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CMS shifts from “pay and chase” to proactive fraud prevention

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The Centers for Medicare and Medicaid Services (CMS) published a final rule¹ (hereinafter referred to as the final rule) in the Federal Register, effective March 23, 2011. It implements certain provisions of the Patient Protection and Affordable Care Act (ACA), which requires CMS and state Medicaid agencies to combat fraud and more closely monitor enrollment in the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs. The final rule represents a monumental shift from “pay and chase” to proactive fraud prevention. This shift could have significant negative financial implications for providers who unwittingly find themselves under investigation or who have failed to adequately prepare for CMS' expanded focus on enrollment requirements.

The final rule provides a greater ability to impose payment suspensions as well as enhances the requirements for providers enrolling and re-enrolling in the Medicare program, state Medicaid programs, and CHIP. Through these changes, CMS now has greater flexibility to prevent entities intent on defrauding Medicare, Medicaid, and CHIP from accessing the programs, as well as creating a faster, less-burdensome method to quickly stop payments to individuals and entities thought to be engaged in fraud, waste, and abuse. As with many other reforms, a significant result of the more stringent process is the imposition of potentially significant administrative burdens and additional costs on legitimate health care service providers. To minimize the financial and business risks associated with the recently announced changes, providers should educate themselves and their staff on the new requirements, and plan strategically for any upcoming enrollment events.

Payment suspension

The final rule broadly expands the ability of CMS, Medicare Administrative Contractors (MACs), and state Medicaid agencies to suspend payments to Medicare, Medicaid, and CHIP providers and suppliers (hereafter collectively referred to as “providers”) in the case of suspected fraud. This expansion is a shift towards a less stringent burden for the government.

Specifically, the final rule allows the U.S. Department of Health and Human Services (HHS), in consultation with the HHS Office of Inspector General (OIG), to suspend Medicare payments “pending an investigation of a credible allegation of fraud” unless the Secretary determines that there is good cause not to suspend payments.² Further, the final rule prohibits the payment of Federal Financial Participation (i.e., certain Medicaid support payments) for items or services furnished while an investigation of a credible allegation of fraud is pending, unless the state Medicaid agency determines that there is good cause not to suspend payments. The suspension of payment is not limited to the funds at issue based on a particular allegation, but rather extends to all payments owed by the agency to a provider.

Medicare program

Previous regulations allowed CMS to suspend payments to providers for up to 18 months based on having “reliable information” that there has been an overpayment, fraud, or willful misrepresentation, or reliable information that payments may not be correct.³ The final rule, however, relaxes the standard by requiring only a “credible allegation of fraud.”

The final rule states that allegations are considered to be credible when they have “indicia of reliability,” but that term is not defined. Rather, the reliability of an allegation is, according to CMS, a process that will occur on a case-by-case basis in consultation with the OIG. CMS specifies, however, that a credible allegation of fraud can come from almost any source, so long as it has an indicia of reliability. These sources include fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases and law enforcement investigations.

The regulations clearly require that CMS “consult” with OIG before suspending payments, but CMS has refused to provide details of the statutory consultation that must occur. Rather, it stated that the details will be contained in a Memorandum of Understanding between CMS and OIG, and that CMS will retain final decision-making authority.

CMS has retained the discretion to determine not to apply a payment suspension if there is “good cause” not to suspend payments. CMS has outlined several grounds for finding “good cause” not to suspend payments, including determinations that:

- 1. Suspension would endanger life or health by jeopardizing beneficiary access to health care.** CMS expressed concern with scenarios where a payment suspension could jeopardize a provider’s ability to continue rendering services to Medicare beneficiaries whose access to the provider’s services would be necessary to prevent danger to the beneficiary’s life or health.
- 2. Suspension would compromise an existing investigation.** Specifically, CMS has indicated that it may find that good cause exists not to suspend payments when law enforcement personnel indicate that imposing a payment suspension might alert a potential perpetrator to an investigation, jeopardize an undercover investigation, or potentially expose whistleblowers or confidential sources.
- 3. Other available remedies would more effectively or quickly protect Medicare funds.** For example, CMS indicated that court injunctions issued against certain activities, such as withdrawing, transferring, or otherwise disposing of funds may more quickly and fully protect program assets.
- 4. Suspension is not in the best interest of the Medicare program.** CMS indicated that, because circumstances may change as an investigation progresses, it may

become in the program’s best interest to terminate a payment suspension prior to the resolution of an investigation. In such cases, CMS will first consult with OIG or other law enforcement agencies to determine whether the other agency’s investigation continues.

- 5. Suspension has continued for 18 months without resolution.** CMS has indicated that a payment suspension should not normally extend past 18 months, and that good cause not to continue the payment suspension shall be deemed to exist, unless the case has been referred to OIG for a pending administrative action or the DOJ submits a written request to CMS requesting the suspension to continue beyond 18 months.⁴

If CMS chooses to implement a payment suspension, the final rule requires CMS to confirm with OIG or DOJ that the matter is still under investigation and re-evaluate the appropriateness of payment suspension every 180 days. During these periods, providers have an opportunity to provide information to rebut the allegations and attempt to convince CMS to close its investigation and end the suspension. Providers may also try to convince CMS that good cause exists, as explained above, to not suspend payments during the course of an investigation.

Medicaid program

Previous regulations allowed a state Medicaid agency to withhold payments based on “reliable evidence” of alleged fraud or willful misrepresentation.⁵ DHS also has long encouraged state Medicaid agencies to withhold payments to providers without first granting administrative review where the state agency has reliable evidence of fraudulent activity. The final rule now adds a requirement that the state Medicaid agency suspend all Medicaid payments to a provider after the

agency determines that an investigation is pending for “a credible allegation of fraud,” unless the agency has good cause to not suspend payment or to only partially suspend payments.⁶

The new regulation specifies that “allegations will be considered to be credible when they have indicia of reliability and the state Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis,” maintaining the “indicia of credibility” standard established for the Medicare program.⁷ Further, much like the impact on the Medicare program, CMS admits that the threshold by which a state Medicaid agency investigation may give rise to a payment suspension is lower than the current threshold.

For each payment suspension initiated by a state Medicaid agency, the agency must make a formal, written suspected fraud referral to its Medicaid Fraud Control Unit (MFCU), or if a state does not have a MFCU, to the appropriate law enforcement agency. This requirement is meant to ensure that an appropriate full investigation by a law enforcement agency promptly follows a payment suspension. If the MFCU declines the referral, the state is required to release the payment suspension unless the state has an alternative authority by which it may impose a suspension. The state Medicaid agency must thereafter request a certification from the MFCU on a quarterly basis to ensure that a suspension will not be continued long after a law enforcement agency has closed an investigation, but neglected to alert the state Medicaid agency to that effect.

Impact

While CMS contends that the final rule has not changed the impact or burden on the

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provider community in circumstances of payment suspension, CMS admits that the standards for payment suspension have been reduced. This reduced standard potentially subjects more providers to significant financial risk during a payment suspension, even if they prevail on the claims at issue.

The uncertainty of the application of the payment suspension rules also raises concerns. Exactly how CMS and state Medicaid agencies will exercise their discretion to impose payment suspension remains to be seen. The final rule did not provide clear guidance on when payment suspension should be used, nor did it provide definitions of the terms used to describe when payment suspension should be imposed. Because CMS left itself the flexibility to decide whether a payment suspension is appropriate on a case-by-case basis, the provider community must adopt a watchful waiting position until a sufficient volume of suspensions permits further meaningful assessment, or until CMS releases additional guidance.

In light of the significant potential negative impact of a payment suspension, providers should redouble their efforts to ensure that they have effective compliance programs in place. Providers should immediately respond to any reports of potential non-compliance by investigating and taking corrective action, as necessary. If the provider believes that an overpayment situation has arisen, it should promptly repay the funds at issue.

Additionally, if faced with allegations of fraud, waste, abuse, or direct threats of possible payment suspension, providers should immediately consult legal counsel while maintaining a cooperative tone with regulators. In consultation with counsel, providers should quickly submit a rebuttal letter as well

as any requested records or information as soon as practicable.

Screening standards

In addition to the payment suspension regulations, the final rule continues to provide means for CMS to transition from “pay and chase” to proactive fraud prevention by implementing new screening standards. The changes were meant to enhance, rather than replace, screening procedures that are carried out by non-CMS entities, such as the screening and site visits for Clinical Laboratory Improvement Amendments laboratories. The screening standards implementation date for newly-enrolling providers and currently-enrolled providers that are submitting a revalidation was March 25, 2011; the implementation date for other currently-enrolled providers will be March 23, 2012.

Medicare program

Prior to the final rule, CMS employed several measures to screen providers who were applying to participate in the Medicare, Medicaid, and CHIP programs. Such screening measures include confirming that the provider holds and maintains all necessary state licenses, and performing site visits through private contractors for certain DMEPOS suppliers and independent diagnostic testing facilities. Medicare contractors also check national databases, including Social Security Administration, National Provider Identifier, OIG, and other databases to confirm the accuracy of information provided regarding certain eligible professionals, owners, authorized officials, and other individuals involved with Medicare providers.

Under the final rule, the prior screening measures will continue with enhanced measures added for certain types of providers.

Table 1: Risk Categories by Provider Type

Limited	Moderate	High
<ul style="list-style-type: none"> Physician or non-physician practitioners (nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, audiologists), medical groups or clinics Ambulatory surgery centers Competitive Acquisition Program / Part B vendors End stage renal disease facilities Federally qualified health centers Histocompatibility laboratories Hospitals Health programs operated by an Indian Health Program or an urban Indian organization that receives funding from the Indian Health Service Mammography screening centers Mass immunization roster billers Organ procurement organizations Pharmacies newly enrolling or revalidating via CMS-855B Radiation therapy centers Religious non-medical health care institutions Rural health clinics Skilled nursing facilities 	<ul style="list-style-type: none"> Ambulance service suppliers Community mental health centers Comprehensive outpatient rehabilitation facilities Hospice organizations Independent diagnostic testing facilities Independent clinical laboratories Physical therapists enrolling as individuals or group practices Portable x-ray suppliers Revalidating home health agencies Revalidating DMEPOS suppliers 	<ul style="list-style-type: none"> Newly enrolling home health agencies Newly enrolling DMEPOS suppliers

All providers will be assigned to a risk category based on provider type, and the screening level will be based on the assigned risk category. CMS debated the use of factors, such as geography and ownership type, in the risk assessment determination. Specifically, CMS proposed the automatic assigning of all providers owned by publicly-traded companies into the limited-risk category. However, in the final rule, CMS indicates that the risk assessment will be based solely on the provider type. The screening standards apply to new enrollments, applications for new practice locations and applications received in response to a MAC request for a revalidation (see table 1 on page 8).

■ Limited risk category

Providers in the limited-risk category, including but not limited to physicians, physician groups, hospitals, and ambulatory surgery centers, will be subject to similar screening procedures as are required under prior regulations, including state license verification and other database checking, as well as verification of any provider-specific requirements established by Medicare.⁸ In assigning these providers to the limited-risk category, CMS indicated that it believes these providers to present less risk of fraud, waste, and abuse because these providers are generally licensed by the state and CMS has no evidence that they pose an elevated risk to the Medicare program.

■ Moderate risk category

Providers in the moderate risk category (including, but not limited to, independent diagnostic testing facilities), currently-enrolled home health agencies, and hospice organizations are subject to the screening performed on the limited-risk category with the added screening of unscheduled site visits.⁹ CMS indicated that in assigning these provider types to the moderate risk category, it based its assessment that they present more risk because

they are generally highly dependent on federal health care programs to pay their salaries and other operating expenses, and are generally subject to less government or professional oversight than the limited risk providers.

■ High risk category

Providers in the high-risk categories, which include newly enrolling home health agencies and newly enrolling DMEPOS suppliers, will be subject to the screening requirements for the moderate-risk category as well as subject to criminal background checks and fingerprinting.¹⁰ The fingerprinting requirement will also be extended to investors who directly or indirectly hold more than a 5% ownership interest in any high-risk provider.

In addition to categorization based on provider type, providers can also find themselves in a high-risk category based on their personal history. Such escalation in risk category will occur when a provider (or any of the provider's owners who hold a 5% or greater stake) has had its Medicare billing privileges revoked or payments suspended in the last ten years; has been excluded by the OIG; or has been subject to a final adverse action, such as a license suspension or accreditation suspension in the last ten years. Moreover, for entity providers, such an elevation in risk category would subject its 5% owners to fingerprint background checks. Elevation to the high-risk category will also occur for any provider whose provider type has been under a moratorium. Those providers will be elevated to the high-risk category for the duration of the moratorium and a period of six months following the moratorium.

Medicaid and CHIP programs

The new screening standards for state Medicaid and CHIP programs are substantially similar to the Medicare program. For dually-enrolled providers, state Medicaid and CHIP programs

are permitted under the new rule to rely on the results of the screening conducted by a Medicare contractor. Similarly, state Medicaid and CHIP agencies may rely on the screening conducted by the Medicaid and CHIP agencies in other states.¹¹ For Medicaid-only or CHIP-only providers, CMS instructs the agencies to follow the same screening procedures as required under the Medicare program. However, state Medicaid and CHIP programs can effectively shift providers to higher risk categories based on the particular state agency's view of the fraud risk presented by the provider.¹²

Enrollment fees

Beginning March 25, 2011, in order to cover the costs of enrollment screening and related program integrity activities, CMS will begin collecting a \$505 application fee from institutional applicants. The fee will be required for new enrollments, revalidation applications, and applications for new practice locations. In subsequent years, the fee will be adjusted by the percentage change to the consumer price index. On a case-by-case basis, CMS may grant hardship waivers exempting a provider from the fee.¹³

Enrollment moratoria

In addition to the enrollment screening measures, the final rule provided CMS with another tool to assist efforts to move from "pay and chase" to proactive fraud prevention. Effective May 25, 2011, when CMS identifies a "trend that appears to be associated with a high risk of fraud, waste or abuse" (e.g., a highly disproportionate number of providers in a category relative to the number of beneficiaries, or a significant increase in enrollment applications within a provider category or geographic area), CMS now has the authority to impose a temporary moratorium on the enrollment of new Medicare providers in

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six-month increments.¹⁴ These moratoria would not extend to currently-enrolled providers undergoing a change in ownership, merger, or consolidation, but it could prevent a currently-enrolled provider from establishing new practice locations.

Further, state Medicaid and CHIP agencies would be required to comply with any moratorium imposed by the Secretary of Health and Human Services unless the agency determines that the imposition of the moratorium would adversely affect Medicaid beneficiaries' access to care. State agencies may also impose their own enrollment moratoria, numerical caps or other limits for providers identified by the Secretary as being at high risk for fraud.

Impact

The final rule continues CMS' trend toward more stringent enrollment standards and highlights its focus on preventing fraudulent providers from becoming enrolled in the Medicare, Medicaid, and CHIP programs. Among the additional burdens facing the provider community, due to the more stringent enrollment, is the impact on the length of time required to enroll in the programs. Providers should anticipate that it will take additional time and resources to prepare the enrollment application. Further, the time that will be required for CMS, MACs, and state Medicaid agencies to process applications will likely be lengthened as they adapt to the additional screening standards. Providers should be mindful of these potential time delays as they plan for growth, new opportunities, and also for mandatory revalidation submissions that must be submitted on a tight deadline.

To prepare for the new enrollment requirements, providers should understand into which risk category they have been placed and the requirements for that specific risk category. Armed with this information,

providers should confirm all information in any enrollment application prior to submitting it to CMS. By performing database checks, license verification, and confirming background information for the individuals reported on the enrollment application, providers will not be surprised by any results and will have the opportunity to correct any erroneous information prior to submitting the enrollment application.

For those in the moderate and high-risk categories, providers should prepare for the unannounced on-site visit by CMS. This preparation should include designating an individual to serve as the point of contact for interfacing with CMS. Staff should be informed of the on-site visit and be educated on the identity of this point of contact and the importance of providing accurate and complete information to CMS representatives.

Finally, as was the case prior to the implementation of the final rule, but which is of even greater import now, providers must make certain to be completely accurate in all enrollment information provided to CMS, MACs, state Medicaid agencies, and CHIP, because any mistake can lead to denial.

Conclusion

As the shift from “pay and chase” to proactive fraud prevention begins in earnest, providers must be even more diligent as they make their way through the Medicare, Medicaid, and CHIP enrollment and re-enrollment processes. This diligence must continue throughout the provider's course of dealings with the agencies, lest the providers find themselves operating under a payment suspension. ■

- 1 See “Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,” 76 Fed. Reg. 5862 (Feb. 2, 2011).
- 2 42 C.F.R. § 405.371(b).
- 3 42 C.F.R. § 405.372(d).
- 4 42 C.F.R. § 405.371(b).
- 5 42 C.F.R. § 455.23.
- 6 76 Fed. Reg. 5932.
- 7 76 Fed. Reg. 5935.
- 8 42 C.F.R. § 424.518(a).
- 9 42 C.F.R. § 424.518(b).
- 10 42 C.F.R. § 424.518(c).
- 11 42 C.F.R. § 455.410.
- 12 76 Fed. Reg. 5896.
- 13 42 C.F.R. § 424.514.
- 14 76 Fed. Reg. 5920. The regulation governing moratoria is found at 42 C.F.R. § 424.570.

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