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CMS Finalizes Regulations Intended to Strengthen Program Integrity





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The Centers for Medicare & Medicaid Services has bolstered its efforts to prevent and detect fraud with its publication of the final 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 final rule enhances 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).

For state Medicaid agencies, the final rule establishes the framework for state-specific rules on provider enrollment, which means that Medicaid and CHIP providers may be subject to more stringent rules at the state level.[1]

These changes are consistent with the five-principle strategy adopted by the Department of Health and Human Services Office of Inspector General to fight health care fraud, waste, and abuse. Both the OIG and CMS are emphasizing the need to more closely scrutinize in-

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[1] States receive federal matching funds for CHIP and for the Medicaid program, but they are free to administer their programs within the framework established by federal law and regulations. In many states, the state Medicaid agency administers the CHIP program as well while in others a separate agency is charged with this responsibility. The ACA's requirements related to provider enrollment apply to both Medicaid and CHIP programs, and CMS's responses to the comments in the Final Rule make clear that the states must implement the requirements to both Medicaid and CHIP providers regardless of whether the Medicaid agency or another state agency oversees the CHIP.

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dividuals and entities seeking to participate in Medicare, Medicaid, and other federal health care programs as well as those revalidating enrollment.

Background Screening

Although the final rule confirms most of the procedures established in the proposed rule for screening providers and suppliers under Medicare, Medicaid, and CHIP, the final rule does make some important modifications.

The ACA requires the HHS secretary (''the Secretary''), in consultation with the OIG, to determine the level of screening based on the risk of fraud, waste, and abuse posed by each type of provider or supplier. Screening must still include a licensure check and also involves a fingerprint-based criminal history report check of the FBI database;[2] unscheduled or unannounced site visits, which may occur pre-enrollment; multi-state database checks; and other screening measures deemed appropriate.

As set forth in more detail below, 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, at a minimum, implement the same screening process mandated by the Secretary but states are free to implement more stringent enrollment or screening requirements.

Exercising the broad discretion granted by Congress in the ACA, CMS finalized the assignment of providers and suppliers to one of three categories of risk: limited, moderate, or high, and the applicable screening measures will vary depending on the category. The following chart summarizes the types of providers and suppliers that fall into each category and the screening measures that apply to each, and it specifies changes made by the final rule.

Notably, the final rule removed the distinction between publicly traded/non-publicly traded and publicly owned/non-publicly owned as one of the criteria for assignment to a lower risk category.

In response to several comments regarding CMS's seemingly arbitrary determination that publicly traded or owned companies are less of a fraud risk than non-publicly traded or owned companies, the final rule removed this distinction and noted that the risk differential between such companies does not warrant an automatic assignment of publicly traded and owned companies to a lesser screening level.

[2] Although the Final Rule was issued subject to a comment period, CMS will only accept comments on the fingerprinting requirements contained in 42 C.F.R. §§ 424.518 and 455.434.

Limited Risk	**Screening Tools**
Physicians Non-physician practitioners (*Final Rule excludes physical therapists and physical therapist groups and instead classifies them as moderate risk*) Medical clinics Group practices Ambulatory surgical centers End-state renal disease facilities Federally qualified health centers Histocompatibility laboratories Hospitals Critical access hospitals Health programs operated by an Indian Health Program or an urban Indian organization that receives funding from the Indian Health Service[3] Mammography screening centers Organ procurement organizations Mass immunization roster billers Religious on-medical health care institutions Rural health clinics Radiation therapy centers Public or government-owned or affiliated ambulatory services suppliers Skilled nursing facilities *Provider/supplier types added in the Final Rule:* Competitive Acquisition Program/Part B Vendors Pharmacies that are newly enrolling or revalidating via the CMS-855B Occupational therapy providers Speech pathology providers	Verification of compliance with applicable federal regulations or state requirements for the provider or supplier type Licensure verification Pre- and post-enrollment database checks (to verify SSN, NPI, the National Practitioner Databank, licensure, 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)

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Moderate Risk	**Screening Tools**
Community mental health centers Comprehensive outpatient rehabilitation facilities Hospice organizations Independent diagnostic testing facilities Portable X-ray suppliers (*moved from Limited to Moderate*) Independent clinical laboratories Nonpublic, nongovernment owned or affiliated ambulance services suppliers Currently enrolled (revalidating) home health agencies Currently enrolled (revalidating) suppliers of DMEPOS *Provider/supplier types added in the Final Rule:* Physical therapists Physical therapist groups All ambulance suppliers (regardless of public or government affiliation)	All tools that would apply to limited risk providers and suppliers Unannounced pre- and/or post-enrollment site visits
High Risk	**Screening Tools**
Prospectively (newly enrolling) home health agencies and suppliers of DMEPOS	All tools that would apply to moderate risk providers and suppliers Fingerprint-based criminal history report check of the FBI Integrated Automated Fingerprint Identification System on all individuals who maintain a 5% or greater direct or indirect ownership interest in the provider or supplier (*replaces the Proposed Rule's general criminal background check and fingerprinting requirements, removes requirement to use the FD-258 fingerprint card, and adds the new requirement for individuals who maintain a 5% or more direct or indirect ownership interest*) 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.

[3] In response to several comments, CMS changed the description of Indian Health Services facilities to ''health programs operated by an Indian Health Program or an urban Indian organization that receives funding from the Indian Health Service.''

In the proposed rule, CMS provided its rationale for the assignment of certain providers and suppliers to each risk category.

The final rule included the following modifications to its assignment criteria: (1) a ''final adverse action'' as defined in 42 C.F.R. § 424.502 is added as a basis for reassigning a provider or supplier to the high risk screening level; (2) a provider or supplier will be assigned to the high risk screening level for six months following the lifting of a temporary enrollment moratorium; and (3) a denial of Medicare billing privileges in the previous 10 years is no longer a basis for reassigning a provider or supplier to the high risk screening level.

Because physicians, non-physician practitioners, medical clinics, and group practices are scrutinized through the state licensure process, CMS continues to believe that they pose a limited risk of fraud, waste, and abuse. In addition to its own screening and enrollment experience, CMS relied on the comments made to the proposed rule in assigning additional providers and suppliers to the limited risk category.

As stated in the proposed rule, most providers and suppliers classified as moderate risk are subject to less government or professional oversight than those in the limited category; however, CMS noted that it has heightened concerns about these entities for various reasons. For instance, they may enter into business without clinical or business experience and are highly dependent on federal health care programs to generate revenue.

In addition, the claims and payment history of certain portable X-ray suppliers, coupled with the fact that there are low barriers to entry in the marketplace, served as grounds for CMS to move these suppliers from the limited to the moderate risk screening level.

Although some of the screening procedures already are in use, others, including fingerprinting, represent a significant departure from current practice.

In the final rule, CMS expanded certain existing procedures, such as criminal background checks and fingerprinting for providers and suppliers classified as high risk, to consist of fingerprint-based criminal history reports of the FBI Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

Complying with these 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.

The final rule also makes vast changes to the existing Medicaid provider disclosure requirements at 42 C.F.R. § 455.104 by mandating that state Medicaid agencies obtain certain information from disclosing entities (as currently defined in 42 C.F.R. § 455.101) and their fiscal agents and managed care entities.

State Medicaid agencies (which, for purposes of this Advisory, include state agencies responsible for administering CHIP) were previously required to obtain such information only from disclosing entities.

The minimum mandatory information to be disclosed in the enrollment process was greatly expanded to include all addresses for corporate entities (including all business locations and post office boxes); employer identification numbers; and names, addresses, dates of birth, and Social Security numbers for all persons with an ownership or controlling interest in a disclosing entity fiscal agent or managed care entity as well as their managing employees.

All Medicaid providers will now be subject to the minimum screening requirements, including those providing services through a Medicaid waiver program, but state Medicaid agencies may rely on the background screening conducted by the Medicare program or by other state Medicaid agencies.

As a result, the state Medicaid agency is not required to categorize the risk level of a dually enrolled provider, but, for new or Medicaid-only providers, the state Medicaid agency must go through this process and apply the appropriate screening criteria.

State Medicaid agencies will therefore need to revise enrollment forms to require providers to consent, as a condition of enrollment, to allow CMS, its agents, and contractors or the state Medicaid agency to conduct unannounced site visits at all provider locations.[4]

If a state Medicaid agency is conducting the initial screening of a Medicaid provider who purports to have a professional license in any state, it must now verify or confirm the provider's licensing status, regardless of the applicable risk category. A criminal background check also may be required for Medicaid providers, depending on the risk level and the specifics of state law.[5]

Further, the state Medicaid agency must check all providers against certain federal data bases, including the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), and the Excluded Parties List System (EPLS), and must run monthly checks of its providers against the LEIE and the EPLS.[6]

The final rule also mandates revalidation of Medicaid enrollment for all providers at least every five years, either through screening by the state Medicaid agency or verification of Medicare or other state screening. Any provider (not just Medicaid providers) deactivated for any reason must be rescreened and must submit a new application fee.

The final rule merely sets the floor for state Medicaid agencies, which are free to enact more stringent screening requirements. Medicaid providers therefore should review applicable regulations in each state of enrollment.

As state Medicaid agencies move toward implementation, they may have difficulty, given the fact that many are under-funded and under-staffed. In particular, compliance with the expanded obligation to conduct site visits may present a challenge because Medicaid-waiver programs in many states have tens of thousands of individual enrolled community-based Medicaid providers.

The new screening procedures in the final rule take effect on March 25, 2011, for newly enrolling providers and suppliers and for currently enrolled providers and suppliers who revalidate their enrollment information on or after March 25, 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.

As is the case with many of the ACA's provisions, the implementation of its requirements is constantly changing. CMS will continue to monitor the effectiveness of these screening procedures and may reconsider or modify its approach in the future as it gains additional experience with these and other related procedures under the ACA.

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[4] The Final Rule does not mention state Medicaid agency contractors. This omission is interesting given that CMS already has announced that it will require states to adopt the Recovery Audit Contractor (RAC) program and to contract with RAC Medicaid auditors. The states may broaden the on-site consent provisions in rules promulgated to carry out this requirement and in individual Medicaid enrollment forms to cover state contractors, or other state actors, such as Medicaid Fraud Control Units.

[5] The regulation addressing criminal background check proceudres, 42 C.F.R. § 455.434, is necessarily vague, due to vastly different state laws and procedures governing when background checks are mandated and the party responsible for conducting the checks, including fingerprints. The regulation therefore mandates that state Medicaid agencies, as part of the provider enrollment process, must require providers to consent to criminal background checks, including fingerprints, ''when required to do so under State law or by the level'' of screening. Additionally, state Medicaid agencies must require a provider, or any person with a five percent or more direct or indirect ownership interest, submit a set of fingerprints, within thirty days of a request from the state Medicaid agency or CMS, but the form and manner for submitting materials and conducting the checks, including fingerprints, is to be determined by each state Medicaid agency. Because these are minimum requirements, a state Medicaid agency is free to impose more stringent procedures, as needed.

[6] This requirement applies to providers, providers' agents, those with controlling interest in providers, and managing employees, but not to all employees. However, a state Medicaid agency is free to mandate additional screening.

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Application Fee

To cover the cost of background screening and other program integrity activities, the ACA requires the Secretary to impose an application fee on institutional providers and suppliers in certain circumstances. The fee will be $500 and will be adjusted each year based on the consumer price index.

The application fee takes effect on March 25, 2011, and will apply to all newly enrolling institutional providers and suppliers billing Medicare (i.e., those submitting a CMS-855A, CMS-855B, or CMS855S) and institutional entities billing Medicaid or CHIP on a fee-for-service basis as well as those re-enrolling and revalidating Medicare enrollment.

The fee does not apply to physicians, nurse practitioners, group practices, clinics, or non-physician practitioner organizations submitting the CMS-855I.

Additionally, CMS confirmed that providers and suppliers would not be required to submit an application fee for simple changes to the CMS 885 forms (e.g., new phone number, changes to bank account information and billing address, changes in the name of the provider or supplier, or other such updates).

By statute, the Secretary may grant exceptions and waivers to the application fee if payment of the fee would result in a hardship or would impede access to care for Medicaid beneficiaries in a particular state. The final rule clarifies that a state, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only institutional providers if imposition of the application fee would impede beneficiary access to care.

Although CMS received several comments regarding implementation of a hardship waiver request form, CMS chose not to vary from the process outlined in the proposed rule for seeking a hardship exception.

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 it is denied, CMS would provide its reason(s) for denial. Providers and suppliers could appeal the determination through the existing appeals process.

Providers and suppliers must diligently observe the effective date of the change because Medicare contractors may revoke billing privileges if a Medicare revalidation application is not accompanied by an application fee or hardship waiver request. The final rule does, however, provide a 30-day grace period for submission of the application fee if a hardship exception request is submitted without an application fee, and the request is ultimately denied.

But the final rule clarifies that providers and suppliers may submit both an application fee and hardship exception request to avoid processing delays. CMS will refund the application fee for those providers and suppliers who opt to submit both an application fee and a hardship waiver request if the waiver request is subsequently approved.

Because CMS will 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. The state Medicaid agency must collect the application fee from non-Medicare providers to offset the cost of screening programs.

Temporary Moratoria on Enrollment

The ACA grants the Secretary broad 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.

Under the final rule, CMS can 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, and can limit the addition of new practice locations.

Pending applications from a provider or supplier subject to a moratorium will be denied, unless the Medicare contractor approved the application before the moratorium was imposed and the application is simply awaiting entry into PECOS. CMS confirmed that the moratoria will not apply to existing providers or suppliers (unless they are expanding operations to an area subject to a temporary moratorium), or to situations involving practice location changes, changes in ownership of existing providers or suppliers, mergers, or consolidations.

Additionally, although the final rule does not establish any specific right for an individual provider or supplier subject to a moratorium to request a review or appeal of a decision to impose a moratorium, the final rule does clarify that a provider or supplier denied enrollment based on a moratorium may appeal the issue of whether the moratorium applies to that specific provider or supplier.

Many commenters expressed concern that the standards for imposing moratoria are too broad and vague, and some claimed that CMS failed to outline the criteria that would lead to a moratorium. CMS consistently responded that the ACA gives the Secretary broad authority to impose temporary moratoria, and that a moratorium will only be used when necessary to fight fraud, waste or abuse in the Medicare, Medicaid, or CHIP programs, and after assessing potential adverse impact on beneficiary access to care and supplies.

Although CMS rejected appeals to provide advance notice of a temporary moratorium, the final rule included a modification specifying that CMS will announce any temporary enrollment moratorium and extension in the *Federal Register*, providing the rationale for the moratorium.

CMS confirmed in the final rule that when considering whether to impose a temporary moratorium, it will 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.

In response to comments, CMS stated that it will identify trends through its review of sources of existing data from various sources, including CMS, Medicare contractors, and law enforcement entities. CMS also will consider imposing a moratorium when a state al-

ready has done so in a particular geographic area or on a particular provider type, and 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.

Despite many comments requesting that CMS exempt certain providers or supplier types from moratoria (such as physicians, those assigned to the limited risk level of screening, and those subject to state licensure or certificate of need requirements), CMS would not constrain its ability to impose a moratorium on any or all providers and suppliers when necessary to address fraud, waste, or abuse.

CMS also declined to identify provider or supplier types that may be subject to imposition of a temporary enrollment moratorium, despite some comments suggesting that CMS immediately propose moratoriums on HHAs, hospices, and DMEPOS suppliers.

Regarding the length of the moratoria, CMS believes a six-month period will enable an assessment of a moratorium's impact on the circumstances it was designed to address. The final rule also added language to adopt a commenter's proposal that the Secretary may lift a moratorium in the event of a public health emergency in the affected geographic area.

In addition, the Secretary may lift a moratorium when the President declares an area a disaster, when circumstances warranting the moratorium have abated, when CMS has implemented safeguards to address the cause of the moratorium, or when, in the Secretary's judgment, the moratorium is no longer needed. CMS also specified in the final rule that it will publish a notice in the *Federal Register* when lifting a moratorium.

With respect to state Medicaid programs, state agencies must comply with any temporary moratorium imposed by CMS, unless it would adversely affect beneficiaries' access to care.

Under the final rule, CMS will consult with affected state Medicaid agencies before imposing a moratorium, and if the agency determines the moratorium will adversely affect beneficiary access to medical assistance, it must notify the Secretary in writing. CMS was clear that it does not intend to impose a moratorium that would impede access to needed services.

State Medicaid agencies also will have permissive authority to impose their own moratoria or to impose caps or other limits on enrollment of provider types, but may only impose such moratoria or limits for an initial period of six months, and the moratoria or limits may only be extended in six-month increments after the Secretary's review of the state Medicaid agency's decision to impose the moratorium or limit enrollment.

Suspension of Payments

Medicare

The ACA also expands the Secretary's ability to suspend payments to providers and suppliers in cases of suspected fraudulent activity by adding a new provision to the Social Security Act that allows for the suspension of payments ''pending an investigation of a credible allegation of fraud . . . unless the Secretary determines there is good cause not to suspend such payments.''

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.

Suspensions are limited to 180 days but may be extended an additional 180 days in certain circumstances. For example, 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 requests continuation based on an ongoing investigation and anticipated filing of a civil action or criminal charges.

The final rule vastly expands CMS's authority to suspend Medicare payments. The current 180-day time limit on suspensions will no longer apply if there is a ''credible allegation of fraud,'' which is defined to include allegations from *any source*, including, among others, fraud hotline complaints, claims data mining, and patterns identified through provider audits, civil false claims act cases, and law enforcement investigations.

Allegations are considered credible when they have ''indicia of reliability.'' Numerous commenters expressed concern about the ambiguity of the definitions of these terms. CMS nevertheless declined to define them further, noting that a case-by-case determination will often be necessary and that CMS or its contractors will review all allegations, facts, and information carefully and ''act judiciously'' in each case.

Because payments may be suspended pending the investigation of a credible allegation of fraud, the final rule specifies when such an investigation has concluded, which is when the suspension of payment will cease.

The relevant regulation 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.'' CMS requested input on this and an alternative definition but received no comments.

The final rule differentiates between 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 the latter, but declined in the final rule to provide details on the consultation process. CMS expects that this process will be detailed in a Memorandum of Understanding between the agencies.

After the initiation of a suspension based on a credible allegations of fraud, CMS will evaluate, every 180 days, whether there is good cause to not continue a suspension and will seek a certification from the appropriate law enforcement agency that an ongoing investigation warrants continued suspension.

After 180 days, good cause to end the suspension is deemed to exist if there has been no resolution of the matter, but CMS may nevertheless extend the suspension if: (1) the matter has been referred to the OIG for administrative action, or such an action is pending; or (2) DOJ submits a written request for continuation based on an ongoing investigation and anticipated filing of criminal or civil action (or both), or the pendency of such an action.

Although numerous commenters raised due process concerns related to the suspension of payments, CMS believes that the criteria for suspension of payments are clear and that providers have ''ample opportunity'' to submit information during the established rebuttal

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statement process to demonstrate why suspension is unjustified.

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 months or even years. In addition, it grants the OIG and DOJ a formal role in determining whether a basis for suspension exists.

Medicaid

Current state Medicaid regulations that permit the suspension of Medicaid payments are based on the authority established by 42 C.F.R. § 455.23, which authorizes state Medicaid agencies to temporarily withhold Medicaid payments upon receipt of ''reliable evidence'' of fraud or willful misrepresentations to the Medicaid program, but only after notice and a right of review. The final rule makes substantial changes to this framework.

The applicable federal regulations, as amended by the final rule, also include the term ''credible allegation of fraud,'' which encompasses allegations of billing fraud from any source that has the indicia of reliability, as determined by the state Medicaid agency.

Once there is a credible allegation of fraud against an enrolled Medicaid provider, a state Medicaid agency is now required to suspend Medicaid payments to that provider, unless it has good cause not to suspend payment, or to suspend only in part (i.e., suspend Medicaid payment as to only a specific type of claim from the provider).

Suspension can occur without prior notice, and the right to administrative review is dependent on state law. After the suspension is in place, the state Medicaid agency must send a notice of the suspension (if it has not already done so), unless a law enforcement agency asks it to withhold such notice, in which case a delay of up to 90 days is permitted.

The notice must set forth the applicable state administrative appeals process and, at a minimum, give the provider an opportunity to present written evidence for consideration.

A determination of ''good cause'' not to suspend payments, to limit a suspension in part, or to lift a suspension may exist based on a variety of factors, including a law enforcement request, due to an ongoing investigation; the availability of other adequate remedies to redress the concern; the lack of recipient access to services if the suspension is in effect; a determination by the state Medicaid agency, based on submitted evidence, that the suspension should be removed; or a determination by the state Medicaid agency that the suspension ''is not in the best interests of the Medicaid program.''

The state Medicaid agency also may enter or lift a suspension in part if, among other things, it determines that the credible allegation of fraud is limited to a particular type of claim or a specific business unit of the provider.

If the state Medicaid agency has instituted a suspension or has a legitimate basis to do so, but the matter had not yet been referred to the state's Medicaid Fraud Control Unit (MFCU), the state Medicaid agency must submit a written referral to the MFCU within one business day.[7] The agency must do so even if it determines that it has good cause not to enforce a suspension.

If the MFCU accepts the case for investigation, the suspension will remain in place until the investigation and any associated enforcement proceedings are complete; if the MFCU declines the case, the payment suspension must end unless the state Medicaid agency makes a referral to another law enforcement agency or has alternate federal or state authority to impose a suspension.

The final rule also amends the regulations governing MFCU activities to provide authority for the MFCU to refer a matter to the state Medicaid agency for suspension. A suspension will remain in effect until legal proceedings governing the fraud allegations are complete or until the state Medicaid agency determines there is insufficient evidence of fraud.

The final rule also requires the state Medicaid agency to provide annually to CMS summary information about suspensions, including details about each suspensions and the outcome and instances where it determined good cause existed not to impose a suspension in whole or in part.

Solicitation of Comments on Ethics and Compliance Program Requirements

Although the proposed rule sought comments on mandatory compliance program requirements set forth in the ACA, CMS declined to move forward with implementation at this time even though it received ''numerous comments'' in response to its request.

At a later, unspecified date, CMS will publish a notice of proposed rule making addressing the required ''core elements'' of a compliance program.

Every Medicare, Medicaid, and CHIP provider and supplier should closely follow the development of these regulations because compliance will be a condition of enrollment.

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[7] In North Dakota, the only state that does not have a MFCU, the referral must be made to the appropriate law enforcement agency.

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

The ACA requires state Medicaid programs to 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. Before enactment of the ACA, the state Medicaid agencies were the arbiters of who did or did not qualify to be a Medicaid provider, except that they were prohibited from paying Medicaid funds to individuals or entities on the LEIE.

According to the final rule, which changes the status quo, state Medicaid agencies cannot enroll, or must terminate, providers in the following circumstances: (1) the provider fails to provide mandatory screening information; (2) the provider fails to allow access for a site visit; (3) any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to Medicaid, Medicare, or a Title 21 program in the last ten years; (4) the provider was previously terminated from a Medicaid program or CHIP; or (5) the state Medicaid agency determines that any information furnished on the enrollment application was false or cannot be verified.

A state Medicaid agency may disregard this mandate only if it documents in writing the reasons why denial or termination ''is not in the best interests of the 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 apply also to suppliers and eligible professionals whose Medicare billing privileges have been revoked, in the final rule, CMS adopted a new definition of the term ''termination'' that reflects this interpretation.

Additionally, in response to several comments, CMS clarified that termination is only triggered when billing privileges are revoked for cause, which may include fraud, integrity, or quality.

Finally, CMS will allow 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 final rule will 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 rule will 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 some aspects of the final regulations are dictated by the ACA, CMS has applied its discretion in many respects. Providers and suppliers should take the time to learn these new rules and be aware of the effective dates of the changes to the provider enrollment and revalidation processes.

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