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CLIENT ADVISORY

New PPACA Proposed Regulations Target Anti-Fraud Effort

Introduction

The Centers for Medicare and Medicaid Services (CMS) recently released proposed new regulations to implement provisions of the Patient Protection and Affordable Care Act (PPACA) that establish new requirements for providers aimed at preventing and detecting fraud and abuse. The regulations proposed on September 23, 2010 (the "Proposed Rule") would impose background screening requirements and fees on providers, allow CMS to suspend payments pending certain allegations of fraud, and allow for temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers. The proposal also solicits comments on ethics and compliance programs and the requirements of the PPACA. See <http://www.gpo.gov/fdsys/pkg/FR-2010-09-23/pdf/2010-23579.pdf>.

To be assured consideration, comments on the proposed rules must be received by CMS no later than November 16, 2010. You should direct your comments to CMS at the address listed in the notice above.

Enhanced Provider Background Screening Under Medicare, Medicaid, and CHIP

Under the PPACA, the Secretary of the U.S. Department of Health and Human Services has the authority to establish the level of screening necessary for suppliers and providers. The Proposed Rule creates a three tiered classification system for providers and suppliers based on risk for fraud, waste and abuse. Those providers and suppliers with higher risk would be required to undergo enhanced screening measures in addition to the mandatory licensure check. Beginning on March 23, 2011, the new screening protocols would apply to all newly enrolling providers and suppliers. The protocols would also apply to currently enrolled suppliers and providers in Medicare, Medicaid and CHIP who revalidate their enrollment information on or after March 23, 2011.

Limited-Risk Screening Procedures

There are three screening provisions proposed for limited risk providers and suppliers. First, the proposal requires verification that the provider or supplier meets any federal regulations or state requirements applicable to its provider or supplier type. The

proposal also requires verification that providers or suppliers comply with all licensure requirements and periodic database checks to verify enrollment criteria.

Moderate-Risk Screening Procedures

The Proposed Rule advises Medicare contractors to conduct unannounced visitations for moderate-risk providers and suppliers. These unscheduled visits are in addition to the categorical screenings performed for limited-risk providers and suppliers. The goal of the Proposed Rule is to ensure that a provider or supplier “remains a viable health care provider or supplier in the Medicare Program.” The visits will also “help ensure that suppliers are operational and meet applicable supplier standards or performance standards.”

High-Risk Screening Procedures

High-risk suppliers and providers must comply with the screening procedures assigned to low and moderate-risk suppliers and providers as well as additional screening protocols. Specifically, during the enrollment process, organizations in the high-risk categories must undergo a criminal background check and submit fingerprints. These additional screening procedures are intended to verify that “a complete and truthful Medicare enrollment application and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges.” It will also reportedly address concerns related to identity theft.

Below, please refer to a list of providers affected by the Proposed Rule based on levels of screening:

Limited Risk	Moderate Risk	High Risk
<ul style="list-style-type: none"> • Physician or non-physician practitioners and medical groups or clinics • End-stage renal disease facilities • Ambulatory surgical centers • Federally qualified health centers • Histocompatibility laboratories • Hospitals (including critical access hospitals) • Indian Health Service facilities • Mammography screening centers 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Newly enrolling HHAs • Newly enrolling suppliers of DMEPOS <p>*If the provider or supplier is publicly traded on NYSE or NASDAQ, then it is considered low risk</p>

<ul style="list-style-type: none"> • Organ procurement organizations • Mass immunization roster billers • Portable X-Ray supplier • Religious nonmedical healthcare institutions 	<p>(revalidating) DMEPOS suppliers</p> <p>*If the provider or supplier is publicly traded on NYSE or NASDAQ, then it is considered low risk</p>	
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Mandatory Enrollment Application Fee

The PPACA requires the Secretary to impose a fee on every “institutional provider of medical or other items or services or supplier.” The Proposed Rule defines such institutions as “any health care provider that bills Medicare, Medicaid, or CHIP on a fee-for-service basis, with the exception of Part B medical groups or clinics and physician and nonphysician practitioners who submit the CMS 855I to enroll in Medicare.” The fee is intended to cover the cost of screening and “other program integrity efforts.” The application fee will be applicable to newly enrolling providers and suppliers on March 23, 2011.

The Proposed Rule establishes a \$500 application fee in 2011 and will be adjusted based on changes in the consumer price index for all urban consumers in the preceding year. The Secretary may exempt a supplier or provider from paying the fee if financial hardship would result. Once paid, the application fee is non-refundable.

Proposed Provisions

The Proposed Rule offers a definition for “institutional provider.” It states that such a provider is “any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (but not physician and nonphysician practitioner organizations), or CMS-855S or associated Internet-based PECOS enrollment application.” More specifically, for Medicare, Medicaid and CHIP providers, the Proposed Rule states that the fee would apply to the range of providers and suppliers listed in the above chart. The Proposed Rule does not limit application to these listed providers.

The Proposed Rule also establishes “that an application fee will be required with the submission of an initial enrollment application, the application to establish a new practice location, as a part of revalidation, or in response to a Medicare contractor revalidation request.” Medicare contractors will not process an application request until the application fee is received and credited to the United States Treasury. Currently enrolled and newly enrolling providers and suppliers must take this stipulation into account to address any possible delays resulting from issues related to the application fee payment. The Proposed Rule specifically offers a new rule to address payment issues related to hardship exemptions, stating “In the case where a provider or supplier did not submit the application fee because they requested a hardship exception that is not

granted, a provider or supplier has 30 days from the date on which the contractor sends notice of the rejection of the hardship exception request to send in the required application fee and application forms.”

Temporary Moratoria on Enrollment of Medicare, Medicaid, and CHIP Providers and Suppliers

Statutory Changes

The PPACA gives the Secretary authority to place temporary moratorium on Medicare, Medicaid and CHIP providers “to prevent or combat fraud, waste, or abuse under the programs.” The Proposed Rule also asserts that States must comply with the moratorium “unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries' access to care.” Given the past concern over home health agency proliferation, such agencies may be the target of this new authority. In addition to the Proposed Rule discussed here, CMS adopted a Final Rule on November 2, 2010 which prohibits the transfer of a provider agreement and corresponding provider number to the new owner of a home health agency (HHA) that acquires an HHA (whether by asset purchase or stock transfer) if the change of ownership takes place within thirty-six months of the HHA's enrollment in Medicare. There are a few limited exceptions to the thirty-six month rule that are intended to allow certain types of transactions, but most HHA transactions will still fall under the thirty-six month prohibition.

Medicare Temporary Moratorium

Under Medicare, CMS can impose moratorium on the enrollment of new Medicare providers and suppliers in six month increments. These six month periods can be extended in additional six month increments. The moratoria would not apply to existing providers and suppliers “unless they were attempting to expand operations to new practice locations where a temporary moratorium was imposed.” The moratoria would also not apply when there are changes in ownership, mergers, or consolidations involving existing providers or suppliers. The temporary moratoria will not be reviewable immediately at the judicial level, but must be appealed administratively through the Departmental Appeals Board (DAB).

The Proposed Rule cites four reasons moratoria can be put in place. First, the moratorium can be placed if CMS finds “high risk of fraud, waste or abuse” for a specific provider or supplier type, geographic region, or both. Second, a temporary moratorium can be placed when a state places a moratorium on Medicaid providers and suppliers that also have enrollment in the Medicare program. Third, if a state imposes moratoria on providers or suppliers in a specific geographic area or on a certain type of provider or supplier, or both. Finally, moratoria can be imposed if CMS identifies a certain supplier or provider type or a particular region as “having a significant potential for fraud, waste or abuse in the Medicare program.” This conclusion must be reached in consultation with the U.S. Department of Justice, the OIG, or both.

In addition, there are proposed reasons for lifting the moratoria. The first situation would be a lifting of the moratorium when there is a presidentially- declared disaster. Moratoria may also be lifted if the factors warranting the moratorium have subsided or CMS has established programs to address the basis of the moratorium. The Secretary can also conclude a moratorium is no longer necessary.

Medicaid and CHIP Temporary Moratoria

The Proposed Rule will require that Medicaid agencies comply with the temporary moratoria established by the Secretary. If the Medicaid agency determines that compliance would adversely affect beneficiaries or CHIP participants, then the agency must present these findings to the Secretary in writing. Medicaid agencies also “have authority to impose moratoria, numerical caps, or other limits for providers that are identified by the Secretary as being at ‘high’ risk for fraud, waste, or abuse.” These agencies must notify the Secretary of moratoria in writing. Similar to Medicare, the Medicaid and CHIP moratoria last for six months and can be further extended in six-month increments.

Suspensions of Payments

Suspension of Medicare Payments

Current policy authorizes the Secretary to “suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud unless the Secretary determines that there is good cause not to suspend payments.” The Secretary must consult with OIG to evaluate the credibility of the allegation of fraud.

The Proposed Rule would alter the definition of “credible allegation of fraud,” potentially making suspension actions more frequent. The new definition would “include 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.” The Proposed Rule notes that evaluating cases under this new definition will require a case-by-case approach.

In addition, the Proposed Rule modifies the definition of “resolution of an investigation.” The definition would establish that “that a resolution of an investigation occurs when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence.” CMS requests comment on this modified definition. Understanding when a case is closed or dropped by an investigating agency is often difficult. Commenters may wish to address the need for clear and quick closure if payment is suspended do to the threat of provider insufficiency.

The Proposed rule also provides that suspensions may be prevented for showing of “good cause.” The Proposed Rule provides four examples of good cause. First, a good cause exception could be “based upon specific requests by law enforcement that CMS not

suspend payments.” Second, the Proposed Rule suggests “a good cause exception not to suspend payments if CMS determines that beneficiary access to necessary items or services may be jeopardized.” In addition, an exception would be appropriate “if CMS determines that other available remedies implemented by or on behalf of CMS more effectively or quickly protect Medicare funds than would implementing a payment suspension.” The final exception proposed would be “a good cause exception based upon a determination by CMS that a payment suspension or continuation of a payment suspension is not in the best interests of the Medicare program.”

After the initial suspicion based on credible allegations of fraud, CMS will reportedly evaluate whether there is a good cause not to continue a suspension every 180 days. CMS proposes to coordinate with OIG and other law enforcement agencies during this process.

Suspension of Medicaid Payments

Currently, State Medicaid agencies are “authorized to withhold payments in cases of fraud or willful misrepresentation.” This conclusion must be based on reliable evidence, which is undefined. Instead, “The HHS OIG noted that while the existence of an ongoing criminal or civil investigation against a provider may be a factor in determining whether reliable evidence exists, that reliable evidence should be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand, and acting judiciously on this information.”

The Proposed Rule suggests modifications to the current regulatory mechanisms. Specifically, CMS proposes to implement section 6402(h)(2) of the PPACA by “modifying the existing 42 C.F.R. § 455.23(a) to make payment suspensions mandatory where an investigation of a credible allegation of fraud under the Medicaid program exists.” The definition of “credible allegation” adopted in the context of Medicare would also be applied to the Proposed Rule.

In terms of the duration of suspensions, the Proposed Rule does not offer any significant changes. The current provisions “specify that withholding (soon to be called suspension) will be temporary and will not continue after: (1) authorities discern that there is insufficient evidence of fraud upon which to base a legal action; or (2) legal proceedings related to the alleged fraud are completed.” However, with no time limits on suspensions or investigations, providers may face indefinitely long suspensions and the threat of insolvency.

In addition, the Proposed Rule addresses referrals for investigation. A state must make “a formal, written suspected fraud referral to its 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.” If the MFCU or particular law enforcement agency does not accept the referral, the Proposed Rule requires that states “immediately release the payment suspension.” This requirement may be delayed if the state refers the issue to another law

enforcement agency or if the state has an alternative authority for imposing the suspension.

Similar to the Medicare suspensions, there are good cause exceptions for the suspension of Medicaid payments. The Proposed Rule states “we propose a good cause exception based upon specific requests by law enforcement that State officials not suspend (or continue to suspend) payment.” Second, good cause is appropriately applied when states determine that other remedies implemented by the state could more effectively protect Medicaid funds. Third, the state agency may determine that suspension is not in the best interests of Medicaid beneficiaries. Also, the state may determine that there is an adverse effect on beneficiaries if the suspension is implemented. Finally, the Proposed Rule suggests “a good cause exception that would permit (but not require) a State to discontinue an existing suspension to the extent law enforcement declines to cooperate in certifying under the requirements of paragraph (d)(3) that a matter continues to be under investigation and therefore warrants continuing the suspension.” The Proposed Rule also establishes partial payment suspensions. While flexibility may be intended, the process is vague.

Solicitation of Comments for Sections 6102 and 6401(a) of the PPACA—Ethics and Compliance Program

Both Sections 6102 and 6401(a) of the PPACA require ethics and compliance programs. CMS is currently seeking comments on these programs that address ways to “protect Medicare, Medicaid, and CHIP from fraud and abuse.” CMS distinguishes the finalization of the compliance plan requirements from the finalization of all other portions of the Proposed Rule.

Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

In an effort to prevent excluded providers from enrolling in government health care programs, the Proposed Rule discusses options for implementing PPACA’s requirement that state Medicaid programs terminate an agency’s participation in program if the agency has been terminated in another state’s Medicaid program or by Medicare. The Proposed Rule stipulates that “The requirement for States to terminate would only apply in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause.” State Medicaid programs will not be able to collaterally terminate a provider that has been terminated by another state until the provider has had the opportunity to exhaust “all available appeal rights in the State that originally terminated the provider.”

Additional Medicare Provider Enrollment Provisions

Based on the reasoning that providers and suppliers whose enrollment has been terminated by a state Medicaid Program pose an increased risk to the Medicare program,

CMS, proposes to allow “CMS or its designated Medicare contractor to revoke Medicare billing privileges when a State Medicaid agency terminates, revokes, or suspends a provider or supplier's Medicaid enrollment or billing privileges.”

Conclusion

The latest Proposed Rule affects the pocketbooks of most providers, through application fees and payment cutoffs. As the new federal health reform legislation is implemented via the regulatory process, providers should expect additional opportunities to comment on new proposed rules. If our firm can be of assistance in this comment stage of the rule process or provide further interpretation of the proposed new rules, please let Peter Mellette, Harrison Gibbs or Nathan Mortier know.

Mellette PC acknowledges with appreciation the assistance of Nicole Sonia, Class of 2012, Marshall-Wythe School of Law, in preparing this advisory.