active role in the course of their behavioral therapy and should be taken into account.

At the clinician level, ASAM members emphasized that practitioners using digital therapeutics should be appropriately-licensed according to the state laws where they practice (and the patient resides), the clinician should have access to a computer for reading patient dashboards, and be able to provide SUD treatment with evidence-based modalities such as cognitive behavioral therapy (CBT) or contingency management. Most importantly, **ASAM members noted that it is important that clinicians and healthcare ecosystems alike understand that digital therapeutics are not intended to substitute for traditional patient/clinician encounters.**

Apart from the issues with appropriately defining digital therapeutics and their suitability for patients, ASAM members emphasized the absence of a defined Medicare benefit category, patient awareness, and electronic health record (EHR) integration as the primary drivers of slow uptake of digital therapies. **Should CMS define a benefit category for digital therapeutics, CMS should support data integration into EHRs with new billing codes or other meaningful incentives.**

Additionally, ASAM members noted that the current guidance for billing remote therapeutic monitoring (RTM) services does not appropriately support digital therapeutic monitoring services for patients with a SUD. Notably, patients with SUD may see one clinician to treat their SUD while they may see a separate clinician for the remainder of their biomedical care. Additionally, existing coding guidance requires that only one clinician be eligible to bill for these services once 16 days of data have been collected. ASAM members noted that while remote monitoring services may ideally begin several times per week for patients with a SUD, patients may require

less frequency over successive weeks or months to only a few times per month. Therefore, in service of promoting health equity and improving patient care and outcomes, **ASAM encourages CMS to make these services available for billing for multiple conditions by multiple practitioners at shorter intervals to support patient care for conditions such as SUD.** While generic coding may be beneficial in the interim, **ASAM supports the establishment of more granular coding that appropriately recognizes the range of digital therapeutic treatment options, as well as the resources involved in furnishing them.**

Furthermore, due to the legal and social ramifications associated with addiction, patients are often reluctant to tell their clinician that they may have addiction or consent to the disclosure of information about their addiction treatment. This is an unfortunate aspect of the stigma and discrimination that surrounds this disease, and it exacerbates the addiction treatment gap that exists in this country.

To address this issue, federal regulations at 42 CFR Part 2 protect the confidentiality of addiction treatment records of any person who has sought treatment for or been diagnosed with addiction at a federally assisted program. 42 CFR Part 2 aims to encourage people to seek treatment without fear of legal or social consequences. Improper sharing of a patient's addiction treatment information can lead to: negative perceptions and discrimination; criminal legal consequences, such as probation or jail time; and civil legal consequences, such as loss of child custody, employment or housing.

ASAM appreciates the heightened need for confidentiality protections of a patient's addiction treatment records as well as the need for complete and accurate medical information to be shared among a patient's treating clinicians. **Furthermore, as CMS considers further rulemaking on digital therapeutics, appropriate attention should be should be given to patient privacy protections and the need for important guardrails to ensure that clinicians providing these services are acting in accordance with federal regulatory standards.**

Finally, ASAM notes that while cognitive behavioral therapy (CBT) is an evidence-based psychosocial intervention that seeks to modify harmful beliefs and maladaptive behaviors, and help patients recognize, avoid, and cope with the situations in which they are most likely to misuse substances, there are other treatment methods for SUDs that involve the use of CBT in conjunction with other types of treatment modalities such as contingency management - an evidence-based psychosocial intervention in which patients are given tangible rewards to reinforce positive behaviors such as treatment participation or abstinence (also referred to as motivational incentives). As CMS works to address existing coverage barriers for digital therapeutics, **ASAM encourages CMS to consider regulatory flexibilities, as well as forthcoming clinical practice guidelines² regarding the use of contingency management in conjunction with other therapies such as CBT.** It is important that all evidence-based modalities for the treatment of SUD be appropriately covered, particularly as overdose deaths involving stimulant drugs (including cocaine, methamphetamine, amphetamine, and prescription stimulants) have been rising precipitously over the past decade and were 50% of all overdose deaths in the United States in 2021.³

ASAM looks forward to reviewing any future CMS rulemaking on this subject.

Social Determinants of Health (SDOH)

CMS is proposing to create a new G code described by GXXX5, *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months.*

CMS proposes that a SDOH risk assessment be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. Required elements would include the administration of a standardized, evidence-based SDOH risk assessment tool ⁴ that has been tested and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties.

SDOH are increasingly recognized as factors that can have a profound effect on an individual's ability to engage in addiction treatment, adhere to a care plan, and maintain recovery. Individuals experiencing substance use disorders are frequently marginalized; they may experience multiple health disparities and inequities that include but are not limited to stigma and discrimination, difficulties with housing and transportation, legal involvement, and comorbid biomedical conditions. Such disparity and inequity may influence a person's ability to participate in treatment at the recommended level of care. Research demonstrates that addressing SDOH leads to better health outcomes and, thus, also influences addiction treatment and recovery outcomes.

Comprehensive wraparound services that address SDOH play an integral role in an individual's ability to achieve long-term recovery. Supporting holistic, individualized treatment for SUD requires clinicians to have a tangible understanding of the relationship between SDOH and addiction treatment and recovery, as well as services and/or support that address and mitigate potential impacts of each individual patient's SDOH.

ASAM encourages CMS to finalize the code descriptor and valuation for GXXX5. ASAM also recommends that this code only be reportable for auxiliary personell (under the general supervision of the billing practitioner) who have the capacity to furnish community health integration (CHI), principal illness navigation (PIN), or other care management services, or have partnerships with community-based organizations (CBOs) to address identified SDOH needs. Identifying these needs without the appropriate capacity to refer or address them is couterintuitive to the health and wellbeing of patients.

Community Health Integration Services

CMS is proposing two new HCPCS codes to describe CHI services. Specifically, these services would be performed by certified or trained auxiliary personnel, which may include a Community Health Worker (CHW), incident to the professional services and under the general supervision of the billing practitioner eligible to bill Medicare. CMS is proposing that CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit. Auxiliary personnel who provide CHI services must be certified or trained to perform all included service elements, and authorized to perform them under applicable state laws and regulations. In states where there are no applicable licensure or other laws or regulations relating to providing CHI services, auxiliary personnel must be trained to provide them.

The specific code descriptors are:

GXXX1 Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*
 - *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*
 - *Facilitating patient-driven goal-setting and establishing an action plan.*
 - *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*
- *Practitioner, Home-, and Community-Based Care Coordination*
 - *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*
 - *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*
 - *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*
 - *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).*
- *Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*
- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*
- *Health care access / health system navigation*
 - *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*
- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*

- *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2 – *Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).*

As noted above, ASAM agrees that identifying SDOH needs is an important component of addiction treatment. CMS' proposal to establish coding and payment for addressing those SDOH needs through CHI services is an important milestone in this effort. **ASAM encourages CMS to finalize the code descriptors and valuations for GXXX1 and GXXX2. ASAM believes that many of the activities described by these codes can be provided via telehealth, and we encourage CMS to make these codes available for billing via telehealth.**

Principal Illness Navigation Services

CMS is proposing to create two new G codes described by GXXX3 (*Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:*

- *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*
 - *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*
 - *Facilitating patient-driven goal setting and establishing an action plan.*
 - *Providing tailored support as needed to accomplish the practitioner's treatment plan.*
- *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*
- *Practitioner, Home, and Community-Based Care Coordination*
 - *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).*
 - *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*
 - *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*
 - *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*
- *Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*
- *Health care access / health system navigation.*
 - *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.*
 - *Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.*
- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*
- *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*
- *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.)*

and –

GXXX4 – Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

CMS proposed that the valuation for GXXX3 would be directly cross-walked to CPT code 99490 (Chronic care management services, first 20 mins of clinical staff time directed by a physician or other qualified health care professional, per calendar month) and the valuation for GXXX4 would be directly cross-walked to CPT code 99439 (Chronic care management service; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month).

CMS proposes that PIN services could be furnished following an initiating E/M visit addressing a serious high-risk condition/illness/disease, with the following characteristics:

- One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death; and
- The condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver.

Similar to the proposal for CHI services, CMS proposes that in order to bill for PIN services, there must first be an E/M initiating visit in which the billing practitioner would identify the medical necessity of PIN services and establish an appropriate treatment plan. The subsequent PIN services would be performed by auxiliary personnel incident to the professional services of the practitioner who bills the PIN initiating visit under the general supervision of the billing practitioner. Auxiliary personnel who provide PIN services must be certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations. In states where there are no applicable licensure or other laws or

regulations relating to providing PIN services, auxiliary personnel must be trained to provide them.

CMS is seeking comment on whether the agency should consider any professional services other than an E/M visit performed by the billing practitioner as the prerequisite for the initiating visit for PIN services.

ASAM believes that PIN services described by these codes for patients with SUD are often provided by addiction counselors without a master's degree⁵. Thus, ASAM requests that CMS explicitly list such addiction counselors (i.e., in addition to patient navigators or certified peer specialists) as auxiliary personnel who can provide PIN services (that is, if certified or trained to perform all included service elements and authorized to perform them under applicable State laws and regulations, and in states where there are no applicable licensure or other laws or regulations relating to providing PIN services, trained to provide them).

ASAM believes that many of the activities described by these codes can be provided via telehealth, and we encourage CMS to make these codes available for billing via telehealth. Additionally, ASAM encourages CMS to allow OTP visit codes, BHI services, and patient visits described under the office-based treatment of substance use disorder code set to serve as initiating visits.

CMS is also seeking public comment on the number of hours of training to require, as well as the training content. **ASAM refers CMS to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Model Standards for Peer Support Certification⁶ which recommends 40-60 hours of training as well as a number of core training elements, as well as The International Certification and Reciprocity Consortium (IC&RC) which has adopted a new credential using SAMHSA's standards.⁷**

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

CMS is proposing to extend the audio-only flexibilities for periodic assessments (HCPCS code G2077) furnished by OTPs through the end of CY 2024, consistent with flexibilities allowed under the CAA, 2023. Under this proposal, CMS proposes to allow periodic assessments to be furnished via audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished and all other applicable requirements are met.

As ASAM has emphasized in years past, we support this proposal and encourage CMS to finalize it.

¹ DTA. (2023). Digital Therapeutics Definition and Core Principles. Digital Therapeutics Alliance.

<https://dtxalliance.org/understanding-dtx/>

² ASAM. (2023). DRAFT Clinical Practice Guideline on the Management of Stimulant Use Disorder. ASAM - American Society of Addiction Medicine. <https://www.asam.org/quality-care/clinical-guidelines/stimulant-use-disorders>

³ Centers for Disease Control and Prevention. Multiple Cause of Death Data on CDC 2 WONDER. Accessed August 25, 2023. <https://wonder.cdc.gov/mcd.html>

⁴ CMS should consider the addition of The ASAM Criteria® Assessment Interview Guide to the list of eligible tools. ASAM. (2023). The ASAM Criteria® Assessment Interview Guide. ASAM - American Society of Addiction Medicine. <https://www.asam.org/asam-criteria/criteria-intake-assessment-form>

⁵ NAADAC, the Association for Addiction Professionals, SAMHSA-NAADAC Addiction Professional Education & Career Ladder. https://www.naadac.org/assets/2416/samhsa-naadac_career_education_ladder_03-2018.pdf

⁶ Substance Abuse and Mental Health Services Administration, National Model Standards for Peer Support Certification. Publication No. PEP23-10-01-001. Rockville, MD: Office of Recovery, Substance Abuse and Mental Health Services Administration, 2023.

⁷ The International Certification and Reciprocity Consortium (IC&RC). (2023 June 23). IC&RC Adopts SAMHSA Model Standards for Peers [Press release]. [Peer Press Release 06.25.23.pdf \(internationalcredentialing.org\)](#)