

Healthcare Reform

Final Rule Update: New Enrollment and Payment Suspension Rules Affect All Medicare, Medicaid, and CHIP Providers and Suppliers

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Editor's Note:

The [January 2011 edition](#) of *The RAP Sheet* featured an analysis of the *proposed* rule on new enrollment and payment suspension requirements mandated by healthcare reform. The following is an update based on the February 2, 2011, final rule. We greatly appreciate the authors of the prior analysis providing this update as well.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010¹ (Affordable Care Act or ACA), made significant changes to Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to reduce fraud, waste, and abuse at the provider enrollment level of program participation. On September 23, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule (Proposed Rule) that implemented the ACA's provisions addressing fraud, waste, and abuse at the enrollment level. The Proposed Rule included new requirements regarding enrollment screening, an enrolling application fee, payment suspension, temporary moratoria on enrollment, compliance programs, and provider and supplier termination. This article summarizes the changes in the final rule with comment period, which was published in the *Federal Register* on February 2, 2011 (Final Rule).²

Screening Under Medicare, Medicaid, and CHIP

In the Final Rule, CMS maintained the three categories of providers classified according to the risk of fraud, waste, and abuse—limited, moderate, and high. Those risk levels in turn affect the level of screening procedures the enrollee will undergo.³ As finalized, effective as of *March 23, 2011*, the new risk categories and the related enrollment screening procedures will be applicable to newly enrolling providers and suppliers as well as to those currently enrolled providers and suppliers whose revalidation is scheduled between March 25, 2011, and March 23, 2012.⁴ For providers and suppliers assigned to the high screening level, the fingerprint-based criminal history record check requirement will be implemented through sub-regulatory guidance and will be effective sixty days following the publication of that guidance. All other screening requirements are effective on March 25, 2011, for those in the high screening level. For all other currently enrolled providers and suppliers, ACA established and the Final Rule confirmed an effective date of March 23, 2012.

Screening Categories—Medicare

In the Final Rule, CMS added certain provider and supplier types to the categories and eliminated others. We have included a revised chart (and affiliated endnotes) showing some of the changes below—noting additions with underlined text and deletions with a ~~strike through~~—See Figure 1 on page 11.

As noted in the Final Rule, commenters urged CMS to more narrowly tailor its risk assignments by geography because previously, fraud, waste, and abuse issues with DMEPOS suppliers and home health agencies (HHAs) have been shown in certain geographical regions (e.g., South Florida, Texas, and California), and it is not clear that issues with such entities are national.⁵ CMS disagreed that the enhanced screening procedures should initially be restricted to high-risk geographical areas, noting, “While some regions of the country evidence fraud, waste and abuse more than others, fraudulent activity can occur anywhere.”⁶ Further, CMS stated that the national approach is the most objective in implementing the screening procedures. To address concerns in particular regions, CMS stated that it will rely on other program integrity tools, including, without limitation, the enrollment moratoria authority contained in the Final Rule.⁷

CMS also declined to subcategorize individual providers and suppliers based on their ownership. As such, there is no default “limited” risk category based on being publicly traded; publicly traded and private companies are treated the same. HHAs owned by hospitals are considered “moderate” or “high” risk based on the HHA provider placement, not based on the hospital ownership. The DMEPOS suppliers also are classified in the moderate- or high-risk category despite ownership by physicians, a community pharmacy, a physical therapist, or an occupational therapist. Ambulance services suppliers now are solely categorized in the “moderate” risk category, rather than as limited or moderate, based on whether the supplier has public or government ownership or affiliation.

Figure 1—Proposed Assignments of Provider Types to Risk Categories (Medicare)

Limited	Moderate	High
<ul style="list-style-type: none"> Physicians, non-physician practitioners (NPPs) (<u>including nurse practitioners, certified registered nurse anesthetists (CRNAs), occupational therapists, speech language pathologists, and audiologists</u>), medical groups, and clinics Pharmacies newly enrolling or revalidating via the CMS-855B Hospitals, including critical access hospitals Skilled nursing facilities Federally qualified health centers (FQHCs) Medical clinics Group practices Publicly traded providers or suppliers Ambulatory surgical centers End stage renal disease facilities Portable x-ray suppliers Others⁸ 	<ul style="list-style-type: none"> Comprehensive outpatient rehabilitation facilities Independent diagnostic testing facilities (IDTFs) Independent clinical laboratories Currently enrolled (re-validating) HHAs Currently enrolled (re-validating) suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Hospice organizations Physical therapists and PT groups Portable x-ray suppliers Others⁹ 	<ul style="list-style-type: none"> Newly enrolled HHAs Newly enrolled suppliers of DMEPOS

Although several commenters thought accreditation should lower the risk category, CMS stated that they do not believe that accrediting bodies perform a sufficient level of oversight to ensure that the entities they accredit are a low program integrity risk.¹⁰ According to CMS, accrediting bodies assist in verifying the supplier's or provider's compliance with Medicare standards, rather than assess the provider's or supplier's risk of fraud, waste, or abuse.

Moving to “High” Risk—Medicare

In the Final Rule, CMS revised the reasons to move providers and suppliers from a limited- or moderate-risk level to the high-risk level. CMS eliminated the identity theft reason, where CMS has evidence from or concerning a physician or NPP that another individual is using his/her identity, as a basis for moving a provider or supplier into a high-risk screening level.¹¹ CMS maintained the following reasons from the Proposed Rule for moving a provider or supplier to a high-risk level:

- The provider or supplier has been excluded by the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) or had its Medicare billing privileges revoked by a Medicare contractor within the previous ten years and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier.
- CMS imposes a payment suspension.

- The provider has been terminated or otherwise precluded from billing Medicaid.
- CMS lifts a temporary moratorium applicable to such providers or suppliers at which point the move to the high-risk level will last for six months after the lifting of the moratorium.¹²

CMS added “final adverse action” as a basis for reassigning a provider or supplier to the high screening level.¹³ “Final adverse action” is defined at 42 C.F.R. § 424.502 as one of the following actions:

- (1) A Medicare-imposed revocation of any Medicare billing privileges;
- (2) Suspension or revocation of a license to provide healthcare by any state licensing authority;
- (3) Revocation or suspension by an accreditation organization;
- (4) A conviction of a federal or state felony offense (as defined in § 424.535(a)(3)(i)) within the last ten years preceding enrollment, revalidation, or re-enrollment; or
- (5) An exclusion or debarment from participation in a federal or state healthcare program.

CMS also will place the provider or supplier into the high screening level if an individual who maintains 5% or greater direct or indirect ownership interest in such provider or supplier has had a final adverse action imposed against it within the previous ten years.¹⁴

With regard to timing, CMS made clear that they will not wait until agency action is final before shifting a provider or supplier

into a new screening level.¹⁵ Thus, if a provider or supplier is appealing an adverse determination noted above, CMS will still move the provider or supplier into the high-risk category despite pending appeals.

Level of Screening—Medicare

As in the Proposed Rule, in the Final Rule, CMS based the level of enrollment screening on the risk category to which a provider or supplier is assigned. We have included a revised chart showing some of the changes below—noting additions with underlined text and deletions with a ~~strike through~~—See Figure 2 below.

In the Final Rule, CMS combined the fingerprinting requirement with the background check requirement, and fingerprint-based criminal history record checks from the Federal Bureau of Investigation will be implemented sixty days following the publication of sub-regulatory guidance.¹⁶ CMS removed the requirement present in the Proposed Rule that fingerprints be submitted solely on the FD-258 card, suggesting that electronic fingerprinting would be faster.¹⁷ CMS made clear that the relevant individuals who are required to undergo a criminal history record check will incur the cost of having their fingerprints taken, while CMS will bear the cost of processing the fingerprint-based criminal history record check.¹⁸

In the Final Rule, CMS restricted its fingerprint-based criminal history record check requirement to individuals with a 5% or greater direct or indirect ownership interests.¹⁹ CMS also removed tax delinquency from the list of database checks in the Final Rule, noting that although CMS has new authorities to obtain tax information as part of ACA and other recently enacted statutes, they are not prepared to operationalize those provisions at this time.²⁰

As a final note on the new enrollment screening requirements, although the normal Medicare revalidation cycle remains three years for DMEPOS suppliers and five years for all other providers and suppliers, CMS can now require that a provider or supplier revalidate its enrollment at any time.²¹ According to CMS, the new authority to conduct off-cycle validations of providers and suppliers will enable them to apply the new screening requirements to all currently enrolled providers and suppliers by the statutory effective date of March 23, 2013.

Screening Categories and Levels—Medicaid and CHIP

Because of the expense and efficiencies involved, CMS will allow states to rely on the results of the Medicare contractor's screening to meet the provider screening requirements under Medicaid and

Figure 2—Comparing Current Screening Requirements and Proposed Screening Requirements

Type of Screening Required (Medicare)	Current Rule	Proposed Rule—Limited	Proposed Rule—Moderate	Proposed Rule—High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X	X
Verification of license (may include licensure checks across states)	X	X	X	X
Database checks: <ul style="list-style-type: none"> • Social Security Number • National Provider Identifier • National Practitioner Data Bank licensure • HHS OIG exclusion • Taxpayer identification number • Tax delinquency • Death of individual practitioner, owner, authorized official, delegated official, or supervising physician 	X	X	X	X
Unscheduled or unannounced pre-enrollment or post-enrollment site visits	Only DMEPOS and IDTFs pre-enrollment; ad hoc for others		X	X
<u>Fingerprint-based</u> Criminal History Record Check of law enforcement repositories—individual owners with 5% or more direct or indirect ownership, authorized or delegated officials and managing employees				X

CHIP. Similarly, state Medicaid agencies can rely on the results of sister state Medicaid programs and CHIP.

With regard to the Medicaid and CHIP programs, CMS confirmed that for types of providers that are recognized as a provider or supplier under the Medicare program, states will use the same screening level that is assigned to that category by Medicare.²² If limited risk, CMS requires the states to do the following:

(1) verify that a provider meets any applicable federal regulations or state requirements for the provider type; (2) license verification; and (3) defined database checks.²³ If moderate risk, the states must do the following: (1) perform limited-risk screening; and (2) conduct on-site visits in accordance with 42 C.F.R. § 455.432.²⁴ If high risk, the states must do the following: (1) perform limited and moderate risk screenings; (2) conduct a criminal background check; and (3) require the submission of a set of fingerprints (§ 455.434).²⁵

For those Medicaid and CHIP provider types that are not recognized by Medicare, states will assess the risk posed by a particular provider type. According to CMS, states can assess the risk of provider type themselves, but CMS expects states will assess the risk using criteria similar to those used in Medicare. For example, physicians, NPPs, medical groups, and clinics that are state licensed or state regulated would generally be categorized as limited risk.²⁶ Those provider types that generally are highly dependent on Medicare, Medicaid, and CHIP to pay salaries and other operating expenses, and that are not subject to additional government or professional oversight, would be considered

moderate risk.²⁷ Those provider types identified by the state as being especially vulnerable to improper payments would be considered high risk.²⁸

Medicaid and CHIP have a five-year enrollment revalidation period.²⁹ Under the new rules, CMS expects the state Medicaid agencies to complete the first revalidation cycle by 2015 with 20% of all providers being revalidated each year beginning 2011.³⁰

In the Final Rule, under Section 455.410, CMS adopted the requirement from Section 1902(kk)(7) of the Social Security Act that states require *all* ordering or referring physicians or other professionals to be enrolled under a Medicaid state plan or waiver of the plan as a participating provider. CMS, however, did not expand the requirement to apply to risk-based managed care organizations.³¹

Application Fee

Institutional providers must pay the application fee (statutorily set at \$500 for 2010 and adjusted yearly based on the Consumer Price Index for all urban consumers) with the submission of an initial enrollment application, an application to establish a new practice location, as part of revalidation, or in response to a revalidation request.³² An “institutional provider” is broadly defined as “any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and non-physician practitioner organizations), CMS-855S or associated Internet-based PECOS enrollment application.”³³

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The application fee is intended to cover both federal and state costs of the screening program.³⁴ The application fee is *not* linked to the risk level associated with the provider or supplier,³⁵ i.e., you do not pay more because you are at a high level versus a limited risk level.

The application fee is nonrefundable except if submitted with one of the following: (1) a request for hardship exception that is subsequently approved; (2) an application that is rejected prior to initiation of screening processes; or (3) an application that is subsequently denied as a result of the imposition of a temporary moratorium.³⁶ An application will be rejected and, in the case of revalidations, billing privileges may be revoked if the institutional provider does not submit the application fee or hardship exception.

A state may rely on the results of the Medicare screening requirements for participation in a state Medicaid program or CHIP, and a provider or supplier enrolled in more than one program (that is, Medicare and Medicaid or CHIP, or all three programs) would only be subject to the application fee under Medicare and that fee would cover screening activities for enrollment in all programs.³⁷ In the Final Rule, CMS stated that the operational logistics to implement this one-fee concept will be addressed in sub-regulatory guidance.³⁸

CMS also finalized the provisions of the Proposed Rule with regard to the application fee with the following exceptions:³⁹

- CMS added language to clarify that a provider or supplier may submit both an application fee and hardship exception to avoid delays in the processing of the application if the hardship exception is not approved at Section 424.514(a) and (b).
- CMS added language to clarify that if a provider submits a hardship exception request without an application fee, and CMS does not approve the hardship exception request, CMS will notify the provider or supplier and allow thirty days from the date of notification to submit the application fee at Section 424.514(h).
- CMS also added language that specifies that states must collect the applicable application fee from Medicaid-only and CHIP-only providers and suppliers at Section 455.460. The state in consultation with the HHS Secretary may waive the fee for Medicaid-only or CHIP-only providers if the state demonstrates that the imposition of the fee will impede beneficiary access to care.⁴⁰

Temporary Moratoria on Enrollment

ACA Section 6401(a) allows the HHS Secretary to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers if necessary to combat fraud, waste, or abuse under those programs.⁴¹ CMS believes these moratoria give it a unique opportunity to develop new regulatory provisions and program incentives that will better ensure quality and prevent abuse.

Under the Final Rule, CMS may impose a temporary moratorium on enrollment of new Medicare providers and suppliers of a particular type or in a particular geographic area.⁴² CMS may impose these moratoria if:

- (1) CMS identifies a trend that signifies a high risk of fraud, waste, or abuse for a particular provider or supplier type or geographic area;⁴³
- (2) A state Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that also participate in Medicare; or
- (3) In consultation with HHS, HHS OIG, or the U.S. Department of Justice (DOJ), CMS identifies either a particular provider or supplier type or a particular geographic area that appears to have significant potential for fraud, waste, or abuse.

The Final Rule emphasizes the HHS Secretary's broad authority to impose temporary moratoria under ACA. In addition, CMS may lift an imposed moratorium under the following circumstances:

- (1) The president declares a disaster area under the Stafford Act;
- (2) The circumstances that merited the moratorium have passed or CMS has imposed safeguards to address the identified risk;
- (3) The HHS Secretary declares a public health emergency; or
- (4) The HHS Secretary determines that the moratorium is no longer necessary.

State Medicaid agencies also must comply with federally imposed moratoria. In addition, a state Medicaid agency, in consultation with the HHS Secretary, may impose its own temporary moratorium, numerical cap, or other limit designed to mitigate risk of fraud or abuse to the Medicaid program.⁴⁴ Before imposing a temporary moratorium, however, the state agency must determine that the action would not adversely affect beneficiary access to Medicaid services and provide the HHS Secretary with written notice of all details of the moratorium. Under both the Medicare and Medicaid rules, moratoria initially will be imposed for six months, though if necessary, the period can be further extended in six-month increments.⁴⁵

The Final Rule, in most respects, is consistent with the provisions in the Proposed Rule regarding moratoria. A few additions are worthy of note.⁴⁶ First, CMS added language to clarify that it will fully assess the impact of any temporary moratoria on beneficiary access to needed services. Second, CMS also added language to clarify that it will publish in the *Federal Register* both the imposition of a temporary moratorium, including the rationale and affected parties, and an announcement lifting the temporary moratorium. Third, CMS clarified that although the moratoria will apply to pending enrollment applications, those that have already been approved will not be impacted. Finally, CMS added the public health rationale for lifting a temporary moratorium at the request of public commenters.

Suspension of Payments

ACA Section 6402(h) permits the HHS Secretary to suspend payments to a provider or supplier pending investigation of a credible fraud allegation.⁴⁷ Under the Final Rule, CMS or a Medicare contractor may entirely or partially suspend payments to Medicare providers and suppliers if, after consultation with HHS OIG or DOJ, it identifies any “credible allegation of fraud.”⁴⁸ Even if no fraud is suspected, CMS or the Medicare contractor also may suspend payments upon receipt of reliable information that Medicare has overpaid for services or if the provider has failed to file a timely cost report.⁴⁹ In all instances, CMS plans to evaluate the need for payment suspension on a case-by-case basis.

Despite credible fraud allegations, CMS may choose not to impose a payment suspension for good cause. Good cause may exist when:

- (1) HHS OIG or other law enforcement officials specifically request that payments not be suspended to avoid jeopardizing an ongoing investigation;
- (2) Beneficiary access to services may be so compromised as to endanger life or health;
- (3) CMS or a Medicare contractor can implement other remedies that would more effectively protect Medicare funds; or
- (4) CMS determines that a payment suspension is not in the best interest of the Medicare program.

CMS must re-evaluate payment suspensions every 180 days. In doing so, CMS will determine whether good cause exists not to continue the suspension and will request certification from law enforcement officials that the investigation is ongoing. CMS or the Medicare contractor will continue to withhold payment from a provider or supplier until the amount of overpayment is determined or, in cases involving credible allegations of fraud, until the investigation has been completed.⁵⁰ Good cause not to continue a payment suspension also will develop if a payment suspension has been in effect for eighteen months and the investigation has not been resolved, except where HHS OIG is considering the case or DOJ requests in writing that the suspension be continued.⁵¹



Similar rules apply to state Medicaid agencies, which *must* suspend Medicaid payments once the agency determines there to be a credible allegation of fraud⁵² so long as no good cause⁵³ exists to avoid the suspension.⁵⁴ The state agency need not notify providers of its intent to suspend payment before taking action, but generally must send notice of the suspension within five days, though it may wait up to ninety days if law enforcement so requests.⁵⁵

Once the Medicaid agency seeks to initiate a payment suspension, it must make a written referral to the Medicaid fraud control unit (MFCU) or, if no formal unit exists, to an appropriate law enforcement agency. If the MFCU or other investigator declines to accept the referral, the agency must discontinue the payment suspension. The state Medicaid agency also must document notices of suspension, fraud referrals to law enforcement, quarterly certifications of continuing investigation, and notices of termination of the payment suspensions for a period of five years.⁵⁶ The agency must similarly document and retain records of instances when good cause prevented the imposition of a payment suspension. Finally, the agency must make an annual report to the HHS Secretary that details any payment suspensions, the nature of suspected fraud and outcome of resulting investigations, and any situations where good cause not to suspend payments existed in cases where there was reliable evidence of fraud.

The provisions regarding suspension of payments in the Final Rule are substantially similar to those published in the Proposed Rule, with a few minor additions. These include the good-cause provision for discontinuing payment suspensions that have been in effect for eighteen months and a statement clarifying that the Medicaid agency may continue a payment suspension even if the MFCU declines to accept a referral if the state has alternative federal or state authority to do so.

Compliance Programs

ACA Section 6102 requires nursing facilities to have effective compliance and ethics programs to detect fraud and promote quality of care. CMS solicited comments in the Proposed Rule regarding future requirements for ethics and compliance program provisions.⁵⁷ As indicated in the Proposed Rule, CMS did not publish a final rule on these requirements. It intends to do further rulemaking and will provide more specific proposals at a future date. Comments received during the comment period will be considered in constructing these requirements.

Effect of Other Program Terminations

ACA Section 6501 requires that a state Medicaid program terminate any provider whose participation in Medicare, Medicaid, or CHIP has been terminated in another state.⁵⁸ The ACA provisions emphasize that states must notify other states when a provider is terminated in order to prevent other states from becoming vulnerable to fraud or abuse. CMS is currently establishing a web-based portal through which states will be able to easily access informa-

tion about terminated providers.⁵⁹ CMS requests that states report terminations monthly in order to help other programs protect themselves from increased risk. State law will dictate when terminated providers are eligible to seek re-enrollment.⁶⁰

Under the Final Rule, state Medicaid agencies must deny or terminate the enrollment of any provider that is terminated from the Medicare program or from another state's CHIP or Medicaid program on or after January 1, 2011, unless the agency provides a written determination that termination or denial is not in the best interests of the state's Medicaid program.⁶¹ In order for this requirement to apply, however, the program termination must be "for cause," rather than based on a voluntary action by the provider or supplier.⁶² To be considered "terminated," the program must have taken action to revoke the provider, supplier, or eligible professional's billing privileges, and the provider must have exhausted all appeal rights or let the timeline for appeal expire.⁶³

The provisions in the Final Rule are substantially similar to those in the Proposed Rule. The only addition was a clarification that the requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had billing privileges revoked for cause, which the Final Rule states may include, but is not limited to fraud, integrity, or quality.⁶⁴

1 Pub. L. No. 111-148 (eff. Mar. 23, 2010), as amended by Pub. L. No. 111-152 (eff. Mar. 30, 2010).

2 76 Fed. Reg. 5862 (Final Rule, Feb. 2, 2011).

3 76 Fed. Reg. at 5865 - 5907 (to be codified at 42 C.F.R. § 424.518 for Medicare providers and suppliers; 42 C.F.R. § 455.400 *et seq.* for Medicaid providers; and 42 C.F.R. § 457.990 for CHIP providers).

4 76 Fed. Reg. at 5891.

5 76 Fed. Reg. at 5883-85.

6 *Id.* at 5884.

7 *Id.* at 5884-85.

8 "Limited" risk category also includes histocompatibility laboratories; Indian health service facilities; mammography screening centers; organ procurement organizations; mass immunization roster billers; religious nonmedical health-care institutions; rural health clinics; radiation therapy centers; competitive acquisition program/Part B vendors; and dentists ;and public or government-owned or affiliated ambulance services suppliers.

9 "Moderate" risk category also includes community mental health centers; and nonpublic, nongovernment owned or affiliated ambulance services suppliers.

10 *Id.* at 5880.

11 *Id.* at 5876.

12 75 Fed. Reg. 58204, 58212 (Proposed Rule, Sep. 23, 2010) (codified at 42 C.F.R. § 424.518(c)(3)).

13 76 Fed. Reg. at 5877, 5894.

14 *Id.* at 5877.

15 *Id.* at 5889.

16 *Id.* at 5872, 5876. CMS continues to seek guidance regarding certain aspects of the fingerprinting requirement.

17 *Id.* at 5879.

18 *Id.* at 5890.

19 *Id.* at 5882 (CMS eliminated the following individuals from the fingerprint-based criminal background checks: officers, directors, and managing employees—to the extent that they do not have a 5% or greater ownership interest.); see 42 C.F.R. §§ 455.434(b)(2); 457.990 (CMS also applied the change to Medicaid and CHIP).

20 *Id.* at 5875.

21 42 C.F.R. § 424.515(e).

22 76 Fed. Reg. at 5895.

23 42 C.F.R. § 455.450(a).

24 *Id.* § 455.450(b).

25 *Id.* § 455.450(c).

26 76 Fed. Reg. at 5895.

27 *Id.* at 5895-96.

28 *Id.* at 5896.

29 42 C.F.R. §§ 455.414; 457.990.

30 76 Fed. Reg. at 5901.

31 *Id.* at 5904.

32 42 C.F.R. § 424.514.

33 *Id.* § 424.502.

34 76 Fed. Reg. at 5915.

35 *Id.* at 5912-13.

36 42 C.F.R. § 424.514(d)(2)(v).

37 76 Fed. Reg. at 5916.

38 *Id.*

39 *Id.* at 5917.

40 *Id.* at 5916.

41 *Id.* at 5917.

42 *Id.* at 5965 (to be codified at 42 C.F.R. § 424.570). Temporary moratoria will not apply to changes in practice location, ownership, or provider or supplier information. They also will not apply to enrollment applications that have been approved, but not yet formally entered into the system.

43 Examples of potential trends include a highly disproportionate number of providers or suppliers relative to the number of beneficiaries in an area or a rapid increase in enrollment applications in a particular category. *Id.*

44 *Id.* at 5970 (to be codified at 42 C.F.R. § 455.470).

45 *Id.*; 76 Fed. Reg. 5965 (to be codified at 42 C.F.R. § 424.570).

46 *Id.* at 5928.

47 *Id.*

48 *Id.* at 5961 (to be codified at 42 C.F.R. § 405.371). A "credible allegation of fraud" may come from any source, including, but not limited to: (1) fraud hotline complaints; (2) claims data mining; (3) patterns identified through audits, false claims cases, or law enforcement investigations. *Id.* (to be codified at 42 C.F.R. § 405.305). To be credible, the allegation must have sufficient "indicia of reliability." *Id.* at 5961 (to be codified at 42 C.F.R. § 405.371).

49 *Id.* at 5961-62 (to be codified at 42 C.F.R. § 405.371).

50 *Id.* (to be codified at 42 C.F.R. § 405.370). An investigation will be considered resolved when legal action is terminated by settlement, judgment, or dismissal or when the case is dropped because of insufficient evidence. *Id.*

51 *Id.* at 5961 (to be codified at 42 C.F.R. § 405.370(b)(3)).

52 CMS did not set forth a definition of what constitutes a "credible allegation of fraud" for purposes of the Medicaid requirement, asserting that states instead should retain the flexibility to determine their own definitions consistent with state law. *Id.* at 5935.

53 The good-cause provisions are substantially similar to those under the Medicare Rule. *Id.* at 5966-67 (to be codified at 42 C.F.R. § 455.23).

54 *Id.* at 5966.

55 Notice must: (1) state that payments are being suspended in accordance with the CMS rules; (2) set forth the general allegations supporting the suspension; (3) state that the suspension is temporary; (4) specify the types of claims or business units for which the suspension is effective; (5) inform the provider of the right to submit written evidence to the state Medicaid agency; and (6) notify the provider of its right to the administrative appeals process and the applicable state law governing that process.

56 76 Fed. Reg. at 5967 (to be codified at 42 C.F.R. § 455.23).

57 *Id.* at 5942.

58 *Id.* at 5943.

59 *Id.* at 5944.

60 *Id.* at 5946.

61 *Id.* at 5968 (to be codified at 42 C.F.R. § 455.416). A provider's enrollment may also be terminated or denied if CMS or the state agency determines that the provider has falsified any of the information on the application or if either entity is unable to verify the applicant's identity. *Id.* at 5969 (to be codified at 42 C.F.R. § 455.416).

62 *Id.* If voluntary action is taken to avoid a sanction, however, the termination provision does apply.

63 *Id.* at 5967 (to be codified at 42 C.F.R. § 455.101).

64 *Id.* at 5946 (to be codified at 42 C.F.R. § 455.101(3)).