

of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

(i) Specific pilot certifications including but not limited to instrument and medical certifications.

(ii) Airworthiness certification.

(f) *Maintaining and providing access to documentation.* (1)(i) A provider or a supplier that furnishes covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

(2)(i) A physician or, when permitted, an eligible professional who orders, certifies, refers, or prescribes Part A or B services, items or drugs is required to—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions or requests for payments for Part A or B services, items, or drugs.

(g) *Skilled nursing facilities.* (1) In addition to all other applicable reporting requirements in this subpart, a skilled nursing facility (as defined in section

1819(a) of the Act) must disclose upon initial enrollment (which, for purposes of this paragraph (g), also includes a change of ownership under 42 CFR 489.18) and revalidation the following information:

(i) Each member of the governing body of the facility, including the name, title, and period of service for each such member.

(ii) Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in § 424.502) of the facility, including the name, title, and period of service of each such person or entity.

(iii) Each person or entity who is an additional disclosable party of the facility (as defined in § 424.502).

(iv) The organizational structure (as defined in § 424.502) of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(2) The skilled nursing facility need not disclose the same information described in paragraph (g)(1) of this section more than once on the same enrollment application submission.

(3) The skilled nursing facility must report any change to any of the information described in paragraph (g)(1) of this section consistent with the applicable timeframes in paragraph (e) of this section.

[73 FR 69939, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008, as amended at 75 FR 24449, May 5, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 25318, Apr. 27, 2012; 82 FR 53368, Nov. 15, 2017; 84 FR 47852, Sept. 10, 2019; 88 FR 79541, Nov. 16, 2023; 88 FR 80168, Nov. 17, 2023]

#### § 424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges

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as specified in § 424.530 or § 424.535 of this part.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider meets either of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B providers.* CMS determines, upon review, that the supplier meets any of the following conditions:

(i) Is unable to furnish Medicare-covered items or services.

(ii) Has failed to satisfy any or all of the Medicare enrollment requirements.

(iii) Has failed to furnish Medicare covered items or services as required by the statute or regulations.

(b) [Reserved]

[73 FR 66940, Nov. 19, 2008]

### § 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, revalidation applications, change of ownership applications pursuant to 42 CFR 489.18, applications to add a new practice location, and applications to report any new owner (regardless of ownership percentage) pursuant to a change of information or other enrollment transaction under title 42, based on a CMS assessment of risk and assignment to a level of “limited,” “moderate,” or “high.”

(a) *Limited categorical risk*—(1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “limited” categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Home infusion therapy suppliers.

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(ix) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(x) Mammography screening centers.

(xi) Mass immunization roster billers

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

(xiii) Organ procurement organizations.

(xiv) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xv) Radiation therapy centers.

(xvi) Religious non-medical health care institutions.

(xvii) Rural health clinics.

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

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk*—(1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “moderate” categorical risk:

(i) Ambulance service suppliers.

(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