

(ii) Community mental health centers.

(iii) Comprehensive outpatient rehabilitation facilities.

(iv) Independent clinical laboratories.

(v) Independent diagnostic testing facilities.

(vi) Physical therapists enrolling as individuals or as group practices.

(vii) Portable x-ray suppliers.

(viii) Prospective (newly enrolling) and revalidating opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018.

(ix) Revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices to which CMS applied the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section upon the provider's or supplier's—

(A) New/initial enrollment; or

(B) Revalidation after CMS waived the fingerprinting requirements, under the circumstances described in paragraph (c)(1)(viii) of this section, when the provider or supplier initially enrolled in Medicare.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a “moderate” categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the “limited” screening requirements described in paragraph (a)(2) of this section.

(ii) Conducts an on-site visit.

(c) *High categorical risk—(1) High categorical risk: Provider and supplier categories.* CMS has designated the following provider and supplier types as “high” categorical risk:

(i) Prospective (newly enrolling) home health agencies.

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(iii) Prospective (newly enrolling) MDPP suppliers

(iv) Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously cer-

tified by SAMHSA since October 23, 2018.

(v) Prospective (newly enrolling) (SNFs).

(vi) Prospective (newly enrolling) hospices.

(vii) Enrolled opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, DMEPOS suppliers, MDPP suppliers, HHAs, SNFs, and hospices that are submitting a change of ownership application pursuant to 42 CFR 489.18 or reporting any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42.

(viii) Except as stated in paragraph (b)(1)(ix) of this section, revalidating opioid treatment programs that have not been fully and continuously certified by SAMHSA since October 23, 2018, revalidating DMEPOS suppliers, revalidating MDPP suppliers, revalidating HHAs, revalidating SNFs, and revalidating hospices for which, upon their new/initial enrollment, CMS waived the fingerprinting requirements outlined in paragraph (c)(2)(ii) of this section in accordance with applicable legal authority due to a national, state, or local emergency declared under existing law.

(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a “high” categorical level of risk, the Medicare contractor does all of the following:

(i) Performs the “limited” and “moderate” screening requirements described in paragraphs (a)(2) and (b)(2) of this section.

(ii)(A) Requires the 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; and

(B) Conducts 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.

(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from

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“limited” or “moderate” to “high” if any of the following occur:

(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.

(ii) The provider or supplier—

(A) Has been excluded from Medicare by the OIG; or

(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—

(1) Enrolling as a new provider or supplier; or

(2) Billing privileges for a new practice location;

(C) Has been terminated or is otherwise precluded from billing Medicaid;

(D) Has been excluded from any Federal health care program; or

(E) Has been subject to any final adverse action, as defined at § 424.502, within the previous 10 years.

(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

(4) Any screening level adjustment under paragraph (c)(3) of this section also applies to all other enrolled and prospective providers and suppliers that have the same legal business name and tax identification number as the provider or supplier for which the screening level under paragraph (c)(3) of this section was originally raised.

(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints for a national background check.

(i) Upon submission of a Medicare enrollment application; or

(ii) Within 30 days of a Medicare contractor request.

(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section,

the provider or supplier will have its billing privileges—

(i) Denied under § 424.530(a)(1); or

(ii) Revoked under § 424.535(a)(1).

[76 FR 5963, Feb. 2, 2011, as amended at 82 FR 53368, Nov. 15, 2017; 84 FR 63203, Nov. 15, 2019; 85 FR 70355, Nov. 4, 2020; 85 FR 85038, Dec. 28, 2020; 87 FR 70231, Nov. 18, 2022; 87 FR 72293, Nov. 23, 2022; 88 FR 77877, Nov. 13, 2023]

### § 424.519 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply to the definition of disclosable event in § 424.502:

(1) “Uncollected debt” only applies to the following:

(i) Medicare, Medicaid, or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties imposed under this title.

(iii) Assessments imposed under this title.

(2) “Revoked,” “Revocation,” “Terminated,” and “Termination” include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid, or CHIP enrollment to avoid a potential revocation or termination.

(b) *General.* Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms “owner” and “managing employee” as defined in § 424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in § 424.502). CMS will request such disclosures when it has determined that the initially enrolling or revalidating provider or supplier may have at least one such affiliation.

(c) *Information.* The provider or supplier must disclose the following information about each reported affiliation:

(1) General identifying data about the affiliated provider or supplier. This includes the following:

(i) Legal name as reported to the Internal Revenue Service or the Social