

The **RAP** Sheet

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—from a declaration of the American Bar Association

Healthcare Reform

CMS Publishes Proposed Rule to Implement Redistribution of Unused Residency Slots Under PPACA

In the healthcare reform legislation enacted earlier this year, Congress provided for a one-time reallocation of unused residency slots, effective July 1, 2011. On August 3, 2010, CMS published a proposed rule providing guidelines for the redistribution process. Although the proposed rule has not yet been finalized, there are several important deadlines in the proposal for which teaching hospitals should begin planning now . . .

Proposed Rule Implements Fraud Protection Steps for Provider Enrollment

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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. These changes included: . . .

Editor's Note:

On March 23, 2010, and March 30, 2010, President Obama signed into law the two companion pieces of legislation that comprise what is commonly referred to as "Healthcare Reform." In this edition of the *RAP Sheet*, two articles focus on pieces of Healthcare Reform. We expect to include at least one article on Healthcare Reform in future editions of the *RAP Sheet* as well.

Healthcare Reform Proposed Rule Implements Fraud Protection Steps for Provider Enrollment

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The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010¹ (collectively, 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. These changes included:

1. Establishing procedures under which more rigorous *screening* is conducted for providers and suppliers;
2. Requiring an *application fee* to be imposed on providers and suppliers;

3. Imposing temporary *moratoria* on enrollment of Medicare, Medicaid, and CHIP providers/suppliers;
4. *Suspending payments* pending credible allegations of fraud;
5. Establishing *compliance programs*; and
6. *Terminating provider participation under Medicaid and CHIP* if terminated under Medicare or another state Medicaid program or CHIP.

On September 23, 2010, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule² (Proposed Rule) to implement the above ACA provisions. This article summarizes the Proposed Rule, which vastly expands the ability of CMS and state agencies to monitor the enrollment of providers and suppliers in Medicare, Medicaid, and CHIP, and to combat fraud, waste, and abuse in those programs through a variety of new techniques. Comments to the Proposed Rule were due by November 16, 2010, and the final rule is expected to be released early this year.

Under the Proposed Rule, CMS develops three categories of providers according to the risk of fraud, waste, and abuse—limited, moderate, and high—which in turn affects the level of screening procedures an enrollee will undergo.³ As proposed, the new risk categories and the related enrollment screening procedures will be applicable to newly enrolling providers and suppliers on March 23, 2011, and to currently enrolled providers and suppliers beginning on March 23, 2012. Although CMS requested comments on what criteria should be considered in making assignments to the different risk categories, the Proposed Rule places providers and suppliers in the different risk categories and screening categories—see Figure 1.

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

Limited	Moderate	High
<ul style="list-style-type: none"> Physicians Non-physician practitioners 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 (ESRD) facilities Portable x-ray suppliers Others⁴ 	<ul style="list-style-type: none"> Comprehensive outpatient rehabilitation facilities (CORFs) Independent diagnostic testing facilities (IDTFs) Independent clinical laboratories Currently enrolled (re-validating) home health agencies Currently enrolled (re-validating) suppliers of DMEPOS Hospice organizations Others⁵ 	<ul style="list-style-type: none"> Newly enrolled home health agencies Newly enrolled suppliers of DMEPOS

CMS proposed to move providers and suppliers from a “limited” or “moderate” risk level to the “high” risk level if the following occurs:

- CMS has evidence from or concerning a physician or non-physician practitioner that another individual is using his/her identity within the Medicare program.
- 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 denied or 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.
- 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.⁶

CMS is considering comments on additional criteria that would justify a move from limited or moderate to a high risk category and vice versa.

The Proposed Rule modifies the level of screening depending on the risk category a provider or supplier is assigned—see Figure 2. Because of the expense and efficiencies involved, CMS proposed to allow states to rely on the results of the Medicare contractor’s screening to meet the provider screening requirements under Medicaid and CHIP. Similarly, state Medicaid agencies could rely on the results of sister state Medicaid programs and CHIP. For Medicaid-only or CHIP-only providers, CMS proposed that states follow the same screening procedures that CMS and its contractors follow with respect to Medicare providers and suppliers.

Application Fee

ACA Section 6401(a) requires the HHS Secretary to impose a fee on each “institutional provider of medical or other items or services or supplier” to cover costs of screening and to carry out screening and other program integrity efforts. “Institutional providers” include any healthcare provider that bills Medicare, Medicaid, or CHIP on a fee-for-service basis, with the exception of Part B medical groups or clinics, physician and non-physician practitioners who submit the CMS 855I to enroll in Medicare.⁸ Under the Proposed Rule, the \$500 application fee (adjusted yearly based on the CPI for all urban consumers) is nonrefundable and is required 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.⁹ 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.

Because CMS proposed that a state may rely on the results of the screening requirements for participation in a state Medicaid program or CHIP, CMS further proposed that 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.¹⁰

Providers or suppliers can apply for a hardship exemption to the enrollment fee by including a letter with the application.¹¹ CMS proposed that such hardship requests will be considered on a case-by-case basis, and provided one example that might support a request for hardship exception of a national public health emergency where a provider or supplier is enrolling for purposes of furnishing services required as a result of the national public health emergency situation.¹²

Temporary Moratoria on Enrollment

ACA Section 6401(a) provides that the HHS Secretary may impose a temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, if the HHS Secretary determines such moratoria are necessary to prevent or combat fraud, waste, or abuse. The Proposed Rule establishes that, for the enrollment of new Medicare providers and suppliers, CMS may impose a moratorium in six-month increments in situations where:

- (1) CMS identifies a trend that appears to be associated with a high risk of, or determines 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;
- (2) A state has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type; or
- (3) CMS, in consultation with OIG or U.S. Department of Justice, identifies a particular provider or supplier type or a particular geographic area as having a significant potential for fraud, waste, or abuse.¹³

Figure 2—Comparing Current Screening Requirements and Proposed Screening Requirements

TYPE OF SCREENING REQUIRED (Medicare) ⁷	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 • 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
Criminal background check—owners, authorized or delegated officials, and managing employees				x
Fingerprinting—owners, authorized or delegated officials, and managing employees				x

Because such decisions are by statute not subject to judicial review, CMS proposed that a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board level of review.

CMS believes that imposing the moratoria will provide time to review and consider additional programmatic initiatives and develop additional regulations. The moratoria would be limited to:

- (1) Newly enrolling providers and suppliers; and
- (2) The establishment of new practice locations, not a change of practice locations.

The moratoria would not apply in situations involving changes in ownership of existing providers or suppliers, mergers, or consolidations. CMS may lift a moratorium in the case of a presidentially declared disaster, if circumstances warranting the moratorium have abated, if CMS has implemented program safeguards, or if the HHS Secretary determines that it is no longer necessary.

State Medicaid agencies must comply with a moratorium unless an agency determines that compliance would adversely affect

Medicaid beneficiaries’ access to medical assistance.¹⁴ States also have the authority to impose moratoria (in six-month increments), numerical caps, or other limits for providers that the HHS Secretary identifies as being at high risk for fraud, waste, or abuse. In such cases, the state must first seek CMS’ concurrence and provide written details of the proposal, including anticipated duration and a “substantial justification” explaining why disallowing newly enrolling providers would reduce the risk of fraud.¹⁵

Suspension of Payments

ACA Section 6402(h) provides that the HHS Secretary may suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud, unless the HHS Secretary determines that there is good cause not to suspend payments. Under current Medicare rules, CMS is allowed to suspend payments for 180 days based upon reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct.¹⁶ The Proposed Rule would eliminate that 180-day limit in cases of “credible allegations of fraud” from any source.

The Secretary is required to consult with OIG in determining whether there is a credible allegation of fraud. The Proposed Rule defines a “credible allegation of fraud” as an allegation from any source, including but not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations.¹⁷ Allegations are considered to be credible when they have indicia of reliability. Any issues related to this definition will be evaluated on a case-by-case basis by looking at all relevant factors, circumstances, and issues. The Proposed Rule also adds a provision for when an investigation is resolved, and thus the basis for suspension of payments no longer exists. A “resolution of investigation” occurs when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence.¹⁸

In accordance with ACA, CMS can choose not to impose a suspension (or not to continue a suspension) if there is good cause, despite credible allegations of fraud. Circumstances that may qualify as good cause include:

- (1) OIG or law enforcement has specifically requested that a payment suspension not be imposed because it may compromise or jeopardize an investigation;
- (2) Beneficiary access to items or services would be so jeopardized as to cause a danger to life or health;
- (3) 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.¹⁹

Although CMS may maintain a suspension for an unspecified period of time, it must evaluate whether there is good cause not to continue a suspension of payments every 180 days after initiation of a suspension.

With regard to the Medicaid program, current regulations provide that a state Medicaid agency may withhold payments to a provider in whole or in part based upon the receipt of reliable *evidence* that the need for withholding payments involves fraud or willful misrepresentation under the Medicaid program.²⁰ Under the Proposed Rule, payment suspensions are mandatory where an *investigation of a credible allegation of fraud* under the Medicaid program exists— thus, as acknowledged by CMS, adopting a lesser threshold for a payment suspension than is in the current regulation.²¹ The “good cause” exceptions in the Medicaid rule are similar to the Medicare rule.²²

The Proposed Rule requires a state to make a formal, written suspected fraud referral to its Medicaid Fraud Control Unit (MFCU) or, where a state does not have a MFCU, to an appropriate law enforcement agency for each instance of payment suspension as the result of a state agency’s preliminary investigation of a credible allegation of fraud. CMS also proposed that on a quarterly basis, a state must request a certification from the MFCU or other law enforcement agency that any matter accepted

on the basis of a referral continues to be under investigation or in the course of enforcement proceedings warranting the continuation of the payment suspension.

Compliance Programs

ACA Section 6102 requires a nursing facility to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations, and in promoting quality of care. Similarly, ACA Section 6401(a) requires providers and suppliers to, as a condition of enrollment in Medicare, Medicaid, or CHIP, establish a compliance program that contains certain “core elements.” The HHS Secretary is responsible for developing regulations and core elements for compliance programs. In the Proposed Rule, CMS solicits comments on “core elements” of a compliance program. CMS does not intend to finalize compliance plan requirements when the other proposals in the Proposed Rule are finalized, but will instead do further rulemaking on compliance plan requirements. CMS is most interested in receiving comments on the use of the seven elements of an effective compliance and ethics program as described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual as the basis for the core elements, but has not limited the core elements to those seven elements.

Effect of Other Program Terminations

ACA Section 6501 requires a state’s Medicaid program to terminate an individual’s or entity’s participation if the individual or entity has been terminated under Medicare or another state’s Medicaid program on or after January 1, 2011. State Medicaid programs would terminate a provider only after the provider exhausted all available appeal rights in the state that originally terminated the provider. States would be required to terminate



participation only in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause (i.e. fraud, integrity, or quality issues). Termination would not be mandatory in cases where providers, suppliers, or eligible professionals were terminated based upon a failure to submit claims over a period of twelve months or more, or any other voluntary action taken by the provider to end its participation in the program, unless it was taken to avoid a sanction. States are required to report adverse provider actions to CMS. The Proposed Rule applies these provisions equally to CHIP.²³

- 1 Public Law No. 111-148, effective March 23, 2010, as amended by Public Law No. 111-152, effective March 30, 2010.
- 2 75 Fed. Reg. 58204 (Sept. 23, 2010).
- 3 *Id.* at 58208 (to be codified at 42 C.F.R. § 424.518).
- 4 “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; and public- or government-owned or affiliated ambulance services suppliers. *Id.* at 58209.
- 5 “Moderate” risk category also includes community mental health centers and nonpublic, nongovernment-owned or affiliated ambulance services suppliers. *Id.* at 58210.
- 6 *Id.* at 58212 (to be codified at 42 C.F.R. § 424.518(c)(3)).
- 7 For Medicaid and CHIP, CMS expects states to assess the risk of fraud, waste, and abuse using similar criteria to those used in Medicare; however, CMS does not intend to limit states from engaging in other screening activities or from assigning a particular provider type to a higher risk level than the level assigned by Medicare. Additional requirements related to Medicaid and CHIP screening are discussed at 75 Fed. Reg. at 58214-17.

- 8 Institutional providers include providers and suppliers who submit a CMS-855A, CMS-855B (but not physician and non-physician practitioner organizations), or CMS-855S or associated Internet-based PECOS enrollment applications. This definition of “institutional provider” will be codified at 42 C.F.R. § 424.502.
- 9 75 Fed. Reg. at 58218-19; to be codified at 42 C.F.R. § 424.514.
- 10 *Id.* at 58219.
- 11 *Id.* at 58219-20.
- 12 *Id.* at 58219.
- 13 *Id.* at 58221; to be codified at 42 C.F.R. § 424.570.
- 14 The Proposed Rule establishes that prior to imposing a moratorium in any state, CMS will consult with the state so that the state may have an opportunity to seek an exception from the moratorium. Additionally, states must provide CMS with written details of the moratorium’s adverse impact on Medicaid beneficiaries.
- 15 75 Fed. Reg. at 58221 (to be codified at 42 C.F.R. § 455.470(a)).
- 16 42 C.F.R. §§ 405.370-405.379.
- 17 75 Fed. Reg. at 58239 (to be codified at 42 C.F.R. § 405.370 for Medicare and 42 C.F.R. § 455.2 for Medicaid).
- 18 CMS is considering comments on an alternate definition of “resolution of investigation” occurring when a legal action is initiated or the case is closed or dropped because of insufficient evidence to support the allegations of fraud.
- 19 75 Fed. Reg. at 58239 (to be codified at 42 C.F.R. § 405.371).
- 20 42 C.F.R. § 455.23.
- 21 75 Fed. Reg. at 58224 (to be codified at 42 C.F.R. § 455.23(a)).
- 22 42 C.F.R. § 455.23(e).
- 23 75 Fed. Reg. at 58229 (to be codified at 42 C.F.R. § 455.416).

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