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September 6, 2024

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 2025 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) 2025.

ASAM appreciates the work that CMS has initiated to improve the substance use disorder (SUD) treatment continuum. While the proposals set forth in this rulemaking undoubtedly continue to set important standards for health insurance coverage across payers, there are still glaring coverage gaps in the treatment continuum, such as non-coverage of residential treatment (ASAM Level 3.0), that continue to limit access to care. Nevertheless, ASAM welcomes many of the proposals set forth in this proposed rule and offers the comments below to assist CMS as it finalizes rules for the CY 2025 payment year.

In our comments detailed below, ASAM recommends that CMS:

- Provide clarification on whether digital mental health treatment codes as proposed allow use for treatment of SUD (including addiction medications);
- Avail new billing codes or other incentives to support data integration from digital therapeutics into electronic health records (EHRs);

- Give appropriate attention to patient privacy protections in the context of digital therapeutics;
- Establish coverage of intensive outpatient (IOP), high-intensity outpatient (HIOP), formerly known as partial hospitalization in *The ASAM Criteria* (ASAM Levels 2.1, and 2.5) in standalone settings that are not covered by Medicare;
- Cover and pay for medical services furnished by medically managed intensive outpatient programs separately;
- Establish coding for IOP/HIOP services under the physician fee schedule that appropriately compensates medical and clinical services, minimizes cost-sharing for patients, and serves as a replicable model for other private and public insurers;
- Ensure that IOP and HIOP services in standalone settings are consistent with *The ASAM Criteria* and that CMS ensures payment that is commensurate with rates for the same services provided in hospital outpatient departments;
- Extend general supervision to IOP, HIOP, and medically managed intensive outpatient services provided in standalone settings to facilitate billing and allow supervision to be provided via real-time audio/video technology;
- Finalize proposals related to coverage and payment of opioid treatment program (OTP) services;
- Revise, then finalize, code descriptors and payment for safety planning interventions and allow this service to be provided by trained clinical staff, working under a licensed practitioner's supervision;
- Finalize coding and payment for post-discharge follow-up services; and
- Finalize coding and payment for interprofessional consultation services and require beneficiary consent to receive services given possibility of duplicate patient cost-sharing.

ASAM appreciates the diligence of the CMS's response to the ever-evolving nature of the addiction and overdose crisis. We look forward to continuing to work with the agency to address these issues. If you have any questions or need further clarification, please do not hesitate to contact Corey Barton, Director, Advocacy at cbarton@asam.org.

Sincerely,

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

Digital mental health treatment

CMS is proposing three new HCPCS codes to describe and report digital mental health treatment devices cleared by the Food and Drug Administration (FDA). Specifically, CMS is proposing the following codes for use by clinicians authorized to furnish services for the diagnosis and treatment of mental illness:

- *GMBT1 (Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan) – billable only if the device is FDA-cleared and the billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary;*
- *GMBT2 (First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month); and*
- *GMBT3 (Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month).*

GMBT1 would be priced based on carrier pricing. GMBT2 would be priced based on a crosswalk to CPT code 98980 (remote therapeutic monitoring first 20 minutes), and GMBT3 would be priced based on a crosswalk to CPT code 98981 (remote therapeutic monitoring each additional 20 minutes). If finalized under the proposed conversion factor, then the national payment rate for GMBT2 would be approximately $51.78, and the national payment rate for GMBT3 would be approximately $39.80.

ASAM welcomes the addition of new codes that will allow clinicians to report services for digital therapeutics. Although the valuations for these proposed codes seem appropriate, ASAM is concerned that the codes as proposed may inadvertently exclude devices cleared by the FDA to treat SUD or lead to confusion about whether these codes may used for devices that have been cleared by the FDA to treat SUD. In the past, CMS has explictly noted when the definition of mental health also includes SUD. However, CMS made no such note in these proposed rules.

CMS cites 21 CFR § 882.5801 which details "computerized behavioral therapy device for psychiatric disorders" that is identified as "a computerized behavioral therapy device for *psychiatric disorders* is a prescription only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric condition." While it may be implied that the term psychiatric disorder/psychiatric condition includes SUD, ASAM notes that these terms are not always inclusive of SUD. **Therefore, ASAM recommends that CMS revise these code descriptors or provide substantive clarification that these codes may also be used for devices that have been cleared by the FDA to treat SUD (including addiction medications). Additionally, ASAM recommends that CMS use the terminology Digital Behavioral Health Treatment (DBHT)**

instead of Digital Mental Health Treatment (DMHT). Furthermore, CMS should support data integration into electronic health records (EHRs) with new billing codes or other meaningful incentives. As CMS considers further rulemaking on digtal therapeutics, appropriate attention 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 privacy standards.

Finally, ASAM recommends that CMS allow billing for other medical devices that have been cleared by the FDA under separate regulatory channels for use as a part of a behavioral health therapy plan.

IOP and HIOP

Following CMS' regulatory changes this year to permit coverage of intensive outpatient (IOP) services in covered settings, ASAM welcomes the request for information (RFI) regarding coverage of these services in standalone facilities that are not covered by Medicare. While ASAM is disappointed that CMS did not take the opportunity to propose coverage and payment for IOP services in standalone settings for the CY 2025 MPFS, we are encouraged by the RFI on IOP services in standalone settings. Covering the entire continuum of addiction treatment by all payers is vital to ensure that patients are able to get the appropriate level of addiction treatment they need, regardless of the type of health insurance they have. **Therefore, ASAM strongly recommends that CMS use its regulatory authority in CY 2026 rulemaking to propose coverage of IOP/HIOP services (ASAM Levels 2.1, and 2.5) in standalone settings that are not covered by Medicare. ASAM further recommends that these services be consistent with *The ASAM Criteria* and that CMS ensures payment that is commensurate with rates for the same services provided in hospital outpatient departments to incentivize uptake of these services and expand access to care.**

IOP/HIOP/Medically Managed Intensive Outpatient Programs Defined

IOP/HIOP/Medically Managed Intensive Outpatient programs are not a monolith, and there are differences between ASAM Levels 2.1, 2.5, and 2.7 in the staffing, clinical services, and time spent providing clinical services. The key differences are that ASAM Level 2.1 programs typically do not have a medical director, while Levels 2.5 and 2.7 do. Further, the medical director of a Level 2.7 program should be a physcian. Additionally, Level 2.1 provides 9-19 hours of clinical services, while Levels 2.5 and 2.7 offer 20 or more hours of clinical services per week. Clinical services provided in Levels 2.1 and 2.5 usually consist of counseling, psychoeducaiton, and psychotherapy, while Level 2.7 provides these services plus biomedical services for people experiencing intoxication, withdrawal, and/or psychiatric complications.

Regulatory Challenges Unique to Level 2.1 Programs

Given the differences between the discrete levels of care in ASAM Level 2 as noted above, establishing payment and coverage for these services under the MPFS requires an approach that recognizes the different resource costs associated with each level of care. At the same time, existing federal rules regarding who may bill Medicare for services are incompatible with elements of IOP care that have been established in other rulemaking, as well as the structure of these programs themselves. To illustrate this complexity, Medicare currently requires a physcian to certify that a patient meets the requirements to enroll in IOP care provided in community mental health centers (CMHCs), hospital outpatient departments, and federally qualified health centers (FQHCs) per statute. CMS extends this requirement to OTPs to promote consistency across programs, which is not a barrier given that OTPs provide medically managed care under *The ASAM Criteria* and are already required to have a physician serve as medical director per federal treatment standards.

However, as noted above, Level 2.1 SUD programs do not typically have a medical director. Thus, although ASAM understands CMS's desire to promote consistency across its programs, extending the physician certification requirement as a condition of billing IOP services in these standalone SUD programs presents more of a challenge and a barrier to access for patients in cases where these programs either do not employ or contract with a physician. Furthermore, the types of clinicians who typically provide services in Level 2.1 programs are not authorized by federal statute to bill Medicare independently for any services other than mental health services. To the extent that CMS establishes payment for IOP services in standalone settings that includes non-mental health services, this would present a challenge.

Hence, CMS should continue to allow mental health services (with explicit clarifcation that these services include SUD) or behavioral health services (as they have been defined to include mental health and SUD) to be provided under the general supervision of a physician who can assess and certify a patient's need for IOP services. CMS should continue to permit this supervision to be provided via real-time audio and visual interactive telecommunications. ASAM also recommends that CMS allow a physician to certify the need for IOP services based on an independement consultation of the diagnosis and assessment of another physician or advance practice provider, such as a nurse practitioner or physician assistant, who has evaluted the patient. While these flexibilities are essential for Level 2.1, they should also be available for Levels 2.5 and 2.7.

Billing and Coding

Acknowledging the regulatory complexities noted above, ASAM believes that CMS can establish coverage of IOP/HIOP services in standalone settings by allowing these services to be billed "incident-to" the professional services of a clinician authorized to independently bill Medicare, including physicians, nurse practitioners and physician assistants. Notably, ASAM encourages CMS to allow the aforementioned clinicians to attest that a physician's certification that a patient needs IOP/HIOP services is contained in the patient's medical record by way of billing for these incident-to services. We believe this will provide greater flexibilities for these programs.

ASAM notes that Medically Managed Intensive Outpatient services may be provided using existing HCPCS/CPT coding to bill for medical services provided in Level 2.7 programs.

Specifically, CMS should establish two new HCPCS codes that define intensive SUD outpatient treatment services billed by clinicians under the MPFS. HCPCS coding for Level 2.1 should outline intensive outpatient services as they are defined at § 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. However, coding for Level 2.5 should align the code descriptor with the definition of partial hospitalization services as defined at § 410.2 and furnished the services as described in § 410.43.[1] CMS should create two base codes for clinicians to bill for separate and distinct ASAM Levels 2.1 and 2.5, recognizing differential resource costs involved with providing each level of care. Similar to existing requirements for billing IOP services, CMS could also require that clinicians provide a minimum amount of services per day from a preselected list of services. As an example, CMS could promulgate codes that look similar to the short descriptions listed below.

- GXXX1: ASAM Level 2.1 (Intensive outpatient services)
- GXXX2: ASAM Level 2.5: (High-intensity outpatient services)

Following a diagnosis of SUD by a clinician appropriately licensed in the state in which they are practicing and an appropriate level of care assessment by a clinician that is documented in the patient's record, CMS should pay for incident-to services for clinicians who attest via billing that an appropriate certification from a physician that the patient meets the requirements for IOP/HIOP services is documented in the patient's medical record.

As noted earlier, Level 2.7 are medical services provided by physicians or other clinicians who provide medical services. In regulations § 410.43 and § 410.44 used to codify partial hospitalization (also know as HIOP) and intensive outpatient services, respectively, medical services provided by physicians, physician assistants, and nurse practitioners are separately covered and not included in the payment for IOP and HIOP services. **To promote consistency across payment systems, ASAM recommends that Level 2.7 programs that provide intensive outpatient medical management and extended nurse monitoring for stabilization of acute withdrawal, biomedical, and psychiatric conditions be separately covered and billed for by the physician or other qualified health professional eligible to bill Medicare independently. Additionally, ASAM recommends that if these same medical services are provided in Level 2.5 programs, that they be separately billable. However, ASAM recommends that non-psychiatric somatic services (blood pressure management, basic wound care, etc.) be included in the daily/weekly rate for IOP/HIOP services.**

Ultimately, ASAM recommends that CMS establish coding for IOP/HIOP services under the physician fee schedule that appropriately compensates medical and clinical services, minimizes cost-sharing for patients, and serves as a replicable model for other private and public insurers.

Payment

As a new service, it is vital that initial payment rates for IOP/HIOP services in standalone programs be both commensurate with the services provided under each Level of Care and increase access by incentivizing uptake by clinicians. **Thus, ASAM recommends that for simplicity, CMS use the payment amounts proposed under CY 2025 rulemaking for ASAM Level of Care 2 services in hospital outpatient deparments to establish payment amounts for these services.**

Specifically, ASAM encourages CMS to use APC 5861 to set the payment amount for Level 2.1 IOP services and APC 5864 for Level 2.5 HIOP services. CMS should permit either daily or weekly bundles for these services, consistent with payments for these services established for OTPs and in statutorily-authorized settings. This rationale reflects the different resource intensities of these services between levels (i.e. 9-19 hrs/week for Level 2.1 vs. ≥20 hrs/week for Level 2.5). Additionally, given that the hospital outpatient APC is the basis for the G0137 add-on code (IOP services in an OTP), ASAM believes that using a similar APCs would be appropriate to base a new code in the MPFS for IOP services in order to ensure people have comparable access to these levels of care.

As noted above, ASAM recommends that CMS follow precedent and separately cover any medical services that are provided in Level 2.5, and 2.7 programs.

Below is a table reflective of the payment structure noted above:

HCPCS code	**Payment/day – or - Payment/week***		**Crosswalk**	**Notes**
GXXX1	$279.97	$839.91	APC 5861	Level 2.1
GXXX2	$428.39	$1,285.17	APC 5864	Level 2.5

* Weekly payment rates reflect 3 days of services, comparable to the calculation of the OTP weekly rate for IOP services.

Finally, related to other regulatory moves that CMS has made to permit telehealth to be used to provide services to treat mental health and addiction, CMS should also allow services provided in IOP/HIOP/Medically Managed Intensive Outpatient settings to be provided via telehealth to the extent they are similarly authorized in other settings.

<u>OTP services</u>

In the CY 2025 MPFS, CMS is proposing a number of continued regulatory flexibilities for OTPs, including allowing audio-only for periodic assessments on a permanent basis, extending audio/video allowed initiation of treatment with methadone, and payment for social determinants of health risk assessments. **ASAM supports these regulatory flexibilities and applauds CMS' efforts to align payment with federal regulation of OTPs. We encourage CMS to finalize these proposals.**

<u>Safety Planning Interventions</u>

CMS is proposing to establish a new HCPCS code to describe safety planning interventions:

GSPI1 (Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe;) (List separately in addition to an E/M visit or psychotherapy).

The code would be valued based on a crosswalk to the valuation of CPT code 90839 (Psychotherapy for crisis), which describes 60 minutes of service. CMS is assuming a typical time of 20 minutes for GSPI1 and is valuing the code at a work RVU of 1.09, based on one-third of the value assigned to 90839. If finalized under the proposed conversion factor, the national payment rate for this code would be approximately $42.46.

According to *The ASAM Criteria*, safety planning is particularly important for patients treated in outpatient settings given that these patients may have limited to no access to clinical support after-hours. ASAM welcomes this proposal from CMS and encourages the agency to adopt it, with changes. Despite CMS acknowledging the increasing usage of safety plans related to overdose prevention, the code descriptor reads as if the code is specific to safety planning to prevent an impending suicidal crisis. **ASAM encourages CMS to revise the code descriptor to read:**

> *GSPI1: Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal <u>or substance use-related crisis</u>; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts <u>or risky substance use</u>; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health <u>or substance use disorder</u> professionals or agencies; and making the environment safe.*

Clincians who may bill Medicare directly for behavioral health services are most likely to bill for these services, though practitioners who may bill Medicare directly for E/M services should also be permitted to bill these services and these codes should be eligible for billing in all levels of care. ASAM also supports the use of trained clinical staff, working under the licensed practitioner's supervision, to provide these services. ASAM also encourages CMS to clarify that this code should also be allowed to be billed when the safety plan needs a revision.

<u>Post-Discharge Follow-ups</u>

CMS is proposing a new HCPCS code to describe post-discharge telephonic follow-up contacts interventions. These services would be used to describe the specific protocols involved in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter. The code would be billed monthly, describing four calls in a month, 10-20 minutes each. The proposed G-code is:

GFCI1 (Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.

CMS is proposing to value the code at 1 work RVU, analogous to CPT code 99426 (principal care management). If finalized under the proposed conversion factor, the national payment rate for this code would be approximately $62.13. **ASAM supports the proposed code and the valuation, and, we encourage CMS to finalized it.**

<u>Interprofessional consultations</u>

Currently, there are six CPT codes that can be used to bill for interprofessional consultations (99451, 99452, 99446, 99447, 99448, 99449). However, these codes are limited to clinicians that can independently bill for evaluation and management (E/M) services. This means that these codes cannot be billed by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors because these practitioners cannot independently bill Medicare for E/M visits. In response, CMS is proposing to create six new HCPCS codes to allow these mental health professionals to bill independently for consultative services with other clinicians.

These services would be described by the following HCPCS codes:

- GIPC1 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5-10 minutes of medical consultative discussion and review),
- GIPC2 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11-20 minutes of medical consultative discussion and review),
- GIPC3 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21-30 minutes of medical consultative discussion and review),
- GIPC4 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 31 or more minutes of medical consultative discussion and review),
- GIPC5 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are 5 CMS Proposed Rule: 2025 Medicare Physician Fee Schedule ASAM Summary of Major Provisions limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time), and
- GIPC6 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes) CMS is proposing to require the treating practitioner to obtain patient consent before the provision of these services, noting that cost-sharing applies, potentially for two services (the treating and the consultative practitioner). CMS is proposing to value the services based on a direct crosswalk to the existing CPT codes that describe these services for clinicians that can directly bill E/M services.

Given the wide array of clinicians involved in the behavioral health field and the time spent communicating back and forth regarding a patient's treatment needs, it is important that all clinicians have the appropriate coding to report the time spent providing these non-patient facing services that are an integral, non-direct part of patient care. **While ASAM encourages CMS to finalize these services, given that there could be duplicate cost-sharing for the patient (copay for requesting and treating clinician), ASAM supports requiring beneficiary consent for these services and explicit advisement that these services may encounter duplicate copays.**

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[1] Level 2.5 and 2.7 treatment programs typically provide at least 20 or more clinical service hours per week. Thus, these programs are more aligned with the definition of partial hospitalization services as they are defined at § 410.43. As noted above, The ASAM Criteria, 4th Edition redesignated ASAM Level 2.5, formerly known as "partial hospitalization" to "high-intensity outpatient."