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 who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered the items of DMEPOS or the clinical laboratory or imaging services) relating to written orders or certifications or requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

[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]

§ 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 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, including applications for a new practice location, and any applications received in response to a revalidation request 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) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(viii) 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.

(ix) Mammography screening centers.

(x) Mass immunization roster billers

(xi) Organ procurement organizations.

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

(xiii) Radiation therapy centers.

(xiv) Religious non-medical health care institutions.

(xv) Rural health clinics.

(xvi) Skilled nursing facilities.

(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) Hospice organizations.

(v) Independent clinical laboratories.

(vi) Independent diagnostic testing facilities.

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

(viii) Portable x-ray suppliers.

(ix) Revalidating home health agencies.

(x) Revalidating DMEPOS suppliers.

(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 home health agencies and suppliers of DMEPOS as ''high'' categorical risk:

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

(ii) Prospective (newly enrolling) DMEPOS suppliers.

(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 ''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.

(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]

§ 424.520 Effective date of Medicare billing privileges.

(a) *Surveyed, certified or accredited providers and suppliers.* The effective date for billing privileges for providers and suppliers requiring State survey, certification or accreditation is specified in § 489.13 of this chapter. If a provider or supplier is seeking accreditation from a CMS-approved accreditation organization, the effective date is specified in § 489.13.

(b) *Independent Diagnostic Testing Facilities.* The effective date for billing privileges for IDTFs is specified in § 410.33(i) of this chapter.

(c) *DMEPOS suppliers.* The effective date for billing privileges for DMEPOS suppliers is specified in § 424.57(b) of this subpart and section 1834(j)(1)(A) of the Act.

(d) *Physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* The effective date for billing privileges for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations is the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor or the date an enrolled physician or nonphysician practitioner first began furnishing services at a new practice location.

[73 FR 69940, Nov. 19, 2008, as amended at 75 FR 50418, Aug. 16, 2010]

§ 424.521 Request for payment by physicians, nonphysician practitioners, physician or nonphysician organizations.

(a) Physicians, nonphysician practitioners and physician and nonphysician practitioner organizations may retrospectively bill for services when a physician or nonphysician practitioner or a physician or a nonphysician organization have met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

(1) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

(2) 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(b) [Reserved]

[73 FR 69940, Nov. 19, 2008]

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

(1) The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the contractor request for the missing information.

(2) The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

(3) The prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend the 30 day period if CMS determines