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Physician Fee Schedule Proposed Rule Would Boost Medicare Reimbursement for Opioid and Substance Use Disorder Treatment

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The CMS Proposed Rule to update the Medicare Physician Fee Schedule for Calendar Year 2021, published in the Federal Register on August 17, 2020 (85 Fed. Reg. 50074), proposes several updates to Medicare payment regulations related to identification and treatment of substance use disorders (SUDs) and opioid use disorder (OUD) in physicians' offices and through opioid treatment programs (OTPs), including:

- Reimbursement and enrollment changes for OTPs,
- New billing option for medication assisted treatment in emergency departments,
- Expanded bundled payments for office-based SUD treatment, and
- Express substance use disorder-related requirements in Medicare physicals.

These proposed regulatory updates reflect CMS' stated belief that it "has a vital role in addressing opioid use disorder prevention, treatment and recovery." Roughly 47,000 Americans died as a result of an opioid overdose in 2018, and 32 percent of those deaths involved a prescription opioid, according to the Proposed Rule.

Comments on the Proposed Rule are due to CMS by October 5, 2020 at 5:00 p.m. EST.

Reimbursement and Enrollment Changes for OTPs

For Calendar Year 2021, which will be only the second year in which CMS has recognized OTPs as a provider type, the Proposed Rule would expand availability of reimbursement for opioid overdose emergency medications, clarify requirements for periodic assessments of patients, and offer a Medicare enrollment alternative to OTPs seeking to submit claims as institutional providers.

- **Reimbursement for Naloxone**. CMS proposes to revise the definition of "OUD treatment services" by an OTP to include dispensing of a take-home supply of naloxone, the FDA-approved opioid antagonist designed to reverse an opioid overdose, and to create new HCPCS codes to allow OTPs to submit reimbursement claims for dispensing take-home doses of the drug in nasal spray or auto-injector form. The OTP would bill the applicable HCPCS code for the form of the drug dispensed as an add-on to the existing bundled payments to OTPs for treatment, and the OTP could bill for one unit of naloxone (which includes two take-home doses) per patient per 30-day period. CMS also seeks public comment on:
  - Whether the definition of "OUD treatment services" should be further revised to include opioid overdose education and whether an additional HCPCS code should be created to allow OTPs to submit claims for an add-on payment for overdose education.
  - Whether an additional HCPCS code should be created to allow OTPs to submit claims for an add-on payment for dispensing take-home doses of injectable naloxone.

Naloxone is currently covered by Medicare Part D, but the drug is subject to a beneficiary copayment. In preamble discussion, CMS states its belief that "allowing beneficiaries to access this important emergency

treatment at the OTP may help decrease barriers to access because there currently are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone."

- **Face-to-Face Requirement for Periodic Assessments**. In response to requests for clarification regarding what activities would merit an OTP billing the add-on HCPCS code for a "periodic assessment" of a patient, CMS states that "a face-to-face medical exam or biopsychosocial assessment would need to have been performed." However, CMS also proposes to make reimbursement for periodic assessments conducted by two-way interactive video communication technology, which is currently available during the public health emergency for the COVID-19 pandemic (PHE), permanently available (provided that all other applicable requirements are met). The Proposed Rule expressly does not propose to make reimbursement for periodic assessments conducted by audio-only telephone calls, which is currently available during the PHE, permanently available, but CMS does seek public comment on whether it should reconsider this position (and, if so, whether the payment rate should reflect any differences in resource costs for the audio-only medium).
- **Institutional Provider Billing**. As part of the proposal, CMS responds to requests from the OTP provider community for the ability to bill on an institutional claim form (837I) rather than a professional claim form (CMS-1500) by proposing an alternative enrollment option to facilitate institutional billing and committing to consider the matter further.

  - Pursuant to the Proposed Rule, OTPs would be permitted to enroll in Medicare using Form CMS-855A, which would allow the enrolled OTP to bill on the institutional claim form. Currently, OTPs enroll in Medicare by completing Form CMS-855B (which requires billing on the professional claim form), and CMS proposes that OTPs would continue to have the option to enroll using Form CMS-855B. Under this proposal, OTPs would have the option to enroll in Medicare using either 855 form (but not both) to suit the OTP's billing needs. An OTP, including one currently enrolled in the program that completed Form CMS-855B or a future enrollee completing either 855 form, would also have the option to change its enrollment type by terminating its current enrollment and re-enrolling using the other 855 form. CMS confirmed that if an OTP elected to change its enrollment type, the effective date of the new enrollment would be retroactive to the effective date of the original enrollment (subject to existing rules that claims for reimbursement must be submitted within one year of the date of service), and the new enrollment would be subject to only limited categorical risk screening (i.e., no site visit or owner fingerprinting).
  - CMS also stated in the Proposed Rule that it is "exploring claims processing flexibilities requested by some OTPs that would allow them to bill services on institutional claims" without changing their Medicare enrollment types. CMS requests information on why the flexibility for an OTP enrolled as a Medicare Part B provider to bill as an institutional provider is needed and committed to "address any changes to provider billing policies in subsequent claims processing instructions."

New Billing Option for Medication Assisted Treatment in Emergency Departments

CMS proposes to create a new add-on HCPCS code, to be billed with E/M visit codes used in the emergency department (ED) setting, for the initiation of medication for the treatment of OUD in the ED. Payment for the new code would cover assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services. As support for this policy, CMS stated that these services do not fit within the existing code set. The drug administered to treat OUD in the ED would continue to be reimbursed separately.

Expanded Bundled Payments for Office-based SUD Treatment

Under the Proposed Rule, CMS would broaden three HCPCS codes implemented for the first time in Calendar Year 2020 for reimbursement of various stages of "office-based treatment for opioid use disorder" to cover "office-based treatment for a substance use disorder." CMS stated that, under the proposal, the expanded

codes would reimburse providers for treatment for any SUD, but CMS is seeking public comment on whether costs vary for treatment of different SUDs, necessitating more "granular" coding.

Express Substance Use Disorder-related Requirements in Medicare Physicals

CMS proposes to amend the Medicare regulations to implement a requirement in Section 2002 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) that a Medicare beneficiary's Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) include screening for potential SUDs and a review of any current opioid prescriptions. Under the proposal, the screening for potential SUDs would include a review of the individual beneficiary's potential risk factors for SUDs and a referral for additional treatment, if appropriate.

CMS asserts that the existing requirements for the IPPE (which is the exam performed on a Medicare beneficiary within one year after the effective date of his or her Medicare Part B coverage) and the AWV, which include a review of a beneficiary's medical and social history and a health risk assessment, mean these encounters likely already include a review of current opioid prescriptions and would bring any potential SUDs to light. Accordingly, CMS notes that the new requirements are unlikely to add significant burdens to providers conducting the IPPE and AWV. Rather, CMS states, "[t]he new regulatory elements elevate the importance of physicians' and other qualified health professionals' vigilance in identifying and addressing opioid risks and SUDs in Medicare beneficiaries."

For more information, please contact Michaela Poizner, or any member of the Baker Donelson Behavioral Health and Substance Use Disorders Team.