On July 10, 2024 the Centers for Medicare and Medicaid Services (CMS) issued a <u>Proposed Rule</u> which revises calendar year (CY) 2025 payment policies under the Medicare Physician Fee Schedule (PFS) and makes other policy changes.

CMS has also published a fact sheet on the 2024 Medicare PFS proposed rule, available here.

A summary of the major proposed changes that impact addiction medicine are listed below.

Conversion Factor

CMS proposes a CY 2025 Medicare conversion factor (CF) of \$32.36, a decrease of \$0.93 or 2.8 percent from the current 2024 CF rate of \$33.29. This number multiplied by the total relative value units applied to a service totals the payment amount for a given service.

Telehealth Services

Changes to the list of telehealth services

CMS received a request to add General Behavioral Health Integration (CPT code 99484) and Principal Care Management (CPT codes 99424 – 99427) services to the list of telehealth services but is declining as they note that the codes do not meet CMS' definition of telehealth services.

Inclusion of Audio-only Under the Definition of Telehealth

During the COVID-19 public health emergency (PHE), CMS used its statutory waiver authority to allow the use of audio-only technology to furnish evaluation and management (E/M) services, as well as behavioral health counseling and education services. Further, the Consolidated Appropriations Act (CAA) of 2021 removed the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and the addition of the patient's home as a permissible originating site for these services. Following this change, CMS changes the regulatory definition of "interactive telecommunications system" to allow for audio-only to be used to furnish services to established patients in their homes for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorder) if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology.

Section 4113 of the CAA, 2023 further extended the availability of telehealth services that can be furnished using audio-only technology and provided for the extension of other PHE-related flexibilities including removal of the geographic and location limitations under section 1834(m) of the Social Security Act through December 31, 2024.

In response to these evolving regulatory flexibilities, CMS is proposing that for CY 2025, audio-only technology can be used to furnish <u>any</u> service on the Medicare telehealth list. Note that the list <u>does not</u> include services furnished in opioid treatment programs (OTPs) as these services described by those codes do not meet Medicare's definition of a telehealth service.

The full list of proposed services on the telehealth list can be found <u>here</u>. It includes services such as social determinants of health (SDOH) risk assessments, psychotherapy, alcohol misuse counselling, office-based substance use disorder (SUD) treatment, chronic pain care, and more.

However, due to changes in regulations from the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), as noted below, *some* of these services may be provided via audio-only technologies even without meeting Medicare's definition of telehealth.

Telehealth Codes Proposed by AMA CPT Editorial Panel

CMS is not proposing to recognize a broad swatch of new telehealth evaluation and management codes authored by the AMA's CPT Editorial Panel. CMS notes that the agency already pays for analogous evaluation and management (E/M) services for telehealth and thus, these new codes are unnecessary. Further, statute would require CMS to pay for these services at equivalent rates to the services that CMS already covers, duplicating payments. Hence, CMS has proposed that clinicians would continue to bill existing E/M codes with a telehealth indicator in 2025.

However, CMS is proposing to adopt CPT code 9X091(*Brief communication technology-based service*, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) and delete code G2012. If finalized under the proposed conversion factor, the national payment rate for this code would be approximately \$15.86.

Distant Site Requirements

CMS is proposing to continue to allow practitioners to use their practice address on enrollment forms, rather than their home address in response to safety and privacy concerns from practitioners.

Direct Supervision

Currently, CMS allows certain services, including most incident-to services to be performed under direct supervision, meaning that the supervising physician or other supervising practitioner must be present in the office suite and "immediately available" to furnish assistance and direction throughout the performance of the procedure. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only). CMS is proposing to continue this status quo through 2025.

After 2025, CMS is proposing to redefine direct supervision for certain services to note that the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only). The services that would be included

under this definition include services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5' (meaning that it's an incident-to service); and office and other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional, such as CPT code 99211.

Services that do not fall in this category after 2025 would require direct supervision without the ability to provide this supervision via audio/video real-time communications technology.

Teaching Physician Services

CMS will continue to require through 2025 the requirement that teaching physicians have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually. This cannot be provided via audio-only.

Visit Complexity (G2211)

CMS is proposing to allow payment of the office/outpatient O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting.

Advancing Access to Behavioral Health Services

Safety Planning Interventions

CMS is proposing to establish a new G 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 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.

CMS is seeking feedback on whether this visit would occur in the context of an E/M visit or psychotherapy, whether there are times this service may be furnished alone, and what types of clinicians would be most likely to bill this code on its own.

Post-Discharge Telephonic Follow-up Contacts Intervention

CMS is proposing a new G 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 HCPCS code *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.* If finalized under the proposed conversion factor, the national payment rate for this code would be approximately \$62.13.

CMS is seeking feedback on whether there should be a specific duration that the code could be billed, the number of calls per month, the billing structure, and any other relevant feedback. CMS is proposing to value the code at 1 work RVUs, analogous to CPT code 99426 (principal care management).

Clinicians would need to have at least one phone call per month to bill for GFCI1 and unsuccessful attempts to reach the patient could not be billed. Since patient cost sharing would apply, CMS is proposing that patient consent would be required before this service can be furnished.

Digital Mental Health Treatment (DMHT)

CMS is proposing to establish three new G codes to describe digital mental health treatment. Specifically, CMS is proposing to establish the following codes to allow 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)
- 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 98980 (remote therapeutic monitoring first 20 minutes), and GMBT3 would be priced based on a

crosswalk to 98981 (remote therapeutic monitoring each additional 20 minutes). If finalized under the proposed conversion factor, the national payment rate for GMBT2 would be approximately \$51.78, and the national payment rate for GMBT3 would be approximately \$39.80.

It is unclear whether these codes could be used to furnish services for the diagnosis and treatment of a SUD, consistent with other related changes that CMS has made in regulations to permit SUD to be included in the definition of mental health.

Interprofessional Consultation Billed by Practitioners Authorized by Statute to Treat Behavioral Health Conditions

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 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 independently bill for consultative services with other clinicians. These services would be described by the following 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

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.

Hence, if Medicare finalizes the current proposed CF and the proposed RVUs for these services, here is an example of the amount Medicare would pay for these services at the non-facility rate before locality and other adjustments:

GIPC1: \$17.15 GIPC2: \$34.63 GIPC3: \$52.42 GIPC4: \$70.22 GIPC5: \$32.36 GIPC6: \$33.98

Comment Solicitation on Payment for Services Furnished in Freestanding SUD Treatment Facilities

The CAA, 2023 authorized payment for intensive outpatient (IOP) services in hospital outpatient departments (HOPDs), Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and Rural Health Centers (RHCs). CMS notes that the agency has received feedback from treatment settings that provide IOP services that do not fall within one of those categories, namely freestanding SUD facilities. Hence, CMS is seeking feedback from stakeholders on whether IOP services are furnished in other settings to determine whether coding and payment for IOP services under the Medicare PFS would facilitate access to care in these settings. CMS is interested in several areas regarding free-standing SUD facilities, including the types of clinicians employed, whether bundled payments would facilitate access to IOP services, whether allowing them to bill for services would impact underserved areas, and whether Medicare and Medicaid patients receive care from these facilities.

CMS has also outlined a several questions in the proposed rule that they are seeking feedback on regarding Certified Community Behavioral Health Clinics (CCBHCs).

Opioid Treatment Program Services

Audio-only for Periodic Assessments and Initiation of Treatment with Methadone

CMS is proposing to allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025. Under this proposal, CMS will 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. This proposal for permanent adoption of the ability to use audio/visual technology to furnish this service follows previous rulemaking that allowed the same flexibility during and after the COVID-19 PHE.

Telehealth for Initiation of Methadone Treatment

Consistent with regulatory changes finalized by SAMHSA under 42 CFR Part 8 for methadone, and to be consistent with regulatory changes made to allow initiation of buprenorphine via telehealth in OTPs, CMS is proposing for the first time to allow OTPs to bill G2076 (intake activities) via telehealth (excluding audio-only). This flexibility would remain in place so long as DEA and SAMHSA permit it.

Payment for Social Determinants of Health (SDOH) Risk Assessments

Consistent with regulatory changes made by SAMHSA under the 42 CFR Part 8 revisions and to sync payment with revised standards for assessing various SDOHs in OTPs, CMS is proposing to update the payment rate for G2076 (intake activities) by adding HCPCS code G0136: Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months to the value of G0136. If finalized, the G2076 would increase from \$201.73 to \$220.39.

RFI on Payment Coordinated Care and Referrals to Community-Based Organizations (CBOs) that Address Unmet Health-Related Social Needs, Provide Harm Reduction Services, and/or Provide Recovery Support Services

CMS is seeking a broad array of information, including, but not limited to:

- Understanding how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, and/or provide recovery support services;
- Additional evidence that demonstrates how OTP linkages to community-based organizations directly helps OTPs address the diagnosis or treatment of an OUD;
- Information on the types of entities, service providers, and organizations that OTPs may interact with on a regular basis to address a patient's unmet health-related social needs (HRSNs) and goals related to harm reduction and recovery support services;
- The types of collaborative arrangements that OTPs typically have with CBOs, including how frequently OTPs coordinate care or make referrals to these CBOs for patients with an OUD, the types of circumstances that warrant an OTP interacting with these CBOs, and the

workflows originating from the initial SDOH assessment to identify these HRSNs to a beneficiary successfully receiving referred services;

- CMS is interested in learning when these coordinated activities and/or referrals occur in the process of furnishing care to a beneficiary;
- The resource costs associated with providing these services, as well as if there is existing coding to describe these services; and
- Whether OTPs already receive funding for these types of coordinated care or referral services from other public or private sources, and if additional payment would be duplicative or unnecessary.

Payment for Brixadi and Opvee

In line with FDA approvals of Brixadi and Opvee, CMS is proposing payment for these medications under the OTP Medicare benefit. Specifically, CMS is proposing GOTP1 [Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)]. The proposed payment for this code would consist of the drug component and non-drug component of the code, consistent with the payment methodology adopted by CMS under previous rulemaking. The drug component would be priced at \$92.03 while payment for the non-drug component of the code would cross-walked to CPT code 96161 (Administration of caregiverfocused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument), which is currently valued at ~\$3.00. Hence, the payment total for Opvee would be about \$95. CMS is further proposing to limit payment for the drug to once every 30 days with an exception for a beneficiary who has an overdose and uses the initial supply of Opvee.

Furthermore, CMS is proposing to revise G2069 (Medication-assisted treatment, buprenorphine (injectable)) to include payment for the monthly formulation of Brixadi. Specifically, the average sales price of Sublocade and Brixadi would be averaged to calculate the payment amount for the drug component of the revised code. Additionally, the code descriptor would be updated to reflect that G2069 is to be billed monthly.

CMS is proposing a new code GOTP2 (Medication assisted treatment, buprenorphine (injectable) administered on a weekly basis; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed) to bill for the weekly formulation of Brixadi. The payment would be cross-walked to the payment amount described by HCPCS code J0577 (Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy).

Require OUD Diagnosis on Claims for OUD Treatment Services

CMS is proposing to require that OTP claims contain an OUD diagnosis to permit payment.

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

General Care Management

CMS is proposing that beginning in CY 2025, rather than pay a weighted average of the compilation of individual CPT and HCPCS codes that bundled by HCPCS code G0511 (care management), Medicare will pay RHCs and FQHCs for billing the individual codes that make up G0511. Under this proposal, HCPCS code G0511 would no longer be payable when billed by RHCs and FQHCs.

CMS is also seeking comments on how the agency can improve the transparency and predictability regarding which HCPCS codes are considered care coordination services.

Direct Supervision

Like the temporary policy that CMS is proposing for services that require direct supervision under the MPFS, CMS is proposing that until December 2025, FQHCs and RHCs may continue to provide direct supervision via virtual presence (audio/video real-time communications technology, excluding audio-only).

Telehealth for Mental Health Services

Currently, regulatory flexibilities are set to expire in December 2024 for mental health services provided by FQHCs and RHCs. Afterwards, individuals visiting FQHCs/RHCs for mental health reasons would need to have an in-person visit at least 6 months prior to a telehealth visit. Furthermore, a subsequent visit within a year following the telehealth visit must occur. CMS is proposing to delay this requirement until January 2026. While CMS is allowed to make this change for FQHCs and RHCs, allowing the same flexibility for mental health visits outside of these facilities would require action from Congress.

Intensive Outpatient Program (IOP) Services

In the 2024 MPFS, CMS established payment for IOP services provided in FQHCs/RHCs, hospital outpatient departments, and community mental health centers. CMS established payment based on 3 and 4 or more services provided per day for hospital outpatient departments and community mental health centers. However, CMS only established a three service per day payment for FQHCs/RHCs. CMS is proposing to establish a four or more services per day payment for FQHCs/RHCs in addition to the current three services per day payment.

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

CMS is issuing a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) services, Principal Illness Navigation (PIN) services, and Social Determinants of Health (SDOH) Risk Assessment to engage interested parties on additional policy refinements for CMS to consider in future rulemaking.

Other Proposals of Interest in the Medicare Hospital Outpatient Prospective Payment System Proposed Rule

Medicaid Clinic Services Four Walls Exceptions

CMS is proposing to amend the Medicaid clinic services regulation to authorize federal reimbursement (at the state's request) for services provided by behavioral health clinics and services provided by clinics located in rural areas. CMS is not proposing a specific definition of rural but is seeking public comment on different alternative definitions for consideration in final rulemaking.

Individuals Formerly in the Custody of Penal Authorities

CMS is proposing to narrow the definition of "custody" to no longer include individuals who are on parole, probation, and home detention. The proposal, if finalized, would remove the presumption that Medicare is prohibited from paying for health care items or services furnished to individuals on parole, probation, or home detention, thus facilitating access to Medicare payment. To facilitate access to Medicare coverage, CMS is also proposing to revise the eligibility criteria for the special enrollment period for formerly incarcerated individuals to include individuals who have been released from incarceration or on parole, probation, or home detention.