

**List of Subjects****42 CFR Part 405**

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

**42 CFR Part 424**

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

**42 CFR Part 438**

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

**42 CFR Part 447**

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

**42 CFR Part 455**

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, and Reporting and recordkeeping requirements.

**42 CFR Part 457**

Administrative practice and procedure, Grant programs—health, Health insurance, and Reporting and recordkeeping requirements.

**42 CFR Part 498**

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 1007**

Administrative practice and procedure, Fraud, Grant programs—health, Medicaid, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapters IV and V as set forth below:

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

1. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

**Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans**

2. The authority citation for subpart C is revised to read as follows:

**Authority:** Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

3. In subpart C, remove the phrase “intermediary or carrier” and add the phrase “Medicare contractor” in its place.

4. Section 405.370 is amended as follows:

A. In paragraph (a), adding the definitions of “Credible allegation of fraud,” “Medicare contractor,” and “Resolution of an investigation” in alphabetical order.

B. In paragraph (a), revising the definitions of “Offset,” “Recoupment,” and “Suspension of payment”.

The additions and revisions read as follows:

**§ 405.370 Definitions.**

(a) \* \* \*  
*Credible allegation of fraud.* A credible allegation of fraud is an allegation from any source, including but not limited to the following:

- (1) Fraud hotline complaints.
- (2) Claims data mining.
- (3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

*Medicare contractor.* Unless the context otherwise requires, includes, but is not limited to the any of following:

- (1) A fiscal intermediary.
- (2) A carrier.
- (3) Program safeguard contractor.
- (4) Zone program integrity contractor.
- (5) Part A/Part B Medicare administrative contractor.

*Offset.* The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by HCFA).

*Recoupment.* The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

*Resolution of an investigation.* An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement,

judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

*Suspension of payment.* The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

5. Section 405.371 is revised to read as follows:

**§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.**

(a) *General rules.* Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be—

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination;

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments; or

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(b) *Good cause not to suspend payments.* CMS may find that good cause exists not to suspend payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(1) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(2) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(3) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare

funds than would implementing a payment suspension; or  
(4) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program. CMS will—

(i) Evaluate whether there is good cause not to continue a suspension of payments under this section every 180 days after the initiation of a suspension based on credible allegations of fraud; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation warranting continuation of the suspension.

(c) Steps necessary for suspension of payment, offset, and recoupment.

(1) Except as provided in paragraph (d) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) Suspension of payment in the case of unfiled cost reports. (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

6. Section 405.372 is amended as follows:

A. Remove the phrase "intermediary, carrier" wherever it appears and adding the phrase "Medicare contractor" in its place.

B. Revising paragraphs (a)(4) and (d)(3).

C. In paragraph (e), removing the cross-reference "§ 405.371(b)" and adding the cross-reference "§ 405.371(a)".

§ 405.372 Proceeding for suspension of payment.

(a) \* \* \*

(4) Fraud. If the intended suspension of payment involves credible allegations of fraud under § 405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

\* \* \* \* \*

(d) \* \* \*

(3) Exceptions to the time limits. (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in (d)(1) and (d)(2) do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

\* \* \* \* \*

PART 424—CONDITIONS FOR MEDICARE PAYMENT

7. The authority of citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

8. Section 424.57 is amended by revising paragraph (e) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

\* \* \* \* \*

(e) Revalidation of billing privileges. A supplier must revalidate its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last revalidation.)

\* \* \* \* \*

9. Section 424.502 is amended by adding the definition of "Institutional provider" in alphabetical order to read as follows:

§ 424.502 Definitions.

\* \* \* \* \*

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and nonphysician practitioner organizations), CMS-855S or associated Internet-based PECOS enrollment application.

\* \* \* \* \*

10. Section 424.514 is added to read as follows:

§ 424.514 Application fee.

(a) Application fee requirements for prospective institutional providers.

Beginning on or after March 23, 2011, prospective institutional providers who are submitting an initial application or an application to establish a new practice location must submit either of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) Application fee requirements for revalidating institutional providers.

Beginning March 23, 2011, institutional providers that are subject to CMS revalidation efforts must submit either of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) Hardship exception for disaster areas. CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act) should receive an exception to the application fee.

(d) Application fee. The application fee and associated requirements are as follows:

(1) For 2010, \$500.00.

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a Medicare contractor revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable;

(vi) Must be resubmitted with an enrollment application that was previously denied or rejected; and

(vii) Must be able to be deposited into a Government-owned account and credited to the United States Treasury.

(e) Denial or revocation based on application fee. A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier

based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor must—

(1) Reject an enrollment application from a provider or supplier that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled provider or supplier or deny the application to enroll and establish billing privileges in the case of providers or suppliers not currently enrolled, with the exceptions noted in § 424.514(b), if an enrollment application, including revalidation, is received that is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to approve or disapprove a hardship exception request.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using § 405.874.

11. Section 424.515 is amended by adding a new paragraph (e) to read as follows:

**§ 424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.**

\* \* \* \* \*

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at § 424.518.

12. Section 424.518 is added to read as follows:

**§ 424.518 Screening categories 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 categorical risk level of “limited,” “moderate,” or “high.”

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

- (i) Physician or nonphysician practitioners and medical groups or clinics.
- (ii) Ambulatory surgical centers.
- (iii) End-stage renal disease facilities.
- (iv) Federally qualified health centers.
- (v) Histocompatibility laboratories.
- (vi) Hospitals including critical access hospitals.
- (vii) Indian Health Service facilities.
- (viii) Mammography screening centers.
- (ix) Organ procurement organizations.
- (x) Mass immunization roster billers.
- (xi) Portable x-ray suppliers.
- (xii) Religious non-medical health care institutions.
- (xiii) Rural health clinics.
- (xiv) Radiation therapy centers.
- (xv) Public or government-owned or -affiliated ambulance services suppliers.
- (xvi) Skilled nursing facilities.

(2) *Limited categorical risk: Screening requirements.* When CMS designates a provider or supplier as a “limited” categorical level of risk or the provider or supplier is publicly traded on the New York Stock Exchange (NYSE) or the National Association of Securities Dealers Automated Quotation System (NASDAQ), the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets any applicable Federal regulations, or State requirement 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 State 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 types.* CMS has designated the following providers and suppliers as “moderate” categorical risk:

- (i) The following prospective providers and suppliers that are not publicly-traded on the NYSE or NASDAQ:
  - (A) Community mental health centers.
  - (B) Comprehensive outpatient rehabilitation facilities.
  - (C) Hospice organizations.
  - (D) Independent diagnostic testing facilities.
  - (E) Nongovernment-owned or -affiliated ambulance service suppliers.
  - (F) Independent clinical laboratories.
- (ii) The following revalidating providers and suppliers that are not publicly-traded on the NYSE or NASDAQ:
  - (A) Community mental health centers.
  - (B) Comprehensive outpatient rehabilitation facilities.
  - (C) Home health agencies.
  - (D) Hospice organizations.
  - (E) Independent diagnostic testing facilities.
  - (F) Nongovernment-owned or -affiliated ambulance service suppliers.
  - (G) Independent clinical laboratories.

(iii) Re-enrolling suppliers of DMEPOS that are not publicly-traded on the NYSE or NASDAQ.

(2) *Moderate categorical risk: 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 types.* CMS has designated home health agencies or suppliers of DMEPOS that are not publicly-traded on the NYSE or NASDAQ as “high” categorical risk:

- (A) Prospective providers or suppliers enrolling in the Medicare program.
- (B) Providers or suppliers establishing a new practice location.

(2) *High categorical risk: 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) Conducts a criminal background check; and

(B) Requires the submission of sets of fingerprints using the FD-258 standard fingerprint card.

(3) *Adjustment in the categorical risk.* CMS adjusts the categorical risk level from "limited" or "moderate" to "high" if any of the following occur:

(i) CMS or its Medicare contractor has information from a physician or nonphysician practitioner that another individual is using their identity within the Medicare program.

(ii) CMS imposes a payment suspension on a provider or supplier.

(iii) The provider or supplier—

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

(B) Had its billing privileges denied or 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.

(iv) CMS lifts a temporary moratorium for a particular provider or supplier type.

(d) *Fingerprinting requirements.* An individual subject to the fingerprints requirements specified in paragraph (c)(2)(ii)(B) of this section—

(1) Must submit a set of fingerprints using the FD-258 standard fingerprint card—

(i) With the Medicare enrollment application; or

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

(2) Who does not submit a set of fingerprints in accordance with paragraph (d)(1) of this section will have his or her Medicare billing privileges—

(i) Denied under § 424.530(a)(1); or

(ii) Revoked under § 424.535(a)(1).

13. Section 424.525 is amended by revising paragraph (a) as follows:

A. Revising paragraph (a) introductory text.

B. Adding a new paragraph (a)(3).

The revision and addition read as follows:

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

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

\* \* \* \* \*

(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.

\* \* \* \* \*

14. Section 424.530 is amended by adding new paragraphs (a)(8) and (a)(9) to read as follows:

**§ 424.530 Denial of enrollment in the Medicare program.**

(a) \* \* \*

(8) *Application fee/hardship exception.* An institutional provider or supplier's "hardship exception" request is not granted.

(9) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.

\* \* \* \* \*

15. Section 424.535 is amended as follows:

A. Revising paragraph (a)(6).

B. Adding a new paragraph (a)(11).

C. Revising paragraph (c).

**§ 424.535 Revocation of enrollment billing and billing privileges in the Medicare program.**

(a) \* \* \*

(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or "hardship exception" request that meets the requirements set forth in § 424.514 with the Medicare revalidation application; or

(B) The "hardship exception" is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) The Medicare contractor is not able to either of the following:

(1) Deposit the full application amount into a government-owned account.

(2) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

\* \* \* \* \*

(11) *Medicaid termination.* Medicaid billing privileges are terminated or revoked by a State Medicaid Agency, not withstanding anything to the contrary in this section, must not apply unless and until a provider or supplier has exhausted all applicable appeal rights.

\* \* \* \* \*

(c) *Reapplying after revocation.* (1) After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar.

(2) The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.

(3) CMS may waive the re-enrollment bar if it has revoked a provider or supplier under § 424.535(a)(6)(i) based upon the failure of the provider or supplier to submit an application fee or a hardship exception request with an enrollment application upon revalidation.

\* \* \* \* \*

16. A new § 424.570 is added to read as follows:

**§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.**

(a) *Temporary moratoria.* CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area or nationally if—

(1) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a—

(i) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(ii) Rapid increase in enrollment applications within a category;

(2) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(3) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(4) CMS, in consultation with the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(i) A particular provider or supplier type.

(ii) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS may lift a temporary moratorium in a specific geographic area or nationally if—

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act); or

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability;

(3) In the judgment of the Secretary, the moratorium is no longer needed.

**PART 438—MANAGED CARE**

17. The authority for part 438 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

18. Section 438.6 is amended by adding new paragraph (c)(5)(vi).

**§ 438.6 Contract requirements.**

\* \* \* \* \*

(c) \* \* \*

(5) \* \* \*

(vi) Contracts with MCOs, PIHPs, and PAHPs must require all ordering or referring network providers to be enrolled as participating providers with the Medicaid program.

\* \* \* \* \*

**PART 447—PAYMENT FOR SERVICES**

19. The authority citation for part 447 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

20. A new § 447.90 is added to read as follows:

**§ 447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.**

(a) *Basis and purpose.* This section implements section 1903(i)(2)(C) of the Act which prohibits payment of FFP with respect to items or services furnished by an individual or entity with respect to which there is pending an investigation of a credible allegation of fraud except under specified circumstances.

(b) *Denial of FFP.* No FFP is available with respect to any amount expended for an item or service furnished by any individual or entity to whom a State has failed to suspend payments in whole or part as required by § 455.23 unless:

(1) The item or service is furnished as an emergency item or service, but not including items or services furnished in an emergency room of a hospital; or

(2) The State determines and documents that good cause as specified at § 455.23(e) or (f) exists not to suspend such payments, to suspend payments only in part, or to discontinue a previously imposed payment suspension.

**PART 455—PROGRAM INTEGRITY: MEDICAID**

21. The authority citation for part 455 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

22. Section 455.2 is amended by adding the definition of “Credible allegation of fraud” to read as follows:

**§ 455.2 Definitions.**

\* \* \* \* \*

*Credible allegation of fraud.* A credible allegation of fraud is an allegation from any source, including but not limited to the following:

(1) Fraud hotline complaints.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

\* \* \* \* \*

23. Section 455.23 is revised to read as follows:

**§ 455.23 Suspension of payments in cases of fraud.**

(a) *Basis for suspension.* (1) The State Medicaid agency must suspend all Medicaid payments to a provider when there is pending an investigation of a credible allegation of fraud under the Medicaid program against an individual or entity unless it has good cause to not

suspend payments or to suspend payment only in part.

(2) The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments.

(3) A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of suspension.* (1) The State agency must send notice of its suspension of program payments within the following timeframes:

(i) Five days of taking such action unless requested in writing by a law enforcement agency to temporarily withhold such notice.

(ii) Thirty days if requested by law enforcement in writing to delay sending such notice, which request for delay may be renewed in writing up to twice and in no event may exceed 90 days.

(2) The notice must include or address all of the following:

(i) State that payments are being suspended in accordance with this provision.

(ii) Set forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.

(iii) State that the suspension is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which suspension will be terminated.

(iv) Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.

(v) Inform the provider of the right to submit written evidence for consideration by State Medicaid Agency.

(c) *Duration of suspension.* (1) All suspension of payment actions under this section will be temporary and will not continue after either of the following:

(i) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider.

(ii) Legal proceedings related to the provider’s alleged fraud are completed.

(2) A State must document in writing the termination of a suspension including, where applicable and appropriate, any appeal rights available to a provider.

(d) *Referrals to the Medicaid fraud control unit.* (1) Whenever a State Medicaid agency investigation leads to the initiation of a payment suspension in whole or part, the State Medicaid Agency must make a fraud referral to either of the following:

(i) To a Medicaid fraud control unit established and certified under part 1007 of this Title; or

(ii) In States with no certified Medicaid fraud control unit, to an appropriate law enforcement agency.

(2) The fraud referral made under paragraph (d)(1) of this section must meet all of the following requirements:

(i) Be made in writing and provided to the Medicaid fraud control unit not later than the next business day after the suspension is enacted.

(ii) Conform to fraud referral performance standards issued by the Secretary.

(3)(i) If the Medicaid fraud control unit or other law enforcement agency accepts the fraud referral for investigation, the payment suspension may be continued until such time as the investigation and any associated enforcement proceedings are completed.

(ii) On a quarterly basis, the State must request a certification from the Medicaid fraud control unit or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation thus warranting continuation of the suspension.

(4) If the Medicaid fraud control unit or other law enforcement agency declines to accept the fraud referral for investigation the payment suspension must be discontinued unless the State Medicaid agency makes a fraud referral to another law enforcement agency. In that situation, the provisions of paragraph (d)(3) of this section apply equally to that referral as well.

(5) A State's decision to exercise the good cause exceptions in paragraphs (e) or (f) of this section not to suspend payments or to suspend payments only in part does not relieve the State of the obligation to refer any credible allegation of fraud as provided in paragraph (d)(1) of this section.

(e) *Good cause not to suspend payments.* A State may find that good cause exists not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation.

(2) Other available remedies implemented by the State more effectively or quickly protect Medicaid funds.

(3) The State determines that payment suspension is not in the best interests of the Medicaid program.

(4) Recipient access to items or services would be jeopardized by a payment suspension because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.

(5) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(f) *Good cause to suspend payment only in part.* A State may find that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Recipient access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area;

(2) The State determines that payment suspension only in part is in the best interests of the Medicaid program.

(3)(i) The credible allegation focuses solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider; and

(ii) The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.

(4) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(g) *Documentation and record retention.* State Medicaid agencies must meet the following requirements:

(1) Maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that was imposed in whole or part, including the following:

(i) All notices of suspension of payment in whole or part.

(ii) All fraud referrals to the Medicaid fraud control unit or other law enforcement agency.

(iii) All quarterly certifications of continuing investigation status by law enforcement.

(iv) All notices documenting the termination of a suspension.

(2)(i) Maintain for a minimum of 5 years from the date of issuance all materials documenting each instance where a payment suspension was not imposed, imposed only in part, or discontinued for good cause.

(ii) This type of documentation must include, at a minimum, detailed information on the basis for the existence of the good cause not to suspend payments, to suspend payments only in part, or to discontinue a payment suspension and, where applicable, must specify how long the State anticipates such good cause will exist.

(3) Annually report to the Secretary summary information on each of the following:

(i) Suspension of payment, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension.

(ii) Situation in which the State determined good cause existed to not suspend payments, to suspend payments only in part, or to discontinue a payment suspension as described in this section, including describing the nature of the suspected fraud and the nature of the good cause.

24. Section 455.101 is amended as follows:

A. Adding introductory text.

B. Adding the definitions of "Health insuring organization (HIO)," "Managed care entity (MCE)," "Prepaid ambulatory health plan (PAHP)," "Primary care case manager (PCCM)," "Prepaid inpatient health plan (PIHP)," and "Termination" in alphabetical order to read as follows:

**§ 455.101 Definitions.**

For the purposes of this part—

\* \* \* \* \*  
*Health insuring organization (HIO)* has the meaning specified in § 438.2.

\* \* \* \* \*  
*Managed care entity (MCE)* means managed care organizations (MCOs), PIHPs, PAHPs, PCCMs, and HIOs.

\* \* \* \* \*  
*Prepaid ambulatory health plan (PAHP)* has the meaning specified in § 438.2.

\* \* \* \* \*  
*Primary care case manager (PCCM)* has the meaning specified in § 438.2.

\* \* \* \* \*  
*Prepaid inpatient health plan (PIHP)* has the meaning specified in § 438.2.

**Termination means—**

## (1) For a—

(i) Medicaid provider, a State Medicaid program has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights; and

(ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges.

(2)(i) In both programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary.

(ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

25. Section 455.104 is revised to read as follows:

**§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.**

(a) *Who must provide disclosures.* The Medicaid agency must obtain disclosures from disclosing entities, fiscal agents, and managed care entities.

(b) *What disclosures must be provided.* The Medicaid agency must require that disclosing entities, fiscal agents, and managed care entities provide the following disclosures:

(1)(i) The name and address of any person (individual or corporation).

(ii) Date of birth and social security number (in the case of an individual).

(iii) Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

(2) Whether the person (individual or corporation) with ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another as a spouse, parent, child, or sibling.

(3) The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

(4) The name and address of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(c) *When the disclosures must be provided—*(1) *Disclosures from*

*providers.* Disclosure from any provider is due at any of the following times:

(i) Submits the provider application.

(ii) Executes the provider agreement.

(iii) Re-enrolls under § 455.12.

(iv) Within 35 days after any change in ownership of the disclosing entity.

(2) *Disclosures from fiscal agents.*

Disclosures from fiscal agents are due at any of the following times:

(i) That the fiscal agent submits the proposal in accordance with the State's procurement process.

(ii) The fiscal agent executes the contract with the State

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the fiscal agent.

(3) *Disclosures from managed care entities.* Disclosures from managed care entities (MCOs, PIHPs, PAHPs, and HIOs), except PCCMs are due at any of the following times:

(i) The managed care entity submits the proposal in accordance with the State's procurement process.

(ii) The managed care entity executes the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the managed care entity.

(4) *Disclosures from PCCMs.* PCCMs will comply with disclosure requirements under (c)(1) of this section.

(d) *To whom must the disclosures be provided.* All disclosures must be provided to the Medicaid agency.

(e) *Consequences for failure to provide required disclosures.* Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by this section.

26. A new subpart E is added to part 455 to read as follows:

**Subpart E—Provider Screening and Enrollment**

Sec.	
455.400	Purpose.
455.405	State plan requirements.
455.410	Enrollment and screening of providers.
455.412	Verification of provider licenses.
455.414	Reenrollment.
455.416	Termination or denial of enrollment.
455.418	Deactivation of provider enrollment.
455.420	Reactivation of provider enrollment.
455.422	Appeal rights.
455.432	Site visits.
455.434	Criminal background checks.
455.436	Federal database checks.
455.440	National Provider Identifier.

455.450 Screening categories for Medicaid providers.

455.452 Other State screening methods.

455.460 Application fee.

455.470 Temporary moratoria.

**Subpart E—Provider Screening and Enrollment**

**§ 455.400 Purpose.**

This subpart implements sections 1866(j), 1902(a)(39), 1902(a)(77), and 1902(a)(78) of the Social Security Act. It sets forth State plan requirements regarding the following:

(a) Provider screening and enrollment requirements.

(b) Fees associated with provider screening.

(c) Temporary moratoria on enrollment of providers.

**§ 455.405 State plan requirements.**

A State plan must provide that the requirements of § 455.410 through § 455.450 and § 455.470 are met.

**§ 455.410 Enrollment and screening of providers.**

(a) The State Medicaid agency must require all enrolled providers to be screened under to this subpart.

(b) The State Medicaid agency must require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

(c) The State Medicaid agency may rely on the results of the provider screening performed by any of the following:

(1) Medicare contractors.

(2) Medicaid agencies or Children's Health Insurance Programs of other States.

**§ 455.412 Verification of provider licenses.**

The State Medicaid agency must—

(a) Have a method for verifying that any provider purporting to be licensed in accordance with the laws of any State is licensed by such State.

(b) Confirm that the provider's license has not expired and that there are no current limitations on the provider's license.

**§ 455.414 Reenrollment.**

The State Medicaid agency must screen all providers regardless of provider type at least every 5 years.

**§ 455.416 Termination or denial of enrollment.**

The State Medicaid agency—

(a) Must terminate the enrollment of any provider where any person with an ownership or control interest or who is an agent or managing employee of the provider did not submit timely and

accurate information and cooperate with any screening methods required under this subpart.

(b) Must deny enrollment or terminate the enrollment of any provider where any person with an ownership or control interest or who is an agent or managing employee of the provider has been convicted of a criminal offense related to that person's involvement with the Medicare, Medicaid, or title XXI program in the last 10 years, unless the State Medicaid agency determines that denial or termination of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act or under the Medicaid program or CHIP of any other State.

(d) Must terminate the provider's enrollment or deny enrollment of the provider if the provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit timely or accurate information, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(e) Must terminate or deny enrollment if the provider, or any person with an ownership or control interest or who is an agent or managing employee of the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency within 30 days of a CMS or a State Medicaid agency request, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(f) Must terminate or deny enrollment if the provider fails to permit access to provider locations for any site visits under § 455.432, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(g) May terminate or deny the provider's enrollment if CMS or the State Medicaid agency—

(1) Determines that the provider has falsified any information provided on the application; or

(2) Cannot verify the identity of any provider applicant.

**§ 455.418 Deactivation of provider enrollment.**

The State Medicaid Agency must deactivate any provider enrollment number that has been inactive as a result of having submitted no claims or making no referrals that resulted in Medicaid claims for a period of 12 months.

**§ 455.420 Reactivation of provider enrollment.**

After deactivation of a provider enrollment number for any reason, before the provider's enrollment may be reactivated, the State Medicaid agency must re-screen the provider and require payment of associated provider application fees under § 455.460.

**§ 455.422 Appeal rights.**

The State Medicaid agency must give providers terminated under § 455.416, and with respect to enrollment, any appeal rights available under procedures established by State law or rule.

**§ 455.432 Site visits.**

The State Medicaid agency—  
(a) Must conduct pre-enrollment and post-enrollment site visits of providers who are designated as "moderate" or "high" categorical risks to the Medicaid program. The purpose of the site visit will be to verify that the information submitted to the State Medicaid agency is accurate and to determine compliance with Federal and State enrollment requirements.

(b) Must require any enrolled provider to permit CMS, its agents, its designated contractors, or the State Medicaid agency to conduct unannounced on-site inspections of any and all provider locations.

**§ 455.434 Criminal background checks.**

The State Medicaid agency—  
(a) As a condition of enrollment, must require providers to consent to criminal background checks including fingerprinting when required to do so under State law or by the level of risk determined for that category of provider.

(b) Must establish categorical risk levels for providers and provider types who pose an increased financial risk of fraud, waste or abuse to the Medicaid program.

(1) Upon the State Medicaid agency determining that a provider, or a person with an ownership or control interest or who is an agent or managing employee of the provider, meets the State Medicaid agency's criteria hereunder for criminal background checks as a "high"

risk to the Medicaid program, the State Medicaid agency will require that each such provider or person submit fingerprints.

(2) The State Medicaid agency must require a provider, or any person with an ownership or control interest or who is an agent or managing employee of the provider, to submit two sets of fingerprints, in a form and manner to be determined by the State Medicaid agency, within 30 days upon request from CMS or the State Medicaid agency.

**§ 455.436 Federal database checks.**

The State Medicaid agency must do all of the following:

(a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

(b) Check applicable databases maintained by the Social Security Administration, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.

(c)(1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and

(2) Check the LEIE and EPLS no less frequently than monthly.

**§ 455.440 National Provider Identifier.**

The State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

**§ 455.450 Screening categories for Medicaid providers.**

A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment request based on a categorical risk level of "limited," "moderate," or "high." If a provider could fit within more than one risk category described in this section, the risk category with the highest level of screening is applicable.

(a) *Screening for providers designated as limited categorical risk.* When the State Medicaid agency designates a provider as a "limited" categorical risk or the provider is publicly traded on the New York Stock Exchange (NYSE) or National Association of Securities Dealers Automated Quotation System (NASDAQ), the State Medicaid agency must do all of the following:

(1) Verify that a provider meets any applicable Federal regulations, or State requirements for the provider type prior to making an enrollment determination.

(2) Conduct license verifications, including State licensure verifications in States other than where the provider is enrolling, in accordance with § 455.412.

(3) Conduct database checks on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type, in accordance with § 455.436.

(b) *Screening for providers designated as moderate categorical risk.* When the State Medicaid agency designates a provider as a "moderate" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" screening requirements described in paragraph (a) of this section.

(2) Conduct on-site visits in accordance with § 455.432.

(c) *Screening for providers designated as high categorical risk.* When the State Medicaid agency designates a provider as a "high" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" and "moderate" screening requirements described in paragraphs (a) and (b) of this section.

(2)(i) Conduct a criminal background check; or

(ii) Require the submission of set of fingerprints in accordance with § 455.434.

(d) *Denial or termination of enrollment.* A provider, or any person with an ownership or control interest or who is an agent or managing employee of the provider, who is required by the State Medicaid agency or CMS to submit a set of fingerprints and fails to do so may have its—

(1) Application denied under § 455.434; or

(2) Enrollment terminated under § 455.416.

(e) *Adjustment of risk level.* The State agency must adjust the categorical risk level from "limited" or "moderate" to "high" when any of the following occurs:

(1) The State Medicaid agency imposes a payment suspension on a provider based on credible allegation of fraud, waste or abuse, the provider has an existing Medicaid overpayment, or the provider has been excluded by the OIG or another State's Medicaid program within the previous 10 years.

(2) The State Medicaid agency or CMS lifts a temporary moratorium for a particular provider type.

#### § 455.452 Other State screening methods.

Nothing herein must restrict the State Medicaid agency from establishing provider screening methods in addition to or more stringent than those required by this subpart.

#### § 455.460 Application fee.

(a) Beginning on or after March 23, 2011, States may collect the applicable application fee prior to executing a provider agreement from prospective or re-enrolling providers other than—

(1) Individual physicians or nonphysician practitioners.

(2) (i) Providers who are enrolled in either—

(A) Title XVIII of the Act; or  
(B) Another State's title XIX or XXI plan.

(ii) Providers that have paid the applicable application fee to—

(A) A Medicare contractor; or  
(B) Another State.

(b) If the fees collected by a State agency in accordance with paragraph (a) of this section exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government.

#### § 455.470 Temporary moratoria.

(a)(1) The Secretary consults with any affected State Medicaid agency regarding imposition of temporary moratoria on enrollment of new providers or provider types prior to imposition of the moratoria, in accordance with § 424.570.

(2) The State Medicaid agency will impose temporary moratoria on enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program.

(3)(i) The State Medicaid agency is not required to impose such a moratorium if the State Medicaid agency determines that imposition of a temporary moratorium would adversely affect beneficiaries' access to medical assistance.

(ii) If a State Medicaid agency makes such a determination, the State Medicaid agency must notify the Secretary in writing.

(b)(1) A State Medicaid agency may impose temporary moratoria on enrollment of new providers, or impose numerical caps or other limits that the State Medicaid agency identifies as having a significant potential for fraud, waste, or abuse and that the Secretary has identified as being at "high" risk for fraud, waste, or abuse.

(2) Before implementing the moratoria, caps, or other limits, the State Medicaid agency must determine that its action would not adversely

impact beneficiaries' access to medical assistance.

(3) The State Medicaid agency must notify the Secretary in writing in the event the State Medicaid agency imposes such moratoria, including all details of the moratoria.

(c)(1) The State Medicaid agency must impose the moratorium for an initial period of 6 months.

(2) If the State Medicaid agency determines that it is necessary, the State Medicaid agency may extend the moratorium in 6-month increments.

(3) Each time, the State Medicaid agency must document in writing the necessity for extending the moratorium.

### PART 457—ALLOTMENTS AND GRANTS TO STATES

27. The authority for part 457 continues to read as follows:

**Authority:** Section 1102 of the Social Security Act (42 U.S.C. 1302).

28. Section 457.900 is amended by adding a new paragraph (a)(2)(x) to read as follows:

#### § 457.900 Basis, scope and applicability.

(a) \* \* \*

(2) \* \* \*

(x) Sections 1902(a)(77) and 1902(ii) relating to provider and supplier screening, oversight, and reporting requirements.

\* \* \* \* \*

29. A new § 457.990 is added to subpart I to read as follows:

#### § 457.990 Provider and supplier screening, oversight and reporting requirements.

The following provisions and their corresponding regulations apply to a State under title XXI of the Act, in the same manner as these provisions and regulations apply to a State under title XIX of the Act:

(a) Part 455 Subpart E of this chapter.

(b) Sections 1902(a)(77) and 1902(ii) of the Act pertaining to provider and supplier screening, oversight, and reporting requirements.

### PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

30. The authority citation for part 498 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

31. Section 498.5 is amended by adding a new paragraph (l)(4) to read as follows:

\* \* \* \* \*

(l) \* \* \*

(4) *Scope of review.* For appeals of denials based on § 424.530(a)(9) related to temporary moratorium, the scope of review will be limited to whether the temporary moratoria applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review.

**PART 1007—STATE MEDICAID FRAUD CONTROL UNITS**

32. The authority for part 1007 continues to read as follows:

Authority: 42 U.S.C. 1320 and 1395hh.

33. Section 1007.9 is amended by adding paragraphs (e) through (g) to read as follows:

**§ 1007.9 Relationship to, and agreement with, the Medicaid agency.**

\* \* \* \* \*

(e)(1) The unit may refer any provider with respect to which there is pending an investigation of a credible allegation of fraud under the Medicaid program to the State Medicaid agency for payment suspension in whole or part under § 455.23.

(2) Referrals may be brief, but must be in writing and include sufficient information to allow the State Medicaid agency to identify the provider and to explain the credible allegations forming the grounds for the payment suspension.

(f) Any request by the unit to the State Medicaid agency to delay notification to the provider of a payment suspension under § 455.23 of this Title must be in writing.

(g) When the unit accepts or declines a case referred by the State Medicaid agency, the unit notifies the State Medicaid agency in writing of the acceptance or declination of the case.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 13, 2010.

**Donald Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: September 15, 2010.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2010-23579 Filed 9-17-10; 11:15 am]

BILLING CODE 4120-01-P