

### ***Section III.H.: Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm***

#### ***Medicare Enrollment of Opioid Treatment Programs***

The SUPPORT Act established a new Medicare benefit category for OTPs and classifies OTPs as Medicare providers for the furnishing of OUD treatment services.

To enroll as a Medicare provider, an OTP must have a current, valid accreditation by an accrediting body or other entity approved by SAMHSA and a current, valid certification by SAMHSA (provisional certifications are not accepted). Further, an OTP must maintain and submit to CMS a list of all physicians and other eligible professionals who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. It must also pay the institutional provider application fee.

All potential Medicare enrollees are assigned a screening category based on a CMS assessment of the level of risk of fraud, waste and abuse posed. The higher the level of risk, the greater the level of scrutiny with which CMS will screen and review providers and suppliers. All newly enrolling OTPs that have been fully and continuously certified by SAMHSA since October 23, 2018, will be assigned to the moderate risk level of categorical screening. Those that have not been fully and continuously certified by SAMHSA since that date will be subject to the originally proposed high-risk level of categorical screening. This means that OTPs would be subject to the same screening procedures that apply to all other enrolling providers and suppliers (regardless of the risk category into which they fall) as well as the following:

- A site visit.
- Submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. (Required only for high-risk level of categorical screening.)
- A fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. (Required only for high-risk level of categorical screening.)

**\*\*OTPs may submit applications immediately, and CMS encourages them to do so to begin billing on and after the OTP benefit commencement date of January 1, 2020.\*\***

#### ***Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm***

CMS added a new revocation and denial reason to its provider enrollment process. To ensure patient safety in all settings, and in light of the ongoing opioid epidemic, it proposed criteria to allow CMS to revoke or deny a physician's or other eligible professional's enrollment "if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm."

In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:

- The nature of the patient harm.

- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional.
- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

In its proposed rule, CMS had included "Required participation in rehabilitation or mental/behavioral health programs" and "Required abstinence from drugs or alcohol and random drug testing" among the disciplinary actions that CMS would consider in its determination. Based on objections from ASAM and others that those criteria might discourage clinicians from seeking treatment for addiction or mental illness, CMS removed these criteria in the final rule and added a new paragraph to the regulatory text that specifically excludes these actions from the provisions' purviews.