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CMS Issues Proposed Rule Addressing Enhanced Program Integrity Requirements

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The Centers for Medicare & Medicaid Services (CMS) has taken another important step in its efforts to prevent and detect fraud with its publication of a Proposed Rule addressing program integrity changes mandated by the Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act, or the ACA). Among other things, the Proposed Rule would enhance background screening procedures for providers and suppliers participating or enrolling in the Medicare and Medicaid programs as well as the Children's Health Insurance Program (CHIP). These changes are consistent with the five-principle strategy adopted by the Office of Inspector General for the Department of Health and Human Services (OIG) to fight health care fraud, waste, and abuse. Both the OIG and CMS are emphasizing the need to more closely scrutinize individuals and entities seeking to participate in Medicare, Medicaid, and other federal health care programs as well as those revalidating enrollment.

Background Screening

The Proposed Rule would establish procedures for screening providers of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP, as required by section 6401(a) of the PPACA. The statute further requires that the Secretary of the Department of Health and Human Services (the Secretary), in consultation with the OIG, determine the level of screening based on the risk of fraud, waste, and abuse posed by each type of provider or supplier. Screening must include a licensure check, and also may involve a criminal background check; fingerprinting; unscheduled or unannounced site visits, which may occur pre-enrollment; multi-state database checks; and other screening measures deemed appropriate. States may rely on the results of the Medicare screening process for Medicare providers and suppliers who are also enrolled in Medicaid or CHIP. For non-Medicare providers and suppliers enrolled in Medicaid or CHIP, states must implement the same screening process mandated by the Secretary.

Exercising the broad discretion granted by Congress, CMS proposes to assign providers and suppliers to one of three categories of risk—limited, moderate, or high—and the applicable screening measures would vary depending on the category. The following chart summarizes the types of providers and suppliers that would fall into each category and the screening measures that would apply to each.

Limited Risk	Proposed Screening Tools
Physicians	Verification of compliance with applicable federal regulations or state requirements for the provider or supplier type
Non-physician practitioners	Licensure verification
Medical clinics	Pre- and post-enrollment database checks (to verify SSN, NPI, the National Practitioner Databank, licensure,
Group practices	

Providers or suppliers that are publicly traded on the NYSE or NASDAQ Ambulatory surgical centers End-state renal disease facilities Federally qualified health centers Histocompatibility laboratories Hospitals Critical access hospitals Indian Health Service facilities Mammography screening centers Organ procurement organizations Mass immunization roster billers Portable x-ray suppliers Religious non-medical health care institutions Rural health clinics Radiation therapy centers Public or government-owned or affiliated ambulatory services suppliers Skilled nursing facilities	OIG exclusion, taxpayer identification number, tax delinquency, death of an individual practitioner, and persons with an ownership or control interest or who are agents or managing employees of the provider or supplier)
Moderate Risk Community mental health centers Comprehensive outpatient rehabilitation facilities Hospice organizations Independent diagnostic testing facilities Independent clinical laboratories Nonpublic, nongovernment-owned or affiliated ambulance services suppliers Currently enrolled (revalidating) home health agencies Currently enrolled (revalidating) suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) *Any provider or supplier type listed above that is publicly traded on the NYSE or NASDAQ is considered limited risk.*	Proposed Screening Tools All tools that would apply to limited risk providers and suppliers Unannounced pre- and/or post-enrollment site visits

High Risk	Proposed Screening Tools
Prospectively (newly enrolling) home health agencies and suppliers of DMEPOS *Any provider or supplier type listed above that is publicly traded on the NYSE or NASDAQ is considered limited risk.*	All tools that would apply to moderate risk providers and suppliers Criminal background checks Fingerprinting *Criminal background checks and fingerprinting would apply to owners, authorized or delegated officials, and managing employees (as defined by 42 C.F.R. § 424.502) of any provider or supplier in the high risk category.*

The Proposed Rule discusses the rationale for the classification of providers and suppliers, which undoubtedly will be the subject of many comments submitted to CMS. Because physicians, non-physician practitioners, medical clinics, and group practices are scrutinized through the state licensure process, CMS believes that they pose limited risk. CMS also believes that providers or suppliers that are publicly traded on the NYSE or the NASDAQ pose a limited risk because of the financial oversight provided by investors, corporate boards of directors, and the Securities and Exchange Commission. CMS also relied on its own screening and enrollment experience in assigning additional providers and suppliers to the limited risk category.

In addition to the fact that most providers and suppliers classified as moderate risk are subject to less government or professional oversight than those in the limited category, CMS noted that it has heightened concerns about these entities because they may enter into business without clinical or business experience by, for example, leasing minimal office space and equipment. Further, most of these entities are highly dependent on federal health care programs to generate revenue. CMS did acknowledge that independent clinical laboratories are subject to survey requirements, but nevertheless believes that the "sheer volume of services and associated billing by these entities" warrants their placement in the moderate risk tier. [1]

Finally, newly enrolling home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are considered high-risk because a high number already are enrolled, and they pose "program vulnerabilities to the Medicare program." [2]

Although some of the screening procedures at issue already are in use, others, including fingerprinting, represent a significant departure from current practice. In addition, CMS proposes to expand certain existing procedures, such as site visits and criminal background checks. Complying with the proposed screening requirements could increase administrative and financial burdens for many providers and suppliers and could result in delays in processing time for enrollment applications, which already is too lengthy in many cases. Further, providers and suppliers classified as moderate or high risk should be particularly wary of unannounced post-enrollment visits, which can lead to revocation of Medicare billing privileges upon short notice if the provider or supplier is not operational (e.g., open during the business hours stated on the enrollment application) or is not otherwise in compliance with applicable performance standards at the time of the visit.

The proposed changes to screening procedures would take effect on March 23, 2011 for newly enrolling providers and suppliers, and for currently enrolled providers and suppliers who revalidate their enrollment information on or after March 23, 2011 and before March 23, 2012. For all other currently enrolled providers and suppliers, the new screening procedures would apply as of March 23, 2012.

Application Fee

To cover the cost of background screening and other program integrity activities, Section 6401(a) of the PPACA requires the Secretary to impose an application fee on each institutional provider of medical or other items or services or supplier. The fee will be $500 and will be adjusted each year based on the consumer price index.

The application fee would take effect on March 23, 2011, concurrent with the new screening procedures, and would apply to all newly enrolling providers and suppliers as well as those re-enrolling and revalidating Medicare enrollment. The fee would apply to all institutional providers and suppliers billing Medicare (i.e., those submitting a CMS-855A, CMS-855B, or CMS-855S) as well as institutional entities billing Medicaid or CHIP on a fee-for-service basis (e.g., personal care agencies, non-emergency transportation providers, residential treatment centers, etc.). The fee would not apply to physicians, nurse practitioners, group practices, clinics, or non-physician practitioner organizations submitting the CMS-855I.

By statute, the Secretary may grant exceptions and waivers to the application fee if payment of the fee would result in a hardship or if it would impede access to care for Medicaid beneficiaries in a particular state. According to CMS, one example of a situation that may warrant an exception would be a provider or supplier that is enrolling for purposes of furnishing services in connection with a national public health emergency.

The Proposed Rule outlines a process for submitting requests for hardship exceptions. The provider or supplier must enclose a letter with the enrollment application, or, if enrolling via the Internet through PECOS, a statement explaining the nature of the hardship with the certification statement mailed to the Medicare contractor. CMS would make its determination within 60 days of receipt and, if hardship is denied, CMS would provide its reason(s) for denial. Providers and suppliers could appeal the determination through the existing appeals process.

Notably, CMS stated that a Medicare contractor should not begin its review of the enrollment application unless it receives the application fee or a hardship request. Further, CMS would allow Medicare contractors to revoke billing privileges if an application fee or hardship exception request does not accompany a Medicare revalidation application. Providers and suppliers therefore must diligently observe the effective date of this change.

CMS is soliciting comments on the criteria that should be used in making a hardship determination and is asking for examples of other instances that may constitute hardship. CMS is also seeking comments on the circumstances in which it should grant waivers where beneficiary access issues are prevalent.

Because CMS would allow state Medicaid programs to rely on the results of the Medicare screening process, Medicare providers and suppliers also enrolled in Medicaid or CHIP would pay only the Medicare enrollment application fee because it would cover the screening activities for Medicaid and CHIP enrollment as well. The state may collect the fee from non-Medicare providers and suppliers to offset the cost of Medicaid and CHIP screening programs.

Temporary Moratoria on Enrollment

Section 6401(a) of the PPACA grants the Secretary wide discretion to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers to prevent or combat fraud, waste, or abuse. CMS believes that having this authority will allow it to review its programs and regulations and, if needed, make changes to ensure that providers and suppliers are meeting program requirements and that beneficiaries are receiving quality care.

The Proposed Rule sets forth the circumstances in which CMS could impose a moratorium in six-month increments on the enrollment of a particular provider or supplier type or on enrollment in a particular geographic area. CMS also could limit the addition of new practice locations. The moratoria would not apply to existing providers or suppliers, or to situations involving changes in ownership of existing providers or suppliers, mergers, or consolidations.

When considering whether to impose a temporary moratorium, CMS would review existing data to identify trends that appear to be associated with a high risk of fraud, waste, or abuse. Examples of such trends offered by CMS include a highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category or geographic area. CMS would also consider when a state has imposed a moratorium on enrollment in a particular geographic area or on a particular

provider type, and also when the OIG or the Department of Justice (DOJ) identifies a particular provider or supplier type or geographic area as presenting a high risk of Medicare fraud, waste, or abuse.

With respect to state Medicaid programs, CMS proposes that state agencies would comply with any temporary moratorium imposed by CMS, unless the moratorium would adversely affect beneficiaries' access to care. In that event, CMS would require the state to provide a written explanation of the adverse impact on Medicaid beneficiaries. CMS would then give the state the opportunity to seek an exception from the moratorium.

Under current law, states have the authority to impose moratoria, numerical caps, or other limits on providers that are identified by the Secretary as being a high risk for fraud, waste, or abuse. The Proposed Rule would require states to seek agreement from CMS for a proposed moratorium by submitting a written justification, including the anticipated duration and the reasons why imposing the moratorium would reduce the risk of fraud.

Suspension of Payments

Medicare

The PPACA also expands the Secretary's ability to suspend payments to providers and suppliers in cases of suspected fraudulent activity. In Section 6402(h), Congress added a new provision to the Social Security Act that allows the Secretary to suspend payments to a provider or supplier "pending an investigation of a credible allegation of fraud" against the provider or supplier "unless the Secretary determines there is good cause not to suspend such payments."[3]

Under current Medicare regulations, CMS may suspend payments in circumstances where it (or a Medicare contractor) has "reliable information" either that an overpayment or fraud or willful misrepresentation exists, or that payments to be made may not be correct.[4] Suspensions are limited to 180 days but may be extended an additional 180 days in certain circumstances. These time limits do not apply if the case has been referred to and is being considered by the OIG for administrative action, or if the DOJ submits a written request to CMS that the suspension be continued based on DOJ's ongoing investigation and anticipated filing of a civil action or criminal charges. Under the Proposed Rule, the current 180-day time limit would not apply if there is a credible allegation of fraud.

The Proposed Rule defines a "credible allegation of fraud" to include allegations from *any source*, including, among others, civil false claims cases and law enforcement investigations.[5] Allegations are considered credible when they have "indicia of reliability."[6] Because payments may be suspended pending the investigation of a credible allegation of fraud, CMS believes that it must define when such an investigation has concluded, which is when the suspension of payment would cease. The Proposed Rule therefore defines "resolution of an investigation" as a legal action that 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."[7] But CMS is requesting comments on an alternative definition, which is that the "resolution of an investigation" occurs when "a legal action is initiated or the case is closed or dropped because of insufficient evidence to support the allegations of fraud."[8]

CMS proposes a modification to the existing regulations to differentiate between those suspensions based on reliable information that an overpayment exists or that payments to be made may not be correct, and those based on a credible allegation of fraud. CMS must consult with the OIG and, as appropriate, the DOJ, with respect to suspensions based on credible allegations of fraud.

CMS also recognizes that it might not want to suspend payments in certain circumstances, such as where suspending payments might alert a potential perpetrator to an investigation at an inopportune time or jeopardize an undercover operation. The Proposed Rule therefore includes several "good cause" exceptions, which include requests by law enforcement and a catch-all provision for suspensions that are "not in the best interests of the Medicare program."[9]

The expansion of CMS's authority to suspend payments based on a credible allegation of fraud is significant because it seems to impose a presumption in favor of suspension, unless good cause exists, and the suspension

could last for many years. In addition, it grants the OIG and DOJ a formal role in determining whether a basis for suspension exists.

Medicaid

The Proposed Rule makes changes to the Medicaid program that are similar to those made under the Medicare program. In Section 6402(h) of the PPACA, Congress amended the Social Security Act to prohibit Federal Financial Participation (FFP) with respect to payments for items or services (other than certain emergency items and services) furnished by any individual or entity against whom an investigation of a credible allegation of fraud is pending, where the state failed to suspend payments. This provision does not apply where the state determines, in accordance with the regulations governing good cause exceptions to payment suspensions discussed above, that there is good cause not to suspend such payments.

Under current regulations, state Medicaid agencies may withhold payments, in whole or in part, to providers upon receipt of "reliable evidence" that such withholding is necessary due to the provider's fraud or willful misrepresentation under the Medicaid program.[10] The Proposed Rule would change the term "withhold" to "suspend"—a change CMS characterized as "merely semantic"—and modify the regulations to make payment suspensions mandatory during a pending investigation of "a credible allegation of fraud under the Medicaid program" against an individual or entity, unless good cause not to suspend exists.[11] The proposed definition of "credible allegation" mirrors that used in the proposed Medicare regulations discussed above.[12] CMS does not believe that pending investigations must originate in or with a law enforcement agency, and stated that state agency investigations are "adequate vehicles" by which the state may determine a credible allegation of fraud exists. CMS recognized that the proposed threshold for the imposition of a payment suspension is "a somewhat lesser threshold" than that in the current regulation but does not anticipate that payment suspension authority will be used more frequently.[13]

The Proposed Rule also would require the state agency to notify the provider of a payment suspension within five days of taking action; however, notification must be delayed for 30 days upon written request by law enforcement, and such request may be renewed twice, with the total delay not to exceed 90 days. The Proposed Rule would not significantly change the current provisions regarding duration, which specify that suspension will be temporary and will not continue after (i) the authorities determine there is insufficient evidence of fraud; or (ii) legal proceedings related to the alleged fraud are completed.

CMS also proposes a new provision requiring a state that has initiated a payment suspension to make a written fraud referral to its Medicaid Fraud Control Unit (MFCU) or the appropriate law enforcement agency. On a quarterly basis, the state must request that the MFCU or law enforcement agency certify that any matter accepted on the basis of a referral continues to be under investigation, thus warranting continuation of the payment suspension. If the MFCU or other law enforcement agency declines to accept the fraud referral for investigation, the payment suspension must be discontinued.

Like the proposed Medicare regulations discussed above, the proposed Medicaid regulations include "good cause" exceptions to payment suspensions, including in cases where the state determines that a payment suspension is not in the best interests of the Medicaid program, or where law enforcement specifically requests such an exception.[14] CMS also chose to continue to allow states the flexibility to suspend payments in part, subject to certain new constraints, via "good cause" exceptions. One such exception allows states to suspend payments in part where (i) the credible allegation is focused 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 that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.[15]

Finally, the Proposed Rule would add several reporting and document retention requirements, including a requirement that states maintain, for at least five years, all notices of suspension of payment in whole or in part, all fraud referrals to MFCUs or other law enforcement agencies, and documentation justifying the exercise of good cause exceptions. CMS expressly states that a state's non-compliance with the reporting and document retention

provisions would not give rise to any enforceable right to redress by aggrieved providers.

Solicitation of Comments on Ethics and Compliance Program Requirements

Although many Medicare providers and suppliers have chosen to implement a compliance program as recommended by the OIG, adoption of a compliance program was not previously a condition of Medicare enrollment. Section 6401(a) of the PPACA made a significant change to the status quo by requiring all providers and suppliers to establish a compliance program that contains certain "core elements" as a condition of enrollment in Medicare as well as Medicaid and CHIP.[16] The PPACA directs the Secretary to establish the core elements in consultation with the OIG.

Nursing facilities (NFs) and skilled nursing facilities (SNFs) are subject to additional compliance requirements. Under section 6102 of the PPACA, NFs and SNFs must implement, within 36 months of the PPACA's enactment, a compliance and ethics program that both effectively prevents and detects criminal, civil, and administrative violations and promotes quality of care consistent with regulations developed by the Secretary. CMS noted that NFs and SNFs are subject to the compliance program requirements of both section 6102 and section 6401(a).

CMS does not intend to finalize the compliance plan requirements at the time it finalizes the other changes discussed in the Proposed Rule. Rather, it plans to propose regulations regarding compliance program requirements at a later date and is soliciting comments before doing so. CMS is particularly 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 (upon which the OIG's various compliance program guidance documents are based);
- suggestions for compliance program elements beyond, or related to, the seven elements referenced above;
- the criteria CMS should consider when determining whether, and how, to divide providers and suppliers into groupings that would be subject to similar compliance requirements, including whether individuals should have compliance obligations that differ from corporations; and
- a reasonable timeline to establish a required compliance program for providers and suppliers of various types and sizes.

Every provider and supplier should closely follow the development of these regulations. Any provider or supplier that already has a compliance program in place likely will need to make changes to comply with the new regulations while those who do not have a compliance program will need to act quickly to come into compliance. The audit, evaluation, and planning process should begin right away.

Concurrent Termination of Participation or Enrollment

Section 6501 of the PPACA requires that state Medicaid programs terminate an individual or entity's participation in the program if the individual or entity has been terminated under Medicare or another state's Medicaid program. The term "termination" applies only to providers under Medicare whose billing privileges have been revoked (and does not apply to Medicare suppliers or eligible professionals). Because CMS believes that Congress intended for this requirement to also apply to suppliers and eligible professionals that have had their Medicare billing privileges revoked, it proposes a new definition of the term "termination" that reflects this interpretation.[17]

Under the Proposed Rule, state Medicaid agencies must deny enrollment to, or terminate the enrollment of, a provider that is terminated under Medicare on or after January 1, 2011, or has had its billing privileges revoked, or is terminated on or after January 1, 2011 under any other state's Medicaid program or CHIP.

Finally, CMS proposes allowing CMS or its designated Medicare contractor to revoke Medicare billing privileges

when a state Medicaid agency terminates, revokes, or suspends a provider's or supplier's Medicaid enrollment or billing privileges. CMS believes this approach works in tandem with the requirements of Section 6501, and that providers and suppliers whose enrollment has been terminated by a state Medicaid program pose an increased risk to the Medicare program.

Conclusion

The Proposed Rule, if implemented, would vastly expand the authority of CMS and OIG in a number of ways. In addition to giving CMS and OIG additional tools to strengthen the program integrity process, the Proposed Rule would augment CMS's current authority to suspend payments during the course of government investigations and qui tam law suits, which can last for many years. Although certain aspects of the proposed regulations are dictated by the PPACA, CMS has applied its discretion in many respects. Providers and suppliers should strongly consider submitting comments, which will be accepted until 5:00 p.m. on November 16, 2010.

Endnotes

1 75 Fed. Reg. at 58,211

2 *Id.*

3 Pub. L. 111-148, § 6402(h), *codified at* 42 U.S.C. § 1395y(o)

4 42 C.F.R. § 405.371(a)

5 75 Fed. Reg. at 58,239

6 *Id.*

7 *Id.*

8 75 Fed. Reg. at 58,222

9 75 Fed. Reg. at 58,239

10 42 C.F.R. § 455.23(a)

11 75 Fed. Reg. at 58,243

12 75 Fed. Reg. at 58,243

13 75 Fed. Reg. at 58,224

14 75 Fed. Reg. at 58,244

15 75 Fed. Reg. at 58,244

16 Pub. L. 111-148, § 6102, *codified at* 42 U.S.C. § 1395cc(j).

17 75 Fed. Reg. at 58,244

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