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NEW REGULATIONS IMPLEMENT HEALTH REFORM'S ENFORCEMENT TOOLS: PROVIDERS AND SUPPLIERS IN FOCUS

February 14, 2011

IMPORTANT DATES

March 25, 2011
Final Rule provisions take effect, including enhanced screening provisions and enrollment fee requirements for newly enrolling providers and suppliers (such as eligible professionals) and providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment

March 25, 2012
Enhanced screening procedures and enrollment fee requirements take effect for currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals

On February 2, 2011, the Centers for Medicare and Medicaid Services ("CMS") published new rules ("Final Rule")[1] authorized by the Affordable Care Act ("ACA")[2] creating a vigorous screening process for new and existing Medicare, Medicaid and the Children's Health Insurance Program ("CHIP") providers and suppliers; giving CMS authority to temporarily stop enrollment of new providers and suppliers; expanding the ability of CMS and States to temporarily suspend payments to providers and suppliers; establishing requirements for States to terminate providers from the Medicaid and CHIP programs; and adding several other enrollment-related provisions. Generally, the new rules are effective **March 25, 2011**.

Publication of the Final Rule follows the recent announcement that the federal government recovered more than $4 billion in FY 2010 from health care fraud prosecutions and settlements – the largest annual amount ever recovered in health care fraud cases. Significantly, the 2010 recoveries from civil health care matters brought under the False Claims Act were more than $2.5 billion, reportedly the largest in the history of the Department of Justice ("DOJ"). These results, and the Final Rule, are further evidence of the increased focus the government will place on enforcement efforts in 2011 and beyond.

Health care entities need to develop proactive measures to prepare for heightened levels of enforcement and the use of new tools to force health care organizations out of the federal health care programs through payment suspension when CMS determines, in its broad and largely undefined discretion, that a "credible allegation of fraud" exists.

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[1] 76 Fed. Reg. 5,862-5,971 (Feb. 2, 2011).

[2] References in this Alert to the Affordable Care Act ("ACA") are to The Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152).

Significantly, these regulations also create substantial barriers to entry for new and expanded health care organizations. New practice locations of existing health care organizations will be treated as new suppliers, subject to rigorous screening, as well as possible imposition of moratoria on enrollment of particular types of health care organizations or in certain geographic areas. Similarly, changes of ownership will undergo enhanced screening, likely to prolong the time and resources necessary to accomplish certain transactions. These barriers to entry and growth come precisely at the time when increased access to health care services, through the creation of new and expanded health care organizations, will be essential to serve newly covered individuals and otherwise meet the objectives of health reform.

This Alert highlights the new tools available to CMS and States under the Final Rule and directs health care entities to the significant changes and key issues the rules present.

I. Suspension of Payments

The Final Rule implements section 6402(h) of the ACA, which establishes requirements for suspension of Medicare and Medicaid payments to providers pending investigation of "credible allegations of fraud." Because ACA enumerates separate standards for Medicare and Medicaid payment suspension, it is important to understand the requirements set forth for each program, and the ways in which they differ.

Suspension of Payments to Medicare Providers

ACA expands the authority of the Secretary of the Department of Health and Human Services ("HHS") 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 such payments. While the ACA requires the Secretary to consult with the HHS Office of Inspector General ("OIG") in determining whether a "credible allegation of fraud" exists, it does not provide a definition for that term and otherwise leaves it to the Secretary to define the limits of this seemingly broad delegation of authority.

In the Final Rule, CMS defines "credible allegation of fraud" as "an allegation of fraud from any source, including but not limited to the following: (1) fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations."[3] The Final Rule further provides that allegations will be deemed credible when they have "indicia of reliability," another undefined term. CMS indicates that it did not intend to delineate a precise definition; rather, it intends a fact-specific, case-by-case review. CMS also notes that while it will consult with OIG, as it is statutorily required to do,[4] the agency retains the ultimate authority whether to impose payment suspension upon a provider or supplier.

Not only has Congress entrusted CMS to establish the parameters by which payment may be suspended in the first instance, it also relied upon CMS to delineate when to forgo suspension for good cause. The Final Rule enumerates four circumstances under which CMS may find that good cause exists to not suspend or continue to suspend payments:

[3] 76 Fed. Reg. at 5961, *amending* 42 C.F.R. § 405.370(a).
[4] CMS indicated that it will also consult with the Department of Justice "where appropriate."

- OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because it may compromise or jeopardize an investigation;
- It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;
- It is determined that other available remedies implemented by CMS or a Medicare Contractor can more effectively or quickly protect Medicare funds than would implementing a payment suspension; or
- CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.[5]

The Final Rule does impose some limits on the length of time payment may be suspended upon a credible allegation of fraud. A suspension will not continue if it has been in effect for 18 months and there has not been a "resolution of the investigation."[6] A resolution of an investigation will occur "when legal action 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] However, a suspension will be allowed to continue beyond 18 months if the case has been referred to OIG and administrative action is pending or being considered, or where the DOJ submits a written request to CMS for continuation of suspension explaining how criminal and/or civil action may be affected if an extension is not granted.

The Final Rule also requires CMS to conduct an evaluation every 180 days to determine whether there is good cause not to continue a suspension based upon a credible allegation of fraud. As part of this evaluation, CMS must request a certification from OIG or other law enforcement agency as to whether that agency will continue to investigate the matter.

Suspension of Payments to Medicaid Providers

ACA provides that States shall not receive Federal Financial Participation in cases where they fail to suspend Medicaid payments during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity, as determined by the State, unless the State determines that there is good cause not to suspend such payments.

The most significant change to the current regulatory scheme is that the ACA and the Final Rule *mandate* suspension of Medicaid payments where an investigation of a credible allegation of fraud exists. The Final Rule also lowers the threshold level of evidence necessary to suspend payments; where the existing regulations require "receipt of reliable evidence," the Final Rule requires only a "credible allegation."

The Final Rule sets forth the same definition of "credible allegation of fraud" used for the Medicare program but adds that the allegation must be "verified by the State," and that allegations are

[5] 76 Fed. Reg. at 5961-62, *amending* 42 C.F.R. § 405.371(b).
[6] The Final Rule clarifies that CMS retains its existing authority to suspend payments in cases that do not involve fraud but are based solely on potential overpayments. Where payments are suspended based on a "credible allegation of fraud," CMS must separately determine if an overpayment exists. Therefore, it is possible for a payment suspension to continue as an overpayment suspension.
[7] 76 Fed. Reg. at 5961, *amending* 42 C.F.R. § 405.370(a).

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.*"[8] CMS declined to provide a more precise definition, or to limit the potential sources from which States may derive credible allegations of fraud, on the grounds that the various States may have different considerations in determining what may be a credible allegation. CMS also declined to require States to consult with HHS in making such a determination.

The Final Rule also clarifies that an investigation need not originate in or with a law enforcement agency in order to satisfy the requirement for a "pending investigation"; investigations conducted by State Medicaid agencies are sufficient to trigger a payment suspension. However, when a State Medicaid agency investigation leads to the initiation of a payment suspension, the Medicaid agency will be required to make a formal, written referral to its Medicaid Fraud Control Unit ("MFCU"), or, where a State does not have a MFCU, to an appropriate law enforcement agency. If the MFCU or other law enforcement agency accepts the referral for investigation, the payment suspension may continue under the standards established under the Final Rule.

Similar to the regulatory scheme for Medicare, the Final Rule establishes several "good cause" exceptions by which States may decide not to suspend payments or continue a payment suspension previously imposed, some of which are substantially similar to those available to CMS for the Medicare program (law enforcement request; more effective available remedies; not in the best interests of the program). The good cause exceptions unique to the Medicaid program are:

- The State determines that suspension should be removed based upon the submission of written evidence by the subject of the payment suspension;
- Recipient access to items or services would be jeopardized by a payment suspension because either the provider is the sole community physician or the sole source of essential specialized services in a community; or the provider serves a large number of recipients within an HRSA-designated medically underserved area; or
- Law enforcement declines to certify that a matter continues to be under investigation.[9]

In addition, a State may find good cause exists to partially suspend payments where an investigation is solely and definitively centered on only a specific type of claim, or arises from only a specific business unit of a provider.

States may suspend Medicaid payments without prior notice to providers; however, the Final Rule requires notice within 5 days of initiating payment suspension. Law enforcement agencies may request, in writing, a delay in notification of up to 30 days, renewable up to two times for a total delay of no more than 90 days. In addition, the provisions of the Final Rule that govern the duration of a Medicaid payment suspension are similar to the standard established for the Medicare program: suspension of payment will not continue after either the agency or prosecuting authorities determine that there is insufficient evidence of fraud by the provider or legal proceedings related to the provider's alleged fraud are completed.

[8] Fed. Reg. at 5966, *amending* 42 C.F.R. § 455.2 (emphasis added).
[9] 76 Fed. Reg. at 5966; *amending* 42 C.F.R. § 455.23(e)

Key Issues

- With the adoption of the Final Rule, CMS will wield a considerable amount of discretion as to whether to impose, or continue, a payment suspension on a provider. As reflected in the comments to the proposed rule, providers have legitimate reason to raise concern over lack of adequate due process, particularly since an 18-month suspension could easily put a provider out of business. CMS continues to provide for a "rebuttal process," whereby providers may submit information to CMS demonstrating why a payment suspension should not be imposed.[10] However, because CMS is not required to supply notice prior to suspending payments, providers will need to be vigilant in reviewing their remittances to promptly identify, and challenge, any attempt by CMS to suspend payments.

- The Medicaid payment suspension regulatory scheme raises many of the same concerns: States are mandated to suspend payments to Medicaid providers under a broad and vaguely-defined standard; suspension can be imposed without prior notice; and the only time limit imposed is that suspension cannot continue once the endpoint is reached (*i.e.*, determination of insufficient evidence or completion of legal proceedings). Moreover, the only appeal rights available to providers are those that are provided for under State law.

- Using fraud hotline complaints as a potential "credible allegation of fraud" is troublesome; disingenuous allegations from competitors and/or disgruntled former employees could intentionally disrupt businesses.

- There is a lack of specificity with respect to the mechanics of the required consultation between CMS and OIG. While CMS indicated that a Memorandum of Understanding between the respective agencies will further detail the process, it is not clear whether it will be made publicly available.

- Providers will need to ensure they have a robust compliance program to prevent and detect potential fraud, and should consider undertaking internal audits and data mining to enhance these efforts.

- Finally, if CMS or a State Medicaid agency attempts to impose a payment suspension, providers should consult with counsel regarding strategies to challenge or reverse the attempted suspension.

[10] *See* 42 C.F.R. § 405.372(b).

II. Termination of Medicaid and CHIP Providers

Section 6501 amends Section 1902(a)(39) of the Act and requires that a State Medicaid program terminate a provider or supplier if the provider's or supplier's participation has been terminated[11] or its billing privileges have been revoked for cause[12] under title XVIII of the Act or another State's Medicaid program. A State Medicaid program will only terminate a provider after the provider has exhausted all available appeal rights in the Medicare program or in the State that originally terminated the provider. Under the rule, a State Medicaid program must deny enrollment or terminate a provider that is terminated (under Medicare or any other State's Medicaid program or CHIP) or had its billing privileges revoked on or after January 1, 2011. According to the rule, the duration of the State's termination should be consistent with State law, and not "necessarily driven by the length of the Medicare termination."[13] In addition, the Final Rule allows CMS to revoke Medicare billing privileges when a State Medicaid agency terminates, suspends, or revokes a provider's or supplier's Medicaid enrollment or billing privileges.

Key Issues

- Employers must run a periodic exclusions check, not only in the OIG and the General Services Administration ("GSA") databases, but also State databases to the extent that they are available. CMS has indicated that it is developing a centralized database; however, it is unclear whether it will be publicly available or available to providers.
- Providers should periodically check these same databases to ensure that they have not been erroneously excluded, as exclusion can have much farther-reaching ramifications.

III. Temporary Moratoria on Enrollment of Providers and Suppliers

The ACA also gave the Secretary of HHS new authority to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines such moratoria are necessary to prevent or combat health care fraud, waste, or abuse.

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[11] Termination is defined to mean, "(1) For a—(i) Medicaid or CHIP provider, a State Medicaid program or CHIP has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and (ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired. (2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary. (ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated. (3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—(i) Fraud; (ii) Integrity; or (iii) Quality. 76 Fed. Reg. at 5967.

[12] For cause may include, "fraud, integrity or quality, but not cases where the providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked based upon voluntary action taken by the provider to end its participation in the program, except where that voluntary action is taken to avoid a sanction, or where a State removes inactive providers from its enrollment files." 76 Fed. Reg. at 5943.

[13] 76 Fed. Reg. at 5944.

The Final Rule allows CMS to impose such temporary moratoria in 6-month increments: (1) where CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste, or abuse; (2) where a State has imposed a moratorium on enrollment in a particular geographic area, or on a particular type of provider or supplier, or both; or (3) where CMS, in consultation with the OIG or DOJ or both, and with the approval of the CMS Administrator, identifies a particular geographic area or a particular provider or supplier type, or both, as having significant potential for fraud, waste, or abuse in the Medicare program.[14]

CMS will announce the implementation of all such moratoria in the Federal Register and also address it in other forums, including CMS press releases, CMS provider open door forums, on CMS provider listservs, and on the CMS Provider / Supplier Enrollment website (www.cms.hhs.gov/MedicareProviderSupEnroll). CMS will also require Medicare contractors to post the moratorium announcement on their websites.

Significantly, the rule states expressly that there will be no judicial review of temporary moratoria. Providers or suppliers affected by such moratoria may administratively appeal adverse determinations based on the imposition of temporary moratoria, up to and including the Departmental Appeal Board level of review. Further, CMS may lift moratoria under certain circumstances: (1) in the case of a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; (2) circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address any program vulnerability that was the basis for the moratorium; or (3) in the judgment of the Secretary, the moratorium is no longer needed.

State Medicaid programs will be required to comply with temporary moratoria imposed by CMS, unless the imposition of such moratoria would adversely affect Medicaid or CHIP beneficiaries' access to medical assistance. The State will be required to provide CMS with written details of the moratorium's adverse impact on Medicaid and/or CHIP beneficiaries.

Key Issues

- The lack of judicial review provides significant new power to CMS to limit provider participation in federal health care programs.
- Because of the limited recourse available to providers, the possibility of a moratorium on enrollment may: (1) deter providers from enrolling in federal health care programs; and/or (2) have a chilling effect on the expansion or investment in health care entities, due to the uncertainty of the ability to enroll in a timely manner.

[14] In comments to the final rule, CMS explained why the duration of moratoria will be 6-month increments. Specifically, according to CMS, "[w]e proposed the 6 month duration because it would be sufficiently long enough to enable an assessment of its impact on the circumstances that the moratorium was designed to address, and would afford us the opportunity to determine whether the circumstances warranting the imposition of a temporary enrollment moratorium have abated or whether we have implemented program safeguards to address program vulnerabilities. The 6 month period would also afford the Secretary reasonable opportunity to determine whether the moratorium was no longer needed."

IV. Enhanced Screening under Medicare, Medicaid, and CHIP

The ACA requires the Secretary of HHS, in consultation with the OIG, to establish screening procedures for providers and suppliers under Medicare, Medicaid and CHIP. These new screening procedures, which include licensure checks, criminal background checks, fingerprinting, and unscheduled/unannounced site visits, are applicable to newly enrolling providers and suppliers, including eligible professionals, beginning on **March 25, 2011.**[15] The procedures also are applicable beginning on **March 25, 2011** for providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information.[16] The procedures are applicable to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals, beginning on **March 25, 2012**.[17]

The Final Rule establishes three levels of screening – Limited, Moderate and High. The type of procedure assigned to each level is outlined below in **Table 1**. CMS assigned the various screening levels as outlined below in **Table 2**.

Table 1. Screening Levels and Procedures for Medicare Physicians, Non-Physician Practitioners, Providers, and Suppliers

Type of Screening Required	Limited	Moderate	High
Verify any provider- / supplier-specific requirements established by Medicare	X	X	X
Conduct licensure verifications (may include licensure checks across states)	X	X	X
Conduct database checks: to verify Social Security Number; National Provider Identifier; National Practitioner Data Bank licensure; OIG exclusions; taxpayer identification number; death of an individual practitioner, owner, authorized official, delegated official, or supervising physician	X	X	X
Conduct unscheduled or unannounced site visits		X	X
Conduct fingerprint-based criminal history check of law enforcement repositories			X

[15] Notably, existing DMEPOS suppliers undergoing a change of ownership or opening a new location will be treated, and must enroll, as a new supplier. Accordingly, DMEPOS suppliers undergoing changes of ownership also will be subject to the high level of screening. 76 Fed. Reg. at 5880.

[16] Within the Medicare program, the March 25, 2011 implementation date will impact those currently-enrolled providers and suppliers whose 5-year revalidation, or 3-year revalidation for DMEPOS suppliers, results in revalidation occurring on or after March 25, 2011 and before March 23, 2012.

[17] The timetable for implementation applies to all the screening procedures except fingerprint-based criminal history record checks that will be required for providers and suppliers in the "high" risk category. CMS will delay implementation of this type of screening until 60 days after the publication of sub-regulatory guidance on how this screening provision will be implemented.

Table 2. Risk Categorization of Providers and Suppliers

Provider / Supplier Category	Limited	Moderate	High
Physician or non-physician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapist groups	X		
Ambulatory surgical centers, competitive acquisition program / Part B vendors, end-stage renal disease facilities, federally qualified health centers, histocompatibility laboratories, hospitals (including critical access hospitals), Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B form, radiation therapy centers, religious non-medical health care institutions, rural health clinics, and skilled nursing facilities	X		
Ambulance suppliers, community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, independent diagnostic testing facilities, independent clinical laboratories, and physical therapy, including physical therapy groups and portable x-ray suppliers		X	
Currently enrolled (revalidating) home health agencies		X	
Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of DMEPOS			X

The relevant Medicare contractor (*e.g.*, fiscal intermediary, regional home health intermediary, carriers, Part A or Part B Medicare Administrative Contractors, or the National Supplier Clearinghouse Administrative Contractor) will utilize the screening tools mandated by CMS to assign a level to a particular provider or supplier type. CMS reserves the right to move a provider or supplier from the "limited" or "moderate" categories of screening to the "high" level of screening if the provider has been excluded by the OIG or has had its billing privileges revoked in the previous 10 years. Additionally, any provider or supplier that has been subject to any final adverse action (as defined in 42 C.F.R. § 424.502) will be moved to the "high" screening level.

The Final Rule requires that State screening methods for Medicaid and CHIP providers follow those established under the Medicare program, but allows States to rely on the results of the screening conducted by a Medicare contractor or by the State Medicaid programs and CHIP of other states.

Key Issues

- This is the first instance in which fingerprinting has been required in order to participate in the federal health care programs, and the costs associated with fingerprinting are not insignificant.
- Providers need to be diligent in ensuring that their licenses and registrations are maintained in good standing, and health care entities should have an internal monitoring process to ensure that employee licenses are maintained. Providers must also make certain that they screen all employees in both the OIG exclusion database and the GSA Excluded Parties List System.
- Because they will be subject the highest level of screening, home health agencies and DMEPOS suppliers seeking to newly enroll in Medicare, Medicaid, or CHIP should be particularly vigilant in their maintenance of information relevant to the screening process.

V. Enrollment Application Fees

ACA requires the Secretary of HHS to impose a non-refundable application fee on each "institutional provider of medical or other items or services or supplier."[18] An institutional provider is defined as "any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and nonphysician practitioner organizations), CMS-855S or associated Internet-based PECOS enrollment application."[19] In addition to the enumerated providers and suppliers, the State may also impose an application fee for any institutional entity that bills the State Medicaid program or CHIP on a fee-for-service basis.

As with the new screening procedures, the enrollment fee is applicable to newly enrolling providers and suppliers, including eligible professionals, beginning on **March 25, 2011**. As of **March 25, 2011,** providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information must also submit the application fee. The application fee requirement is applicable to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals beginning on **March 23, 2012**. The Secretary, acting through CMS, may, on a case-by-case basis, exempt a provider or supplier from the required application fee if CMS determines that the

[18] The application fee for providers and suppliers is $500 in 2010 and is adjusted annually by the "percentage change in the consumer price index for all urban consumers (all items; United States city average), ("CPI-U") for the 12-month period ending with June of the previous year." 76 Fed. Reg. at 5907. If the fee is at an uneven dollar amount, the fee will be rounded to the nearest whole dollar.

[19] Physicians and non-physician practitioner organizations are excluded from the application fee requirement. The rule provides that institutional providers include, but are not limited to: "the range of ambulance service suppliers; ASCs; CMHCs; CORFs; DMEPOS suppliers; ESRD facilities, FQHCs; histocompatibility laboratories; HHAs; hospices; hospitals, including but not limited to acute inpatient facilities, inpatient psychiatric facilities (IPFs), inpatient rehabilitation facilities (IRFs), and physician-owned specialty hospitals; CAHs; independent clinical laboratories; IDTFs; mammography centers; mass immunizers (roster billers); OPOs; outpatient physical therapy/occupational therapy/speech pathology services, portable x-ray suppliers; SNFs; radiation therapy centers; RNHCIs; and RHCs." 76 Fed. Reg. at 5907.

fee would result in a hardship. Likewise, the Secretary may waive the enrollment application fee for Medicaid providers for whom the State demonstrates that fee requirement would hinder Medicaid beneficiaries' access to care.

The application fee is required with the submission of a new application, an application to establish a new practice location, as part of a revalidation, or in response to a CMS revalidation request. The fee, or hardship exception request, must be submitted at the time of filing of a Medicare enrollment application or revalidation. CMS will not begin processing the application/revalidation until the application fee is received and credited to the United States Treasury. If the provider or supplier fails to submit the application fee or hardship exception request, CMS will reject and return the application, without further review. Similarly, CMS may reject an application if the full application amount is not able to be deposited into a government-owned account, or the funds are not able to be credited to the U.S. Treasury.

In addition to rejecting the application, CMS may revoke the provider's or supplier's billing privileges: (1) for the failure of an institutional provider to submit an application fee or request for hardship exception with the Medicare revalidation application, or when the hardship exception is not granted;[20] or (2) when CMS is unable to deposit the full amount, or when the funds cannot be credited to the U.S. Treasury.

Key Issues

- The imposition of an application fee, and the requirement that the fee is deposited and credited to the U.S. Treasury prior to CMS' review of the application, may pose a delay in CMS' processing of enrollment applications and validations.
- Currently enrolled providers filing a Medicare revalidation application must ensure timely submission of the application fee or hardship exception request, as failure to do so may result in revocation of a provider's billing privileges.

Commentary on Mandatory Compliance Programs

As part of the Proposed Rule, CMS solicited comments on the compliance program requirements imposed by sections 6102 and 6401(a) of the ACA. However, in the Final Rule, CMS decided not to finalize the proposed compliance plan requirements at this time. Instead, CMS is in the process of developing a new Notice of Proposed Rulemaking that will incorporate the compliance plan provisions and comments received to be published at a later date. CMS also confirmed that it will offer another opportunity for further public comment. CMS indicated that it is most interested in receiving comments on the use of the seven elements of an effective compliance and ethics program from the U.S. Federal Sentencing Guidelines Manual as the basis for the core elements of the required compliance programs for Medicare, Medicaid, and CHIP enrollment.

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[20] The institutional provider must submit the application form and fee within 30 days of receiving notification that the hardship exception was not granted or that the application was not accompanied by the application fee.

The Final Rule provides the mechanisms needed to implement new tools plainly designed to assist the Government's efforts in pursuing health care entities. However, it will likely also have a chilling effect on Health Reform's effort to expand access to health care. While the Final Rule attempts to provide "carve outs" to address access issues, it places major roadblocks in the path of individuals and businesses seeking to participate in government programs; there is no question that otherwise qualified providers and suppliers will be deterred from enrolling as a result of these onerous new requirements. Existing providers, particularly those looking to expand their businesses, are also faced with significant new challenges. The tacit result will be fewer providers, which means a greater limitation on healthcare access – exactly the opposite of a principal stated purpose of the ACA.

While CMS has suggested that it intends to use its new powers judiciously, health care entities, both current and prospective, cannot be complacent. They need to be prepared to challenge CMS's efforts to derail their participation, both for their own benefit and for the welfare of the public at large.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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