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THE MEDICARE ENROLLMENT PROCESS – CMS'S MOST POTENT PROGRAM INTEGRITY TOOL

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Introduction

In recent years, the Centers for Medicare & Medicaid Services ("CMS") has begun to place paramount importance on its ability to deny or revoke billing privileges as a means of protecting the Medicare program (the "Program") and its beneficiaries from fraud and abuse. The Patient Protection and Affordable Care Act ("PPACA")[1] and the Healthcare and Education Reconciliation Act of 2010 (the "Reconciliation Act")[2] greatly added to the enrollment-related weapons at CMS's disposal, and CMS has not lost any time implementing some of them. Unfortunately, because of the sheer number of enrollment rules, many of which are time sensitive, and because the enrollment process is largely implemented though CMS's contractors, whose procedures may not always be consistent with each other or those of CMS, even competent and ethical suppliers and providers can have their billing privileges delayed, denied, or revoked due to unintentional errors on their part (or on the part of the CMS contractors). This article explains the workings of the Medicare enrollment process, outlines the relevant provisions of PPACA and the Reconciliation Act, discusses the administrative appeals process for adverse enrollment actions, and offers some practical advice on preventing and resolving problems.

Prelude to the Medicare Enrollment Process

When Medicare was enacted in 1965, there was a concern among policymakers that buy-in among the medical community was needed and that placing significant conditions on enrollment would put the viability of the Program in jeopardy. As a result, until fairly recently, there were very few barriers to enrolling in Medicare as a provider or supplier.[3] About fifteen years ago, however, there was a visible shift in CMS's position, spurred on by the discovery that non-existent durable medical equipment, prosthetics,

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Chair's Corner

The 12th Annual EMI Conference is the Best One Yet

As those of you who were there can attest, our Emerging Issues Conference ("EMI"), held in New Orleans from Feb. 23-25, 2011, was a tremendous success. Over 300 people attended a wide range of outstanding, informative and enjoyable programs in the wonderful ambiance of pre-Mardi Gras New Orleans. There were parades (complete with bead-catching opportunities) and street bands right outside the hotel, in the Garden District and other venues, fantastic food and fellowship. Aside from the Section's various receptions, numerous ad hoc groups got together after the days' programs and headed out en masse to some of New Orleans' great restaurants, often guided by our New Orleans members. Numerous Section members stayed through the weekend to attend the Open Council meeting on Saturday, compete in the Margarita Cup Golf Tournament, attend a New Orleans cooking class, visit the World War II Museum or otherwise enjoy the city. Many, many thanks are due to Co-Chairs Hilary Young and Joyce Hall, the outstanding Planning Committee and the awesome efforts of Section staff! See page 63 to see photos from EMI.

Highlights from the Council Meeting

The Council Meeting at EMI is traditionally open to the public, and was particularly notable this year because all Section Interest Group ("IG") Chairs were invited to participate and report on their IG's activities. It was gratifying to learn that so many IGs are increasing their membership, and to see how many projects are in the works. New initiatives included membership surveys, free teleconferences, new IG topical subgroups and mentoring programs. The Council meeting also included presentations by candidates for ABA President and the Chair of the House of Delegates, as well as a discussion of Section initiatives, including our obtaining authority to submit comments to government agencies on behalf of the Section as a whole. (We are a disparate group and the ABA has a process in place to help assure that all perspectives are represented.) The Council also discussed upcoming programs and publications.

The Publications Committee

Most of you know about the Section's IGs and Task Forces. However, we have numerous administrative committees that help facilitate the Section's various activities. The Publications Committee, chaired by

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orthotics and supplies ("DMEPOS" or "DME") suppliers in South Florida were bilking the Program out of millions of dollars. The fraud was made possible because it was relatively easy to supply CMS with phony names and addresses for phantom DMEPOS suppliers, obtain billing numbers, and submit claims for services that were not furnished. CMS reported in 1996 that 32 of 36 new DMEPOS supplier applicants in the Miami, Florida area were not bona fide businesses.[4]

Due to the discovery of the bogus applicants in Miami, CMS requested the Department of Health and Human Services' ("HHS") Office of Inspector General (the "OIG") to determine whether similar problems existed elsewhere in the country. The OIG conducted unannounced site visits to 420 DMEPOS suppliers that were issued billing numbers between January and June of 1996, and inspected 35 applicants that had not yet been approved, in 12 large metropolitan areas in California, Florida, Illinois, New York, and Texas.[5] In its December 1997 report, the OIG stated that it found that one of every 14 DMEPOS suppliers and one of every nine new applicants did not have a verifiable physical address; 41 percent of existing suppliers and 40 percent of new applicants failed to meet at least one supplier standard.[6] It further found that oversight of home-based DMEPOS suppliers was particularly difficult (*e.g.*, often, suppliers were not at home during normal business hours and had answering machines that did not identify the business).[7] The ease and low expense of acquiring a supplier number facilitated the entry of abusers into the Program.

The OIG concluded that CMS and its contractors were approving many inexperienced, unqualified, and unethical applicants for DMEPOS supplier numbers. Among other recommendations, the OIG proposed that the enrollment application form for DMEPOS suppliers, which it identified as "inadequate," be revised.[8]

About the same time, Congress was taking action to require CMS to obtain more information from the individuals and entities with which it does business. For example, section 31001(i)(1) of the Debt Collection Improvement Act of 1996[9] amended section 7701 of 31 U.S.C. by adding paragraph (c) to require any person or entity doing business with the Federal Government to provide its Tax Identification Number ("TIN"). The following year, section 4313 of the Balanced Budget Act of 1997 ("BBA")[10] amended sections 1124(a)(1) and 1124A of the Social Security Act (the "Act"), requiring providers and suppliers to disclose the Employer Identification Number ("EIN") and Social Security Number ("SSN") of each person with an ownership or control interest in the provider or supplier, or in any subcontractor in which the provider or supplier directly or indirectly has a five percent or more ownership interest, as well as any managing employees, including directors and board members of corporations and non-profit organizations and charities.

The Medicare Enrollment Process

The 855 Gateway

CMS developed its enrollment application at about the same time as the government discovered the fraudulent DME suppliers. In order to receive payment for covered items or services from Medicare (in the case of an assigned claim) or from a Medicare beneficiary (in the case of an unassigned claim), a provider[11] or supplier[12] must first be enrolled in the Program. Beginning in 1996, CMS has required all new providers and suppliers of healthcare items and services seeking reimbursement under the Program to submit the appropriate CMS Form 855 Provider/Supplier Enrollment Application (the "CMS-855") in order to enroll in the Program.[13] Once enrolled, the provider or supplier receives its billing privileges and is issued a valid billing number.

The CMS-855 is an instrument CMS uses to obtain important information about providers and suppliers for the purposes of authorizing billing and establishing eligibility to furnish services to Medicare beneficiaries. The information submitted on the CMS-855 allows CMS to identify providers and suppliers uniquely. The CMS-855 enrollment process is conducted through the applicable Medicare contractor (*i.e.*, carrier, fiscal intermediary, Medicare Administrative Contractor ("MAC"),[14] or the National Supplier Clearinghouse ("NSC") for DMEPOS suppliers) that services the supplier's or provider's state or geographic area. There are several versions of the CMS-855; the appropriate application depends on whether the applicant is a provider or a certain type of supplier, or whether the applicant is attempting to reassign benefits.[15]

As part of the CMS-855 enrollment application process, providers and suppliers must report complete and accurate information applicable to their respective provider or supplier type, submit any documentation CMS requires to identify the provider or supplier (*e.g.*, TIN, SSN), and submit any documentation CMS requires to establish the provider's or supplier's eligibility to provide the services (such as medical license or proof of qualified technicians).[16] Further, the CMS-855 must be signed by an authorized official who has authority to bind the provider or supplier and who has ownership or control in such entity (*e.g.*, CEO, President, etc.).[17]

Reportable Events

An important aspect of the enrollment process is the requirement that certain events are required to be reported to the applicable Medicare contractor within specified time frames. This requirement allows CMS

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to continuously verify that a provider or supplier is compliant with the enrollment requirements and that continued enrollment is appropriate. The first page of the CMS-855 notifies providers and suppliers that the enrollment application is used to report changes in information previously provided on their initial enrollment application. The regulations provide that significant events, such as a change in ownership ("CHOW"), change in location, or an adverse legal action taken against a provider or supplier, must be reported within 30 days of the event, and that all other changes in the enrollment status must be reported within 90 days.[18] The updated CMS-855 may be signed by the provider's or supplier's delegated official. If the delegation of authority has not been established, CMS will accept only the signature of the authorized official whose name and signature appears on the initial CMS-855.[19]

Revalidation

In addition to reporting changes in their enrollment information—if and when they occur—providers and suppliers are required to update and certify periodically the accuracy of their enrollment information in order to receive and maintain their billing privileges (the "Revalidation Cycle").[20] For most[21] providers and suppliers, the Revalidation Cycle occurs every five years. The Revalidation Cycle's enrollment requirements are independent and distinct from survey and certification requirements; thus, new surveys and certifications are not required as part of the Revalidation Cycle. However, providers and suppliers are required to continue to meet the applicable mandatory state survey and certification requirements as set forth in 42 C.F.R. Parts 488 and 489.[22] As part of the Revalidation Cycle, CMS reserves the right to perform on-site inspections, if deemed necessary, to verify information submitted to CMS (or its agents) and to ensure that the provider or supplier is in full compliance with the enrollment requirements.[23]

CMS's Enrollment Regulations

CMS's regulations relating to enrollment appear at 42 C.F.R. Part 424. Initially, CMS's regulations were limited to the standards that DMEPOS suppliers were required to meet in order to be enrolled and maintain their billing privileges. In addition to expanding the number of standards that DMEPOS suppliers have to meet,[24] the enrollment regulations now include detailed procedural requirements and consequences for all types of suppliers and providers.

In 2003, CMS proposed that all providers and suppliers (other than physicians and practitioners who have opted out of Medicare) be required to submit an enrollment application, containing specific information to enroll in the Program, obtain a Medicare billing number, and receive Medicare billing privileges.[25] The Medicare Modernization Act of 2003[26] (the "MMA") then added section 1866(j) to the Act, which required the Secretary of HHS (the "Secretary") to establish, by regulation, a process for the enrollment in Medicare of all providers of services and suppliers, including deadlines for actions on initial and renewal applications for enrollment; the monitoring of Medicare contractors in meeting such deadlines; consulting with providers and suppliers before making changes in the CMS-855; and provision of an administrative law judge ("ALJ") hearing and the opportunity for judicial review of denials of initial and renewal enrollment applications. As a result of the MMA changes, CMS delayed finalizing the 2003 proposed rule until 2006.

In the 2006 Medicare Enrollment Final Rule,[27] CMS added subpart P to 42 C.F.R. Part 424, entitled "Requirements for Establishing and Maintaining Medicare Billing Privileges," which greatly expanded the enrollment regulations as follows:

- Required all prospective providers and suppliers to enroll in Medicare and receive a billing number in order to receive payment from Medicare;[28]
- Required all providers and suppliers to submit complete and accurate information on the applicable enrollment form in order to become enrolled in Medicare;[29]
- Required all enrolled providers and suppliers to resubmit and recertify the accuracy of their enrollment information every five years;[30]
- Set forth reasons and the process for denying an application;[31]
- Set forth reasons and the process for rejecting an application;[32]
- Set forth reasons and the process for revoking billing privileges;[33]
- Set forth reasons and the process for deactivating billing privileges;[34] and
- Prohibited the sale or transfer of a billing number.[35]

The Medicare Enrollment Final Rule implemented many important provisions that were intended to allow CMS to ensure that all Medicare providers and suppliers are, in fact, qualified to provide services to Medicare beneficiaries. CMS implemented these requirements, in part, with the intent to safeguard beneficiaries and the Medicare Trust Funds by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing Medicare for such items or services.[36]

Post-Application and Post-Enrollment Actions

Filing an enrollment application will result in one of three actions: (1) the granting of billing privileges; (2) the rejection of the CMS-855; or (3) the acceptance of the CMS-855 but a denial of billing privileges.[37] Providers and suppliers already enrolled into the Program are subject to having their billing privileges revoked or their billing numbers deactivated for a number of reasons. Prospective providers and suppliers denied enrollment, or providers and suppliers that have had their billing numbers revoked, are entitled to appeal the contractor's determination in accordance with the appeals rules described later in this article.

Rejection of the Enrollment Application

The CMS contractor acts as the gatekeeper for entry into the Program, since it has the authority to reject the provider's or supplier's CMS-855 application if the application is incomplete and the provider or supplier fails to furnish the missing information or necessary documentation within 30 calendar days of being notified to do so. However, the CMS contractor also has the authority to work with providers and suppliers to extend the 30-day period if it determines that the prospective supplier or provider is actively working with CMS to resolve the issues.[38] If the CMS-855 is formally rejected, the provider or supplier must again initiate the enrollment process by completing a new CMS-855 and resubmitting all other documentation. Rejected CMS-855 applications are not afforded appeal rights[39] (as will be discussed more fully below).

Denial of Enrollment

If CMS or its contractor determines that a provider or supplier is ineligible to receive Medicare billing privileges, it has the authority to deny the provider's or supplier's enrollment in the Program.[40] CMS has the authority to deny enrollment for a myriad of reasons, including, but not limited to: the provider's or supplier's non-compliance with the Medicare enrollment requirements and failure to submit an acceptable corrective action plan ("CAP") (*e.g.*, lack of qualified location); the provider or supplier (or other employee/official) is excluded from any federal healthcare program or such individual or organization has committed certain crimes (*e.g.*, tax fraud, robbery, etc.); the supplier or provider has submitted false information on the CMS-855; the supplier or provider does not pass an on-site review; the current owner has an existing overpayment; or the entity has been placed on Medicare payment suspension.[41] Further, a provider or supplier will be prohibited from submitting a new CMS-855 until after its appeal rights have lapsed (if the denial was not appealed), or the provider or supplier may reapply after notification that the determination was upheld (if the denial was appealed). This requirement was implemented by CMS to avoid anticipated administrative difficulties that could result in CMS processing two applications if a new application were submitted during a time period in which the provider or supplier may appeal the denial.

Where the denial was due to some adverse activity by an owner or managing employee (or another individual in the organization), CMS will reverse the denial if the applicant submits satisfactory proof that it has terminated the business relationship with such individual within 30 days of the notice of denial.[42]

Finally, it should be noted that when CMS denies the enrollment of a provider or supplier, it will automatically review its enrollment records to determine whether there are other applicants or enrolled providers or suppliers that are associated with the denied provider or supplier (such as a common manager, owner, or authorized official) so that it can make a determination if the denial warrants an adverse action (*e.g.*, revocation) against the associated provider or supplier.[43]

Revocation of Billing Privileges

A revocation of billing privileges occurs when an existing enrolled provider or supplier fails to comply with a condition of continued enrollment.[44] When determining whether to revoke billing privileges, CMS will consider certain factors such as the severity of the offense, mitigating circumstances, risk of Program abuse, the possibility of an acceptable CAP, and beneficiary access to care issues.[45]

As with a denial of enrollment, CMS has the authority to terminate a supplier or provider's billing privileges for many reasons, including, but not limited to, the provider or supplier: (1) is not compliant with the Medicare enrollment requirements; (2) fails to report certain information (*e.g.*, CHOW or change of location); (3) fails to complete information during the Revalidation Cycle; (4) has not paid any applicable user fees (such as fees for revisit surveys); (5) has been excluded from any federal healthcare program or has committed certain crimes (such as tax fraud, rape, and robbery); (6) has certified as "true" misleading or false information on the initial or subsequent enrollment application; (7) does not pass an on-site review (*e.g.*, the supplier or provider is no longer operational); (8) sells, or knowingly allows another individual or entity to use its billing number; or (9) abuses its billing privileges (such as submitting claims for services not furnished).[46] Except in the case of revocations based on exclusion of the provider or the supplier, or the commission of a criminal offense, or being non-operational, the provider or supplier will be granted an opportunity to correct the deficiency before CMS makes a final determination on revocation.[47]

In addition to the termination of billing privileges upon revocation, a provider that has a provider agreement in effect with CMS will also have its provider agreement terminated effective on the date of revocation.[48]

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Similar to a denial of enrollment, CMS will reverse the revocation if it was due to some adverse activity by an owner, managing employee (or another individual in the organization) and the provider or supplier submits satisfactory proof that it has terminated the business relationship with such individual.[49] If a provider or supplier seeks to re-establish enrollment in the Program after receipt of the revocation notice (either after the appeals process is exhausted or in place of the appeals process), the provider or supplier is required to re-enroll by submitting a new CMS-855 as a new supplier or provider; in the case of a provider, the provider must also be resurveyed or recertified by a state survey agency and must establish a new provider agreement with the applicable CMS regional office.[50] Further, similar to a denial, where a provider or supplier has had its billing privileges revoked, CMS automatically will review its enrollment files so that it can make a determination if the revocation also warrants an adverse action against any other associated provider or supplier.[51]

Generally, a revocation will become effective 30 days after CMS or its contractor mails notice to the supplier or provider of such revocation. However, in certain cases, such as a felony conviction, the revocation is effective on the date of the triggering event (*e.g.*, the date of conviction).[52] Where a provider or supplier has had its billing privileges revoked, and does not appeal or is unsuccessful on appeal, that provider or supplier will be barred from participating in Medicare from the effective date of revocation until the end of the "re-enrollment bar." The re-enrollment bar ranges from a minimum of one year to a maximum of three years, depending on the severity of the basis for the revocation.[53]

Deactivation

CMS's regulations also provide for the suspension or "deactivation" of a provider's or supplier's billing privileges. Deactivation is considered a temporary action to protect the provider or supplier from misuse of the billing number and is also used to protect the Medicare Trust Funds from overpayments. A provider or supplier can restore its billing privileges by submitting updated or recertified information. CMS is required to deactivate billing numbers in cases where the provider or supplier has not submitted any claims during a consecutive 12-month period.[54] CMS may also deactivate billing privileges when a provider or supplier does not report a change of information, such as a change in location or managing employee. Unlike revocation, however, deactivation will not require a new certification of the provider (or supplier, where the supplier is of a type that must be initially certified) by a state survey agency or require a new provider agreement.[55]

Retroactive Billing (or Lack Thereof)

A recent, significant change in the Medicare enrollment process is the limitation on a provider's or supplier's ability to bill retroactively for services that were provided before its enrollment application is approved. This change arguably has had the most direct financial impact on providers and suppliers that are awaiting the conveyance of their billing privileges by the CMS contractor. For example, in the past, upon enrollment in the Program, a physician or non-physician practitioner ("NPP") was able to bill Medicare for services he or she provided more than two years before the date of enrollment. However, pursuant to changes in the Calendar Year ("CY") 2009 Physician Fee Schedule Final Rule,[56] the effective date for billing privileges for physicians, NPPs,[57] and their respective organizations, is the later of the date of filing a Medicare enrollment application subsequently approved by the Medicare contractor or the date an enrolled physician or NPP first began furnishing services at a new practice location. CMS's rationale for placing limits on the retroactivity of billing was that it was "concerned that some physician and NPP organizations and individual practitioners may bill Medicare for services when they are not meeting our other program requirements, including those related to providing beneficiary protections, such as Advance Beneficiary Notices."[58]

The rule for retrospective billing for providers, and for those suppliers required to be surveyed prior to enrollment, differs from that described above for physicians and NPPs. Generally, a provider or a supplier can bill Medicare for services furnished on or after the effective date of the provider agreement or the effective date of the approval of the supplier.[59]

For surveyed providers and suppliers, a provider or supplier agreement is effective as of the survey date, provided the provider or supplier met all federal requirements as of the survey date.[60] If, however, the provider or supplier did not meet all federal requirements as of the date of the survey, the following rules apply. For a provider that is not a skilled nursing facility ("SNF"), and for suppliers, the effective date is the earlier of (i) the date on which the provider or supplier met all federal requirements, or (ii) the date of an acceptable CAP or approvable waiver request, where a provider or supplier met all conditions of participation (providers) or coverage (suppliers), but had lower level deficiencies.[61] For SNFs that did not meet all federal requirements as of the date of the survey, the effective date of the provider agreement is the date the SNF is in substantial compliance.[62] The effective date of an agreement with a community mental health center ("CMHC") or a federally qualified health center ("FQHC") is the date on which CMS accepts a signed agreement under which the CMHC or FQHC provides assurance that it meets all federal requirements. The

approval of a laboratory supplier is effective only while the laboratory has in effect a valid certificate under the Clinical Laboratory Improvement Amendments ("CLIA")[63] (only for the specialty and subspecialty tests it is authorized to perform).

In order for a DMEPOS supplier to be eligible to receive payment for a Medicare covered item, the supplier must have submitted a completed Medicare enrollment application for DMEPOS (the "CMS-855S") and the item must be furnished on or after the date that the NSC[64] issued the DMEPOS supplier a billing number.[65] The DMEPOS supplier cannot bill for Medicare covered items that were furnished before receipt of the billing number.[66]

With respect to independent diagnostic testing facilities ("IDTFs"), the effective date for billing privileges for newly enrolled IDTFs is the later of (1) the filing date of a signed provider enrollment application that the Medicare contractor is able to process to approval, or (2) the date the IDTF first started furnishing services at its new practice location.[67]

Finally, where a provider or supplier has had its billing number revoked and wishes to submit claims for services that were furnished before the effective date of revocation, a physician organization, physician, NPP, or IDTF must submit all claims for items and services within 60 days of the effective date of revocation.[68]

Special Rules Relating to DMEPOS Suppliers and Home Health Agencies ("HHAs")

DMEPOS Suppliers

Additional Supplier Standards

As noted above, CMS's enrollment concerns began with DMEPOS suppliers, and DMEPOS suppliers continue to invite special scrutiny from the agency. Moreover, the list of DMEPOS supplier standards that must be met in order to become and remain enrolled in Medicare continues to grow. On August 27, 2010 CMS issued a final rule that adds even more requirements.[69] The 2010 DMEPOS Final Rule:

- Requires DMEPOS suppliers that supply oxygen to obtain oxygen from a state-licensed oxygen supplier (applicable only in the 38 states that require oxygen licensure[70]);
- Requires DMEPOS suppliers to remain open to the public for at least 30 hours a week, with exceptions for physicians or licensed NPPs furnishing services to their own patient(s) as part of their professional service, and DMEPOS suppliers working with custom made orthotics and prosthetics;
- Requires DMEPOS suppliers to continue to maintain ordering and referring documentation from physicians or NPPs;
- Prohibits DMEPOS suppliers from sharing a practice location with any other Medicare provider or supplier (subject to certain exceptions);[71]
- Clarifies and expands the existing enrollment requirements that DMEPOS suppliers must meet to establish and maintain billing privileges in the Program;[72]
- Prohibits the use of cell phones, beeper numbers, and pagers as a primary business telephone number. In addition, answering machines and answering services may not be used exclusively as a supplier's primary telephone number during posted business hours; and
- Expands the statutory prohibition on a DMEPOS supplier's telephone solicitation of a Medicare beneficiary[73] to also include in-person contacts, e-mails, instant messaging and internet coercive advertising.

DME Surety Bonds

In the BBA, Congress mandated that prospective and existing DMEPOS suppliers obtain a surety bond of not less than $50,000 and in a form specified by CMS. CMS published a proposed rule in early 1998 that would have implemented the BBA changes;[74] however, in the October 11, 2000 final rule pertaining to additional standards for DMEPOS suppliers,[75] CMS stated that it had decided not to incorporate the provisions related to surety bonds into that final rule. CMS stated that it wanted to build on its experience with surety bonds in the HHA industry and review issues addressed in the General Accounting Office study of Medicare surety bonds, and that it would issue the surety bond provisions as a proposed rule at a future date.[76]

It was not until August 2007 that CMS issued a proposed rule,[77] and not until January 2009 that CMS issued the final rule.[78] The requirements in the 2009 DME Surety Bond Final Rule became operative nine months after the effective date of the rule (March 3, 2009) for those DMEPOS suppliers that were enrolled as of the publication date, and 120 days after publication for those suppliers that sought to become enrolled after the publication of the rule. Those grace periods have long since passed, and today, any DMEPOS supplier seeking to enroll in Medicare and subject to the bonding requirement is required to obtain and submit a $50,000 bond for each National Provider Identifier ("NPI") as part of its enrollment application to the NSC (NPIs are discussed in more detail below). Because DMEPOS suppliers must obtain an NPI by practice location,[79] certain large DMEPOS suppliers with several practice locations are subject to significant surety bond requirements. For example, an organizational DMEPOS supplier with 20 practice locations would be required to secure a $1 million surety bond.

In the 2009 DME Surety Bond Final Rule, CMS also imposed an "elevated surety bond amount" for certain suppliers. Specifically, the NSC requires an additional bond

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amount of $50,000 per occurrence of an "adverse legal action" within the 10 years preceding enrollment, revalidation, or reenrollment.[80]

For purposes of this high-risk surety bond requirement, "adverse legal action" means a Medicare-imposed revocation of any Medicare billing number; suspension of a license to provide healthcare by any state licensing authority; loss of accreditation for failure to meet DMEPOS quality standards; a conviction of a federal or state felony offense within the last 10 years preceding enrollment, revalidation, or re-enrollment; or an exclusion or debarment from participation in a federal or state healthcare program.[81] For example, a DMEPOS supplier would be required to obtain a surety bond in the amount of $100,000 (a $50,000 increase from the base surety bond amount of $50,000) if the DMEPOS supplier or any of its owners, authorized officials, or delegated officials[82] had their Medicare billing privileges revoked within the 10 years preceding enrollment, revalidation, or reenrollment.

DMEPOS suppliers failing to obtain, maintain, and/or timely file a surety bond will be subject to having their billing numbers revoked, effective the date the bond lapsed, and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier. Further, CMS will deny billing privileges to a supplier if the supplier seeking DMEPOS enrollment fails to obtain and timely file a surety bond.[83]

The following types of DMEPOS suppliers are exempt from the surety bond requirement: (1) physicians and NPPs who furnish items only to their patients as part of their professional services; (2) physical and occupational therapists in private practice, who solely own their business, who furnish items to their patients only as part of their professional services, and who bill only for orthotics, prosthetics, and supplies; (3) state-licensed orthotic and prosthetic suppliers in private practice who make custom-made orthotics and prosthetics, who solely own the business, and who bill only for orthotics, prosthetics, and supplies; and (4) government-operated DMEPOS suppliers that have furnished CMS with a comparable surety bond under state law.[84]

Where a supplier no longer qualifies for an exception, it must submit a conforming surety bond to the NSC within 60 days after it knows, or has reason to know, that it no longer satisfies the criteria for an exception.[85]

Up to this point, the surety bond requirement has not been particularly onerous, as the annual premium for a $50,000 bond can be about $500. It is true, however, that despite the modest cost to obtain a bond, the requirement that a DMEPOS supplier have one can be an effective check on dishonest or incompetent suppliers, because if a surety has to pay a claim on behalf of a DMEPOS supplier, that supplier may have a difficult time getting another bond from that surety or from any other surety.[86] Note also, that pursuant to PPACA, the surety bond requirement must be at least $50,000 and CMS is now required to take into account the volume of billing when determining the amount of surety bond for a particular DMEPOS supplier.[87]

Accreditation

Under section 1834(a)(20) of the Act, as added by section 302(a) of the MMA, the Secretary is required to establish and implement quality standards for suppliers of DMEPOS.[88] A supplier that furnishes an item or service that is (1) described in section 1834(a)(20)(D) and (2) determined appropriate by the Secretary must be accredited by an independent accrediting organization[89] as a condition of initial and continued enrollment in Medicare.[90] As described in section 1834(a)(20)(D) of the Act, the affected items and services include:

- DME;
- Medical supplies;
- Home dialysis supplies and equipment;
- Therapeutic shoes;
- Parenteral and enteral nutrient, equipment and supplies;
- Transfusion medicine;
- Prosthetic devices, prosthetics, and orthotics.[91]

CMS's enrollment regulations are unqualified in their statement that "[a]ll suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number,"[92] but there are delays in the effective date and exceptions for certain individual suppliers. The MMA imposed a deadline of September 30, 2009 for all suppliers to obtain accreditation, but this was extended for pharmacies until January 1, 2010 by special legislation in 2009,[93] and extended again for pharmacies until January 1, 2011 by PPACA.[94] Also, section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA")[95] provided that "eligible professionals" and "other persons" were exempt from meeting the September 30, 2009 accreditation deadline unless the Secretary determined that the quality standards were specifically designed to apply to such professionals and persons. The "eligible professionals," as defined by the statute,[96] are:

- Physicians (as defined in section 1861(r) of the Act);
- Physical and Occupational Therapists;

- Qualified Speech-Language Pathologists;
- Physician Assistants;
- Nurse Practitioners;
- Clinical Nurse Specialists;
- Certified Registered Nurse Anesthetists;
- Certified Nurse-Midwives;
- Clinical Social Workers;
- Clinical Psychologists;
- Registered Dietitians and nutrition professionals.

The "other persons," as defined by CMS, are:

- Orthotists;
- Prosthetists;
- Opticians;
- Audiologists.[97]

Suppliers that are presently subject to the accreditation requirements must provide proof of accreditation and other information on the CMS Form 855-S.

HHAs – The 36 Month Rule

Typically, where there has been a CHOW of a provider of services, the new owner assumes the provider agreement of the old owner (unless the new owner expressly declines to do so),[98] and there is no need for the provider to be resurveyed or reaccredited due to the CHOW. However, a different rule applies for HHAs in certain situations. CMS added some restrictions on the enrollment of certain HHAs when it became aware of a proliferation of HHAs in certain parts of the country, and because it had concerns that owners of HHAs were enrolling or attempting to enroll in the Program with the sole purpose of selling the Medicare billing privileges and the Medicare provider agreement to a third party buyer (sometimes referred to as "flipping" the HHA), instead of operating the HHA. Specifically, in the CY 2010 Home Health Prospective Payment System ("HHPPS") final rule (the "2010 HHPPS Final Rule") CMS amended its enrollment regulations to provide that, effective January 1, 2010, where an HHA undergoes an "ownership change" (including asset sales and stock transfers[99]) within 36 months after the effective date of the HHA's enrollment in Medicare, the new owner must obtain an initial state survey or accreditation by an approved accreditation organization (the "36 Month Rule").[100] In other words, enrollment of the HHA does not continue seamlessly; rather, the new owner is required to enroll in the Program as a new provider and obtain an initial state survey or accreditation.[101]

Notably, CMS began to make changes to the 2010 HHPPS Final Rule even before it became effective. First, in December 2009, CMS expanded the 36 Month Rule through a December 18, 2009 Transmittal ("Transmittal 318," since rescinded),[102] which, arguably, went beyond the scope of the proposed and final rules. Transmittal 318 purportedly implemented the 2010 HHPPS Final Rule, which it claimed provides that an HHA may not undergo a CHOW if the effective date of said change occurs within 36 months after: (1) the effective date of the provider's enrollment in Medicare, or (2) the effective date of the HHA's last ownership change. Note that an "ownership change" was defined in the manual instructions as including not only a "change in ownership" (as that term is defined in 489.18 of the regulations), but also a reporting of a five percent or greater ownership change and a reporting of a change in partners, regardless of the percentage of ownership involved.

Thus, under the manual instructions, if an HHA was sold in 2010 and the HHA had its provider agreement for 20 years or more but reported ownership change information in 2008, such as a transfer of a five percent interest or the death of a five percent owner, the purchaser of the HHA in 2010 would not be able to have the provider agreement assigned to it but instead would have to enroll as a new HHA and obtain a state survey or an accreditation from an approved accreditation organization. Transmittal 318 was rescinded on May 5, 2010.

Second, on February 18, 2010, CMS issued a revised Medicare Learning Network ("MLN") article, which "clarified" that the new requirements are effective for CMS-855A applications received on or after January 1, 2010. The MLN provided that applications received prior to January 1, 2010, will be handled in accordance with the policies in place prior to January 1, 2010.[103] The preamble to the 2010 HHPPS Final Rule stated that the 36 Month Rule would apply to CMS-855A applications that were *pending* on January 1, 2010.[104]

CMS made further changes to the 36 Month Rule in the CY 2011 HHPPS Final Rule.[105] First, CMS revised the rule's trigger point from a "change of ownership" to a "change in *majority* ownership" (emphasis added). A change in majority ownership occurs:

> when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.[106]

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Note that the affected ownership interest is not only a majority ownership interest; it is also a *direct* ownership interest. Thus, a change in an indirect ownership interest would not fall under the purview of the 36 Month Rule.

Moreover, the CY 2011 HHPPS Final Rule provides for four exceptions to the 36 Month Rule: (1) the HHA has submitted two consecutive years of full cost reports (note: low or no utilization cost reports do not qualify); (2) the HHA's parent company is undergoing a corporate restructuring; (3) the HHA's owners are undergoing a change in the HHA's current business structure with the owners remaining the same; or (4) an individual owner of an HHA dies.[107] If any of these four exceptions are met, the 36 Month Rule does not apply. Because of these exceptions and the substitution of a "change in majority ownership" for a "change in ownership," the 36 Month Rule is not as stringent as CMS had initially proposed.

Recent Enrollment Initiatives

In an attempt to ensure that only qualified providers and suppliers participate in the Program, CMS has finalized a variety of regulatory initiatives aimed at establishing more stringent controls on providers and suppliers with respect to their ability to bill and receive payment for covered items and services.[108] In addition to the myriad of regulatory enrollment initiatives that have taken place over the last 10 years, there have been several significant changes—most notably, changes imposed by PPACA—that will have a direct impact on many providers and suppliers and their ability to enroll and actively maintain their Medicare billing privileges. A summary of some of these significant changes is set forth immediately below.

PPACA

PPACA contains several provisions that expand CMS's authority to use the Medicare enrollment process[109] to protect the Program from questionable providers and suppliers. These new PPACA Program integrity measures include, for example, mandated screening procedures, entrance fees, mandatory compliance programs, enhanced oversight, transparency and reporting requirements, various financial disclosure requirements, and limitations and requirements related to ordering DME and HHA items and services.[110] Some of the PPACA provisions specifically encompass new applicants as well as existing providers and suppliers. Other PPACA provisions do not state specifically that they apply to existing providers and suppliers, but one should expect that CMS will apply them to providers and suppliers that are going through a scheduled (or unscheduled) revalidation.

Provider and Supplier Screening

Prior to the enactment of PPACA, provider and supplier screening was not part of the Medicare enrollment process. Section 6401(a)(3) of PPACA states that "in no case" may a provider or supplier that has not been screened be initially enrolled or reenrolled on or after three years after PPACA's enactment date (March 23, 2010). This strong language raises the possibility that if CMS does not have the necessary resources to complete screenings of all existing providers and suppliers by the three-year deadline, some providers and suppliers could have their billing privileges temporarily revoked, and new applicants could have their enrollment delayed while the contractors attempt to complete the screenings for the existing providers and suppliers.

On September 23, 2010, pursuant to Section 6401(a) of PPACA, CMS released its proposed rule to establish new screening procedures for enrollment into the Medicare, Medicaid, and CHIP programs (the "September 2010 Proposed Rule").[111] On February 2, 2011, CMS finalized its screening procedures (the "February 2011 Final Rule").[112] These new screening procedures were effective March 25, 2011 for newly enrolling providers and suppliers as well as those currently enrolled providers and suppliers whose revalidation cycle ends between March 25, 2011 and March 25, 2012. For all other currently enrolled providers and suppliers, the new screening procedures will be effective March 25, 2012.[113,114]

Previously, CMS did not distinguish between types of providers and suppliers for purposes of conducting background checks. CMS examined licensure requirements, performed site visits, checked databases, checked criminal backgrounds, and checked the Medicare Advantage Organization ("MAO")[115] reports for *all* enrolling providers and suppliers.[116] To improve its screening procedure, CMS created a three-tiered system in which providers and suppliers are categorized based on their level of risk—limited, moderate, and high—with each category having its own screening procedures.[117] Although CMS originally proposed to include in the limited risk category any provider or supplier that is publicly traded and publicly owned, in the February 2011 Final Rule CMS eliminated the distinction between publicly traded and non-publicly traded, and publicly owned and non-publicly owned, as criteria for assignment of any provider type to a level of screening.[118]

Limited Risk Providers and Suppliers

Typically, CMS has considered physicians, NPPs, medical clinics, and group practices to be of low risk for fraud, waste or abuse because they are subject to state licensing

requirements.[119] Based on its own data and experience, CMS included the following types of providers and suppliers in the limited risk category: ambulatory surgical centers ("ASCs"), Competitive Acquisition Program/ Part B Vendors, end stage renal disease ("ESRD") facilities, FQHCs, histocompatibility laboratories, hospitals, including critical access hospitals ("CAHs"), Department of Veterans Affairs hospitals, health programs operated by an Indian Health Program, mammography screening centers, organ procurement organizations ("OPOs"), mass immunization roster billers, pharmacies newly enrolling or revalidating via the CMS-855B application, religious non-medical healthcare institutions ("RNHCIs")[120], rural health clinics ("RHCs"), radiation therapy centers and SNFs.[121]

This limited risk group is subject to the least stringent pre-enrollment screening procedures. CMS proposes that the screening measures would include: verification that a provider or supplier meets any applicable federal regulations and state requirements for the provider or supplier type; verification of licenses; and pre-and post-enrollment database checks.[122]

Moderate Risk Providers and Suppliers

Moderate risk providers and suppliers are those "that easily enter a line or business without clinical or business experience, for example by leasing minimal office space and equipment, [and thus] present a higher risk of possible fraud…."[123] Furthermore, CMS contends that "most of the provider and supplier categories in the moderate screening level are generally highly dependent on Medicare, Medicaid, or CHIP to pay their salaries and other operating expenses and are subject to less additional government or professional oversight than the providers and suppliers in the limited risk screening level."[124] Because CMS pays 1.2 billion claims per year, out of necessity it pays the claims and subsequently asks questions. CMS believes that placing these providers and suppliers in the moderate-risk category will help prevent this "pay and chase" approach.[125] Those providers and suppliers that would be considered to be of moderate risk for fraud, waste or abuse are ambulance service suppliers, community mental health centers ("CMHCs"), comprehensive outpatient rehabilitation facilities ("CORFs"), hospice organizations, IDTFs, independent clinical laboratories, physical therapists enrolling as individuals or as group practices, portable x-ray suppliers, and revalidating HHAs and DMEPOS suppliers.[126]

The moderate risk suppliers and providers would be subject to all of the screening procedures of the limited risk category as well as pre-and post-enrollment unannounced site visits.[127] CMS believes that the unannounced site visits will "help ensure that suppliers are operational and meet applicable supplier standards or performance standards," and that unscheduled and unannounced pre-and post-enrollment site visits are an essential tool in determining whether a provider or supplier is in compliance with its reporting responsibilities…."[128]

High Risk Providers and Suppliers

Based on CMS's experience, CMS has placed prospective (newly enrolling) HHAs and DMEPOS suppliers in the high risk category.[129]

Providers and suppliers designated as high risk will be subject to: (1) all of the "limited" and "moderate" screening requirements; (2) required submission of a set of fingerprints for a national background check from all individuals who maintain a five percent or greater direct or indirect ownership interest in the provider or supplier; and (3) a fingerprint-based criminal history record check of the Federal Bureau of Investigation's ("FBI") Integrated Automated Identification System on all individuals who maintain a five percent or greater direct or indirect ownership interest in the provider or supplier.[130]

CMS will use these additional screening measures to ensure that the information contained in the CMS 855 submitted on behalf of the high risk supplier or provider is truthful. Moreover, fingerprinting will aid in verifying the individual's identity in instances of identity theft.

Providers and suppliers should be aware that, regardless of what risk category CMS has assigned to them, the initial classification is subject to change. CMS has the ability to adjust the classification of a provider or supplier into a higher risk level than would generally apply to the category of provider or supplier to address specific program vulnerabilities.[131] CMS will increase a provider's or supplier's risk-level to "high" if any of the following occur:

- CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.
- The provider or supplier:
  - Has been excluded from Medicare by the OIG;
  - Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by:
    - o Enrolling as a new provider or supplier; or
    - o Obtaining billing privileges for a new practice location;
  - Has been terminated or is otherwise precluded from billing Medicaid;
  - Has been excluded from any federal healthcare program; or
  - Has been subject to any final adverse action, as defined in the rules establishing and maintaining Medicare billing privileges as defined at 42 CFR Section 424.502, within the previous 10 years.

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- CMS lifts a temporary moratorium for a particular provider of supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within six months from the date the moratorium was lifted.[132]

Enrollment Application Fee

PPACA requires the Secretary to impose an application fee on each "institutional provider of medical or other items or services or supplier" to cover the cost of the screening procedure.[133] In the February 2011 Final Rule, CMS stated that an "institutional provider of medical or other items or services or supplier" 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) or CMS-855S or associated Internet-based Medicare Provider Enrollment Chain, and Ownership System ("PECOS") enrollment application."[134] Moreover, the enrollment application fees are applicable to newly enrolling providers, suppliers, and eligible professionals who are not enrolled in Medicare, Medicaid, or CHIP by March 25, 2011.[135] The enrollment application fee will be $500 in 2011 and will increase each subsequent year according to the increases in the Consumer Price Index ("CPI-U").[136] The full application fee is required for CMS to begin processing an application.[137] Failure to submit the full application fee is grounds for revoking an institutional provider or supplier's Medicare billing privileges.[138]

In order to pay for the screening procedures referred to above, Section 6401(a)(2)(C) of PPACA directs the Secretary to impose an entrance fee of $500 (adjusted annually for inflation) on each "institutional" provider and supplier.[139] Although an entrance fee of $500 for "institutional" providers and suppliers would appear to be a not insignificant amount of money to put toward the cost of screening a provider or supplier, it also appears unclear as to whether the entrance fees will entirely offset the costs of the screening process (remember that the screening process applies to individual suppliers as well as "institutional" suppliers), and if not, whether CMS will have the additional funds necessary in order to timely screen all providers and suppliers. As noted above, Section 6401(a)(3) states "in no case" may a provider or supplier that has not been screened be initially enrolled or reenrolled on or after three years after the date of enactment of PPACA.

Temporary Moratoria

Section 6401 of PPACA has created a powerful tool in the Government's fight to prevent fraud and abuse under Medicare by authorizing CMS to impose a "temporary" moratorium on the enrollment of new providers and suppliers (including categories of providers and suppliers) into Medicare if it determines that it is necessary to prevent or combat fraud, waste, or abuse.

CMS may impose any temporary moratoria on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area.[140] These temporary moratoria may be imposed in six-month increments with the option of imposing consecutive six-month moratoria where deemed necessary.[141] According to CMS, imposing moratoria will allow it to "review and consider additional programmatic initiatives, including the development of additional regulatory and sub regulatory provisions to ensure that Medicare providers and suppliers are meeting program requirements, beneficiaries receive quality care, and that an adequate number of providers of [sic] suppliers exists to furnish services to Medicare beneficiaries."[142] CMS may impose moratoria in the following situations:

1. CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS' determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a
   a. Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or
   b. Rapid increase in enrollment applications within a category;
2. A state Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Program;
3. A state has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or
4. CMS, in consultation with the HHS OIG or the Department of Justice ("DOJ"), or both, and with the approval of the CMS Administrator identifies either or both of the following as having significant potential for fraud, waste or abuse in the Program:
   a. A particular provider or supplier type.
   b. Any particular geographic area.[143]

The temporary moratoria will not apply to changes of practice location, changes in provider or supplier information such as phone number, address or changes in ownership (except changes in ownership of HHAs that would require an initial enrollment

under 42 CFR 424.550).[144] The temporary enrollment moratoria also do not apply to any enrollment applications that have been approved by the enrollment contractor but not yet entered into PECOS at the time a moratorium is imposed.[145] A decision by CMS to impose a temporary moratorium will not be subject to judicial review; however, providers and suppliers subjected to the temporary moratorium may administratively appeal the decision up to and including the Department Appeals Board ("DAB") level of review (the appeals process and the DAB's role in it is explained in further detail later in this article).[146] CMS may lift a temporary moratorium prior to the expiration of the six-month period in four situations: the President declares a national disaster; the circumstances warranting the moratorium no longer apply; the Secretary has declared a public health emergency; or the Secretary determines the moratorium is no longer needed.[147]

CMS will announce any imposition of or lifting of temporary moratoria in the Federal Register.[148]

Preclusion of judicial review is not uncommon to the Program, and the bounds of the preclusion often are not absolute. For example, the Act provides that decisions of the Medicare Geographic Classification Review Board ("MGCRB") are final and not subject to judicial review,[149] but it was established early after the creation of the MGCRB that the preclusion on judicial review applied only to the MGCRB's decisions themselves and not to the criteria established by regulation that guided the MGCRB's decisions. However, whereas the Act required CMS to publish guidelines for the MGCRB's use in rendering decisions, Section 6401 does not require CMS to engage in rulemaking (or even sub-regulatory guidance) as to what criteria will be employed to determine whether an for how long to impose a moratorium on a provider's or supplier's enrollment.

Enhanced Oversight

Section 6401 requires the Secretary to establish procedures to provide for a provisional period of not less than 30 days and not more than one year during which new providers and suppliers (including categories of providers or suppliers), would be subject to enhanced oversight, such as prepayment review and payment caps.[150] Section 6401 provides that the enhanced oversight procedures may be established through Program instructions instead of notice and comment rulemaking. That the procedures may include prepayment review is notable because section 934 of the MMA placed limits on nonrandom prepayment review.[151]

Increased Financial Disclosure and Payment Adjustments

In the past, certain providers or suppliers would collect significant overpayments and declare bankruptcy; the owners would then simply form a new entity and enroll it in Medicare. Generally, the owners were not personally liable for the debts of their incorporated entities and CMS was unable to deny enrollment to the new entity or offset payments owed to the new entity due to the overpayment incurred by the old entity. Two related provisions of PPACA now give CMS the authority to make it much more difficult for individuals and entities to employ such cut and run tactics.

First, Section 6401 establishes newly increased financial disclosure obligations on providers and suppliers that are submitting enrollment applications for Medicare, Medicaid, or CHIP. These new disclosure obligations were effective beginning March 23, 2011. The disclosure obligations relate to any current or previous affiliation with a provider or supplier that has uncollected debt or that has been (or currently is) subject to a payment suspension under a federal healthcare program, that has been excluded from participation in Medicare, or that has had its billing privileges denied or revoked. CMS will now have the authority to deny an application if it believes that any such affiliation poses an undue risk of fraud, waste, or abuse. Such a denial is subject to appeal.[152]

Second, a companion provision in Section 6401 establishes new authority for CMS to make necessary payment adjustments to payments made to applicable providers and suppliers that share the same TIN so that it can satisfy any past-due obligations such provider or supplier owes under the Program. This new payment adjustment authority, for example, will allow CMS to reduce the payments it may owe to one provider or supplier for items or services in order to satisfy the past-due obligations of another provider or supplier, regardless of whether they have different billing numbers or different NPI numbers, provided that they share the same TIN.[153]

Suspension of Payments – Credible Allegations of Fraud

In cases of suspected fraudulent activity, CMS' longstanding regulations have authorized it to suspend payments.[154] Payment suspensions generally are limited to 180 days (with the opportunity for a one-time extension of 180 days), unless an exception applies.[155] This suspicion can arise upon "possession of reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct."[156] Pursuant to Section 6402(h) of PPACA, CMS' authority to impose suspensions has expanded, as CMS may now impose suspensions if "a credible allegation of fraud exists." In the February 2011 Final Rule, "credible allegation of fraud" includes, but is not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations."[157] Moreover, an allegation is

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considered credible if it has "an indicia of reliability."[158]

While PPACA provides for when payments may be suspended, it does not specify when the suspension must terminate. Pursuant to the February 2011 Final Rule, CMS will terminate a suspension of payment upon "resolution of an investigation," which CMS defined as either "when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence" or "when a legal action is initiated or the case is closed or dropped because of insufficient evidence to support the allegations of fraud."[159]

Although CMS provides instances when it will suspend payments, it also provides a good cause exception.[160] Specifically, law enforcement may request this exception to preserve the integrity of a current investigation or to protect access to items or services to protect the health of beneficiaries.[161] Other instances for the good cause exception are a CMS determination that there is a more effective way to protect Medicare funds than a payment suspension (for instance, law enforcement could request a court to enjoin potentially unlawful conduct or prevent the withdrawal, removal, transfer, disposal, or dissipation of assets), and a CMS determination that termination of the suspension is in the best interest of the Program.[162]

After initiating the suspension or payments due to a credible allegation of fraud, every 180 days CMS will evaluate whether there is good cause not to continue the suspension and will request certification from the appropriate enforcement agency(ies) that the matter continues to be under investigation warranting continuation of the suspension.[163] If, in 18 months, the matter has not been resolved, good cause will be deemed to exist, unless the action has been referred to the OIG, for say administrative action and is being considered by such agency, or the DOJ submits a written request that the suspension of payments continue based on an ongoing investigation and anticipated filing of criminal or civil actions.[164]

Mandatory Compliance Plans

Prior to the enactment of PPACA, compliance plans, although strongly encouraged by the OIG,[165] were strictly voluntary. However, pursuant to Section 6401, providers and suppliers within certain industries will now be required to establish a compliance program as a condition of enrollment in Medicare.[166] Unlike other enrollment provisions in Section 6401, the provision requiring mandatory compliance programs does not specify that it applies to re-enrollments in addition to initial enrollments. It would be surprising, however, if CMS were to implement the provision with respect to only initial enrollments. CMS, in consultation with the OIG, will establish core elements for the mandatory compliance programs which will be applicable within a particular industry and category of healthcare providers and suppliers.

One could surmise that such core elements will be similar, at least in part, to the core elements already established and included in many of the OIG's current voluntary compliance program guidance, such as those pertaining to physicians, DME, HHAs, hospitals and others. In establishing the date by which providers and suppliers must have a compliance plan, CMS is required to consider the extent to which particular types of providers and suppliers already have widespread adoption of compliance programs.[167] Given that certain industries appear to have a much more widespread adoption of compliance programs (hospitals) compared to other industries (small physician practices), one would expect that the timeline for implementation may vary greatly across different sectors in the healthcare industry.

Moreover, Section 6401(a) requires that a provider of medical or other items or services or supplier must have in place a compliance program with certain "core elements." In the September 2010 Proposed Rule, CMS did not offer proposals on the required core elements of a compliance program or make other proposals relating to mandatory compliance plans. In the February 2011 Final Rule, CMS stated that it is in the process of developing a Notice of Proposed Rule Making incorporating the compliance plan provisions and comments received from the September 2010 Proposed Rule and that such rule is to be published "at a later date."[168] In the September 2010 Proposed Rule, CMS had solicited comments regarding what the core elements should be, including comments on the potential use of the seven elements of an effective compliance and ethics program contained in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual, as recently amended (effective November 1, 2010).[169]

The requirement that every provider and supplier have a compliance program, depending on how CMS implements it, could be the most important (and intrusive) enrollment provision in PPACA. For example, one of the seven basic elements of an effective compliance program according to the OIG is establishing policies and procedures for the investigation of systemic problems and for taking corrective action. The OIG maintains that appropriate action includes returning self-discovered overpayments to the government. Thus, irrespective of how CMS might implement the requirement in section 6402 of PPACA pertaining to the

mandatory return of "overpayments," it could require prospective and existing providers and suppliers to agree to return self-discovered overpayments upon penalty of having their billing numbers revoked for up to three years.

Likewise, the OIG also considers the use of audits and other risk evaluation techniques to be an essential element of an effective compliance program, and suggests that providers and suppliers engage in compliance audits. If CMS were to require such audits as a condition of initial or continued enrollment, the cost to providers and suppliers could increase significantly and the number of self-disclosures could rise dramatically. In short, the authority granted to the Secretary to require mandatory compliance plans with "core elements," coupled with CMS's ability to revoke a provider's or supplier's billing number for up to three years, imbues CMS with exclusion-like authority and could blur or eviscerate the present distinction between voluntary compliance programs and no-so-voluntary corporate integrity agreements ("CIA"s).[170]

DME Suppliers Subject to Enhanced Oversight – 90-Day Waiting Period

Due to the significant amount of fraudulent and abusive billing practices that have recently surfaced in the DME industry, Section 1304 of the Reconciliation Act further amended Section 1866(j) of the Act to include a 90-day period of enhanced oversight for initial claims submitted by DME suppliers who are initially enrolling. Specifically, effective January 1, 2011, if CMS determines there to be a significant risk of fraudulent activities among DME suppliers in a certain "category" or in a certain geographic area, it may withhold payments to newly enrolled DME suppliers in such "category" or located in such geographic area during the 90-day period beginning with the date of the first submitted claim.[171]

NPIs, Required Enrollment for Referring and Ordering Physicians, and Documentation Requirements – PPACA and the May 5, 2010 Interim Final Rule

On May 5, 2010, CMS published an Interim Final Rule (the "May 2010 Interim Final Rule") implementing certain enrollment related provisions in PPACA.[172] The May 2010 Interim Final Rule implements the PPACA provisions that require all providers of medical items or services and suppliers that qualify for an NPI to include their NPI on all enrollment applications and on all claims for payment submitted under the Medicare and Medicaid programs. The May 2010 Interim Final Rule also requires that physicians and eligible professionals that refer and order Medicare-covered items and services be enrolled in Medicare. Finally, the May 2010 Interim Final Rule adds requirements for providers and other suppliers participating in Medicare to provide certain documentation on their referrals for services susceptible to fraud and abuse, including DMEPOS and HHA services. The May 2010 Interim Final Rule, which was effective on July 6, 2010, is summarized below.

NPIs

As part of Congress's continued efforts to maintain integrity in the Program, section 1128J(e) of the Act, as added by section 6402(a) of PPACA, requires CMS to promulgate a regulation to require all Medicare providers and suppliers that qualify for an NPI to include their NPI on all Medicare enrollment applications and on all claims submitted under the Medicare and Medicaid Programs. This requirement, however, is not new. Since May 2006, CMS has required providers and suppliers to report their NPIs on their CMS-855 enrollment applications, and since May 2008 CMS has required providers and suppliers to report their NPIs on their Medicare and Medicaid electronic and paper claims submissions. Thus, the PPACA requirement is redundant. The Interim Final Rule fine tunes the existing policy by formally establishing that a Medicare claim from a provider or supplier will be rejected if it fails to provide the required NPI.[173]

CMS notes that these new formal NPI requirements build on its current requirements that every healthcare provider obtain an NPI, that any claim submitted by a Medicare fee-for-service or Medicaid provider or supplier include its NPI as well as that of any other provider or supplier noted on the actual claim, and that NPIs are reported on the applicable Medicare enrollment applications.[174] Notably, with respect to any provider or supplier that enrolled in the Program prior to obtaining an NPI and for which its NPI is not in its enrollment record, the provider or supplier must report such NPI to Medicare in an enrollment application so that it can be added to the enrollment record maintained in PECOS.[175] Further, under the Interim Final Rule, Medicare beneficiaries who submit claims are required to include the legal name and NPI of the applicable provider or supplier that rendered the at-issue services. If the NPI is unknown, the beneficiary can submit the claim as long as it contains the provider's or supplier's legal name.[176]

Ordering and Referring Physicians for DME, Home Health Services, and Other Services

Section 6405(a) of PPACA amended section 1834(a)(11)(B) of the Act specifying, with respect to DMEPOS suppliers, that payment may be made only if the written order for the item has been communicated to the DMEPOS supplier by a Medicare-enrolled physician or eligible professional[177] before delivery of the item. Section 6405(b) of PPACA, as amended by Section 10604 of the Reconciliation Act, amended Sections

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1814(a)(2) and 1835(a)(2) of the Act to specify, with respect to home health services under Part A or B, that payment may be made to providers only if a Medicare-enrolled physician certifies (and recertifies, as required) that the services are, or were, necessary. In addition, section 6405(c) of PPACA authorizes CMS to extend to all other categories of items or services covered by Medicare, including covered Part D drugs, the requirement that the ordering or referring physician or eligible professional be enrolled in Medicare.

The Interim Final Rule implements the PPACA provisions by requiring that, with respect to DMEPOS claims, Part A and Part B home health claims, and with respect to all other Part B services (except for drugs), a provider or supplier may receive Medicare payment only if such services are ordered or referred by a physician or eligible professional who has an enrollment record in PECOS (unless the referring physician or eligible professional has opted out of the Program).[178] CMS stated that it may address Part B drugs in future rule making.[179] Further, pursuant to the new requirements of the Interim Final Rule, all claims for the above-referred services must contain the legal name and the NPI of the ordering or referring physician or eligible professional (if applicable).[180] Compliance with these new requirements is mandatory for providers and suppliers, as claims that do not contain the required information will be rejected and payment to the provider or supplier will not be made.[181]

Documentation and Access Requirements

Section 6406 of PPACA amended Sections 1842(h) and 1866(a)(1) of the Act authorizing CMS to revoke a supplier's or provider's enrollment, based on the failure to maintain and allow access to documentation relating to the written orders or requests for payment for DME, HHA certifications, or referrals of other items or services written or ordered by the physician or supplier on or after January 1, 2010. In order to implement these requirements, the Interim Final Rule expands current CMS regulations by now requiring providers and suppliers that *furnish* covered ordered DMEPOS, HHA, laboratory, imaging, or specialist services to maintain documentation for seven years from the date of the services, and to provide access to such documentation upon the request of CMS or its contractors. The documentation includes written and electronic documents (including the NPI of the physician or eligible professional who ordered or made the referral for such services) in connection with written orders and requests for payments for such items or services. Referring or ordering physicians or eligible professionals are also required to maintain such documentation for seven years.[182] Finally, the Interim Final Rule adds a new regulation to provide that any supplier or provider that does not comply with the new documentation and access requirements, will be subject to revocation of its Medicare billing privileges for a period not more than one year for each act of noncompliance.[183]

Revalidation Initiatives

In addition to the five-year Revalidation Cycle (which is now applicable to most supplier and provider types), CMS also has the regulatory authority to undertake off-cycle revalidation efforts to assess and confirm the validity of a provider's or supplier's enrollment information, when it deems it necessary to do so.[184] Off-cycle revalidations may be triggered as a result of random checks or national initiatives or other reasons that cause CMS to question the provider's or supplier's compliance with the enrollment requirements (such as local healthcare fraud).[185] Importantly, where CMS requests a revalidation application, a provider or supplier must respond to the request in a timely manner (*i.e.*, 60 days from the request) or its billing privileges will revoked for a period of one year.[186]

In 2009 and 2010, CMS mandated off-cycle revalidation initiatives that affected a substantial number of providers and suppliers.[187] In fact, as a result of revalidation initiatives beginning in late 2009, several Part B suppliers (including physicians) are receiving notification from CMS of revocation for failure to submit information as a result of such revalidation requests. Thus, providers, suppliers, and their legal representatives must stay attentive to these initiatives to ensure that the entity will be permitted to continue to bill and receive payment from Medicare for the items and services provided to Medicare beneficiaries. Many of these Part B suppliers have claimed that they never received a revalidation letter from CMS (since it was sent to the wrong address or some other reason), making it important for providers and suppliers to regularly review the CMS website for information on revalidation initiatives.[188]

Moreover, due to these recent off-cycle revalidation efforts, providers and suppliers enrolling in the Program for the first time can expect significant delays with the processing of their CMS-855 applications, as the contractors are inundated with large inventories of applications. For example, it can take as long as six months to process the initial CMS-855 application for HHAs. This slow enrollment process significantly delays an HHA's ability to obtain its Medicare billing privileges, as a state agency or other accreditation body cannot commence a survey until the application is initially processed by the CMS contractor. Moreover, these significant delays in

processing the CMS-855 applications have a great financial impact on new suppliers and providers in light of CMS's recent rule restricting retroactive billing, as described above. Given CMS's broad authority and its zeal to protect the Medicare Trust Funds, it is likely that CMS will continue such off-cycle revalidation efforts in the future.

Appeals

Originally, the appeals process was limited to DMEPOS suppliers.[189] While CMS was in the process of expanding, by regulation, the appeals process to all suppliers that were not covered by the process at 42 C.F.R. Part 498 (the "Part 498 Appeals Process"), Congress enacted the MMA, which required that CMS provide for the opportunity for an ALJ hearing and the opportunity for judicial review of denials of initial and renewal enrollment applications. Subsequently, CMS decided that appeal rights for providers and suppliers whose enrollment applications for Medicare billing privileges have been denied and/or whose Medicare billing privileges have been revoked will be governed by the Part 498 Appeals Process.[190] However, 42 C.F.R. 405.874 contains important and binding information related to provider and supplier enrollment appeals, and practitioners would do well to consult that section also, instead of focusing only on the Part 498 Appeals Process regulations. This section of the article will describe the provider and supplier enrollment/billing privileges appeals process; describe current issues arising in the appeals process; and provide practice tips to successfully appeal enrollment/billing privileges denials.

Overview of the Appeals Process

Initial Determinations

Appeal rights apply to all providers and suppliers of Medicare services and supplies and all prospective providers and suppliers of Medicare services and supplies.

The appeals process is triggered once CMS provides notice of an unfavorable "initial determination." The notice of initial determination must be mailed and include the basis for the determination, the effect of the determination, and the party's appeal rights.[191] Among other actions constituting initial determinations, examples include: a determination of whether a provider qualifies as a provider; a determination of whether a supplier meets conditions for coverage; and the effective date of a Medicare provider agreement or supplier approval.[192] The regulations also make clear that certain administrative actions are not initial determinations (*e.g.*, a finding that a provider or supplier which has been found to be in compliance with conditions for participation or for coverage has deficiencies), and thus, these actions would not trigger the appeals process.[193]

Outside of the formal appeals process, an existing provider or supplier that has received notice of a determination to revoke its billing may submit a CAP.[194] Additionally, a provider or supplier whose Medicare enrollment is denied or whose Medicare billing privileges have been revoked may file a formal appeal of the determination. Generally speaking, the appeals process, as it relates to unfavorable initial determinations affecting provider or supplier enrollment, is a four-stage process. In particular, the four stage appeals process includes the following stages: (1) reconsideration; (2) ALJ hearing; (3) DAB review; and (4) judicial review.[195] An appeal may be brought either by the affected provider or supplier, or by the provider's or supplier's representative. The representative may be anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary, and may be (but need not be) an attorney.[196]

CAP

Where CMS proposes to revoke a provider or supplier's Medicare billing privileges, that provider or supplier generally may submit a CAP in order to correct any deficiencies that caused the proposal to revoke billing privileges. The CAP should establish that the provider or supplier is in compliance with Medicare requirements. The CAP must be submitted in writing within 30 days from the date of the notice of the proposal to revoke billing privileges. If the CAP does not include all of the information originally requested and needed to establish compliance, the Medicare contractor is directed to contact the provider or supplier to request the additional information before rendering a final decision. The Medicare contractor is required to process a CAP within 60 days.

Following its review, the Medicare contractor will issue a letter setting forth its enrollment determination. Note that a provider or supplier does not have appeal rights with respect to a determination not to accept a CAP.[197] The regulations provide that a provider or supplier cannot submit a CAP where the reason for the revocation is (1) the provider or supplier has been excluded from federal and state healthcare programs; (2) the provider or supplier has been convicted of a felony within the last 10 years preceding enrollment or revalidation; or (3) CMS determines, upon on-site review, that the provider or supplier is no longer operational or does not meet Medicare enrollment requirements.

However, legal counsel representing a provider or supplier in the appeals process should be cognizant that the CAP process takes place outside of the formal appeals process. Therefore, although a provider or supplier does not have appeal rights with respect to an unfavorable CAP decision, the provider or supplier could file a formal appeal at the same time as it files its CAP submission in order to preserve its appeal rights. The Medicare contractor will first render a decision on the CAP before considering the appeal. Note that Medicare does not toll the

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timeframes for appeal during the CAP process. Therefore, legal counsel should consider filing a CAP and reconsideration request concurrently in order to preserve the provider's or supplier's appeal rights.[198]

Reconsideration

If a provider or supplier receives an unfavorable initial determination related to its enrollment, that provider or supplier has the right to request a reconsideration of the unfavorable initial determination. This request must be filed in writing within 60 days from the provider's or supplier's receipt of the notice of initial determination. CMS will presume the notice is received five days after the date of the notice, unless there is evidence to the contrary.[199] If the 60-day timeframe is not met, CMS may nevertheless process the request for reconsideration upon a showing of good cause (*e.g.*, destruction by fire).[200] The request for reconsideration must list the findings of fact with which the provider or supplier disagrees and describe the basis for the provider's or supplier's disagreement.[201] Importantly for providers and suppliers pursuing these types of appeals, CMS requires that all relevant facts and supporting documentation be submitted prior to or during this reconsideration stage of appeal.[202] CMS believes that this early presentation of evidence requirement will "help to ensure an efficient and effective administrative appeals process."[203]

A request for reconsideration will be reviewed by a hearing officer who was not involved in the initial determination.[204] The hearing officer will consider the initial determination and the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted by the provider or supplier. The hearing officer will then render his/her reconsideration decision.[205] The reconsideration decision will be mailed to the provider or supplier, set forth the reasons for the determination, describe the conditions or requirements of law that the provider or supplier failed to meet (if applicable), and inform the provider or supplier of its right to an ALJ hearing.[206]

ALJ Hearing

If a provider or supplier is dissatisfied with a reconsideration decision, it may file a request for ALJ hearing in writing within 60 days from the date of receipt of the notice of reconsideration decision. CMS will presume the reconsideration decision was received five days after the date of the decision, barring evidence to the contrary. If the 60-day deadline is not met, the ALJ may nevertheless process the request for ALJ hearing upon a showing of good cause.[207]

The parties to an ALJ hearing include the affected provider or supplier and CMS.[208] At any time prior to conducting an ALJ hearing, after providing proper notice, the judge may call a prehearing conference to establish the issues remaining in controversy, identify the evidence and witnesses to be presented at the hearing, and obtain stipulations.[209] The ALJ will set a time and date for the ALJ hearing, and will open the hearing to the parties, their representatives, and any other persons whose presence the ALJ considers necessary or proper.[210] The parties may present oral arguments, question and cross-examine witnesses, and file briefs or other written statements for consideration as part of the ALJ hearing.[211]

Note that, at any time prior to issuing its decision, the ALJ may dismiss a hearing request. The dismissal may be made: (1) at a party's request[212] if the ALJ believes the request for hearing has been abandoned by the appellant (*i.e.*, if an appellant fails to appear at a prehearing conference or hearing without good cause; or if an appellant fails to respond to an ALJ's good cause notice within 10 days);[213] or (2) for cause (*i.e.*, if a previous determination or decision was issued with respect to the rights of the appellant based on the same facts and law, if the appellant is not properly a party, or if the appellant did not timely file its request for hearing and the time has not been extended).[214] An ALJ dismissal of a hearing request may be vacated by the ALJ or vacated upon appeal to the DAB.[215] Additionally, note that at any time prior to the ALJ's mailing of its decision to the parties, the ALJ may (but is not required to) remand any case before it to CMS, if CMS requests the remand.[216]

Regulations require the ALJ to issue a written decision as soon as is practical after the close of the hearing (but in any event within 180 days from the date the appeal was filed with the ALJ). The written decision is based on the evidence contained in the record, and includes separate numbered findings of fact and conclusions of law.[217] For enrollment appeals, the ALJ must issue a decision, dismissal order or remand to CMS no later than 180 days after the date the hearing request was filed.[218] At any time before an ALJ receives oral testimony, the DAB may remove any pending request for hearing to itself (*i.e.*, the DAB may choose to consider the appeal itself, before the ALJ receives oral testimony or issues a decision).[219]

DAB

Either party, if dissatisfied with an ALJ's decision, may request DAB review of the ALJ's decision or dismissal.[220] The request for DAB review must be filed within 60 days from the date the ALJ's decision is received (which is presumed to be five days following the date on the decision, barring any evidence to the contrary). If the 60-day deadline is not met, the DAB may process the request for review upon a showing of good cause.

The request must specify the issues, findings of fact or conclusions of law with which the appellant disagrees, and the basis for contending that the findings and conclusions are incorrect.[221] The DAB may grant, deny or dismiss a request for review.[222] Upon request to the DAB, the parties will be permitted to file briefs or other written statements and an opportunity to present to the DAB oral arguments and evidence.

When the DAB reviews an ALJ's decision or dismissal order, the DAB may issue a decision, or it may remand the case back to the ALJ either for a hearing and decision or for a recommended decision (in which case, the final decision will be issued by the DAB). For enrollment appeals, the DAB must issue its remand or decision no later than 180 days after the appeal was received by the DAB. The written decision is based on the evidence contained in the record, and includes separate numbered findings of fact and conclusions of law.[223]

Judicial Review

A party dissatisfied with the decision of the DAB may seek judicial review. In order to pursue judicial review of a DAB decision, a party must file a civil action in a United States District Court within 60 days from the receipt of notice of the DAB's decision (receipt is presumed to have occurred five days after the date of the DAB decision, unless there is evidence to the contrary). A party may request from the DAB an extension of this 60-day timeframe for appeal, which may be granted upon a showing of good cause.[224]

Current Issues Arising in the Appeals Process

Appeals Regarding the Effective Date of Billing Privileges

Over the past year, several ALJ cases and one DAB case have questioned whether federal regulations, codified at 42 C.F.R. 489.3(b)(15), grant providers and suppliers the right to challenge decisions regarding the effective date of their Medicare billing privileges. As noted above, the appeals process is triggered once CMS provides notice of an unfavorable "initial determination."[225] Regulation 42 C.F.R. 489.3(b) sets forth actions that are initial determinations giving rise to appeal rights:

> (b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the following matters:
>
> … (15) The effective date of a Medicare provider agreement or supplier approval.

The commentary to this specific regulation indicates that the purpose of the regulation is to make "existing appeals procedures available to entities that are dissatisfied with any effective date determination."[226] Additionally, the commentary to the appeals regulations generally states that, "When a Medicare contractor makes an adverse enrollment determination (for example, enrollment denial or revocation of billing privileges), providers and suppliers are afforded appeal rights."[227]

Recently, a split arose among ALJs with respect to the issue of whether 42 C.F.R. 489.3(b)(15) in fact gives rise to appeal rights with respect to decisions regarding the effective dates of billing privileges.

- First, in two cases decided in February 2010, an ALJ found that federal regulations did not grant providers and suppliers the right to challenge effective date decisions. The ALJ acknowledged that the plain language of the regulation would seem to indicate that a determination of the effective date of a Medicare provider agreement or supplier approval (triggering Medicare billing privileges) is an initial determination giving rise to appeal rights. However, the ALJ accepted CMS's interpretation of the regulatory history of the regulation that Section 489.3(b)(15) should be understood to restrict appeals to those providers and suppliers subject to survey and certification or accreditation.[228]
- Thereafter, numerous other ALJs considered this same issue and found that the plain language of 42 C.F.R. 489.3(b)(15) was clear, and that CMS's interpretation limiting the regulation's application was not supportable. One such ALJ stated the following as part of her decision:

  > The wording of section 498.3(b)(15) appears straightforward in providing that "the effective date of a Medicare provider agreement or supplier approval" is an appealable initial determination and includes no qualifying or limiting language… I am thus bound to follow the regulations in permitting an appeal by any provider or supplier dissatisfied with a determination as to the effective date of its provider agreement or supplier approval.[229]

On May 7, 2010, the DAB considered this issue and found that the effective date of a Medicare provider agreement or supplier approval is an appealable initial determination. The DAB agreed with the ALJs that found the plain language of Section 489.3(b)(15) to be clear and unambiguous. The DAB noted that while:

> Regulatory history and other sources of guidance are relevant in interpreting language which is ambiguous or which is unclear in its application or which leaves gaps[,] CMS has not identified in what respect the wording of section 489.3(b)(15) may be said to be ambiguous or unclear or where the language leaves a gap requiring interpretation to give it meaning. I thus find little room for interpretation.

The DAB nonetheless considered the regulatory history cited by CMS, including the commentary to the regulation as cited herein, and found that the regulatory history supported the

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conclusion that the effective date of a Medicare provider agreement or supplier approval is an appealable issue.[230]

Based upon all of the case law cited above, and particularly considering the recently-decided DAB case, a strong argument can be made (until such time, if ever, that CMS changes its regulations) that the effective date of a Medicare provider agreement or supplier approval (giving rise to billing privileges) is an appealable issue.[231]

Issues Involving Parties and Representatives

As noted above, the parties to an appeal include both CMS and the "affected party." The regulations define "affected party" to include the following:

> [A] provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and "party" means the affected party or CMS, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.[232]

Recently, ALJs have been asked to consider whether an entity to which a physician or other supplier has reassigned Medicare payment may pursue an appeal in instances where an unfavorable initial determination has been rendered against the physician or other supplier. Cases that have considered this issue have held that the entity that has been reassigned Medicare payment is not authorized to pursue the appeal in its own right; however, the entity that has been reassigned Medicare payment may pursue the appeal as a representative of the provider or supplier.[233]

Practice Tips to Successfully Appeal Enrollment Denials

Presentation of Evidence

In preparing a provider or supplier enrollment appeal, it is essential that all evidence is compiled and the best case possible is prepared at the first stage, or reconsideration stage, of appeal. The preparation of the appeal will likely include drafting a legal brief or position statement setting forth the basis for the provider's or supplier's appeal; preparing affidavits of witness testimony; and compiling all documentation or other evidence necessary to support the provider's or supplier's position. Significantly, the regulations make clear that, for enrollment appeals, all evidence must be submitted at or before the reconsideration stage of appeal, and may not be submitted at the ALJ hearing stage of appeal, unless there is good cause for having failed to present the evidence earlier.[234] There is no good cause exception that allows a party to submit evidence for the first time at the DAB stage of appeal.[235] Thus, it is essential that a provider's or supplier's best case is prepared at or before the reconsideration stage of appeal.

Avoiding Dismissal

As set forth above, at any time prior to issuing a decision, an ALJ may dismiss a provider's or supplier's hearing request for the following reasons: at a party's request;[236] if the ALJ believes the request for hearing has been abandoned by the appellant;[237] or for cause.[238] An ALJ may find that a request for hearing has been abandoned where an appellant fails to appear at a prehearing conference or hearing without good cause; or if an appellant fails to respond to an ALJ's good cause notice within 10 days.[239] Therefore, it is essential that representatives of providers and suppliers in the enrollment appeals process timely respond to all correspondences and communications from the ALJ. Failure to do so could result in a dismissal for abandonment.

Some Practical Tips for Avoiding and Resolving Enrollment Problems

Due to the continuing changes in the enrollment rules, many of which are technical in nature, combined with severe penalties associated with noncompliance with the requirements, it is imperative that providers and suppliers stay attentive to the enrollment requirements and initiatives to avoid delays with enrollment (which is particularly important in light of the recent limitations on retroactive billing) or potential revocation of their billing privileges. The following practical tips will assist attorneys representing healthcare providers and suppliers to avoid and resolve enrollment-related issues.

1. **Ensure that information on the CMS-855 is complete, correct, and current.** Providers and suppliers should maintain their Medicare enrollment record by submitting changes to reassignments, practice location, ownership, business structure, and taxpayer identification number. It is especially important that address information be up-to-date. If a notice of revalidation is not obtained because the provider or supplier has changed its address without updating the CMS-855, the provider or supplier could have its billing privileges revoked.
2. **Keep copies of all CMS-855 forms and other documents submitted to, and received from, the MACs, the NSC, and CMS (and in a secure place).** There are several reasons for keeping at least one copy of all correspondence. The authors have encountered at least one instance in which a contractor has not been able to locate a previously filed CMS-855 and one instance in which an employee either discarded or

absconded with the supplier's enrollment correspondence. If a provider or supplier does not receive important correspondence from a contractor because the contractor failed to update its records as to a change in address, the provider or supplier needs to be able to prove that it notified the contractor of the change.

3. **Maintain a pleasant and professional relationship with the applicable CMS contractors.** Remember that the contractors do not write the enrollment policies but simply implement them. Where an attorney representing providers or suppliers believes that the contractors are going beyond what CMS requires, s/he should make his/her point in a professional and courteous way. Sooner or later, s/he may be asking the contractor for a favor (such as sending a copy of previously filed paperwork or expediting an application) and s/he does not want to burn bridges.

4. **If the provider's or supplier's billing number is revoked, take advantage of the 30-day CAP.** Attorneys representing providers or suppliers should keep in mind that even if one believes that the contractor was incorrect to revoke the billing number, engaging in a protracted discussion with the contractor may be fruitless, and worse, unnecessary, if the reason for revocation can be "corrected" (for example, where the NSC revokes a DMEPOS supplier's billing number for the arguably invalid reason that the supplier did not sign the surety bond, it would be easier to have the supplier sign the bond rather than argue with the NSC about the matter). Note that the revocation notice may say that a request for a CAP must be clearly marked as such; it is important to ensure that the provider or supplier is requesting a CAP and that documentation forwarded to the contractor is marked as being part of that provider's or supplier's CAP. Because revocations generally are not final and not effective until 30 days after notice of the revocation is mailed,[240] a timely, successful CAP will have the effect of nullifying the revocation and restoring billing privileges back to the date of revocation. Note that CAPs are not offered where the purpose of revocation is that a site review determines that the provider or supplier is not operational.

5. **Do not depend on getting the CAP approved: file a request for reconsideration.** Where a provider or supplier has an opportunity to file a CAP, it should do so. Unless the provider or supplier is *absolutely certain* that the CAP will be accepted, the provider or supplier should also file a request for reconsideration. Just as the request for a CAP should be clearly marked as a CAP, so too should the request for reconsideration be clearly identified as a request for reconsideration. If a provider or supplier fails to request a reconsideration because it has good reason to believe, or the provider or supplier has been assured by the contractor that it is not necessary to do so (*i.e.*, the CAP will be accepted and full retroactivity of billing privileges will be restored), and if, for some reason, the CAP is rejected, and the time for requesting reconsideration has lapsed, the provider or supplier may request a good cause extension for filing the reconsideration request.[241] However, it is within the contractor's discretion to grant an extension, and relying on an extension being granted is a poor substitute for filing a protective request for reconsideration, even if the provider or supplier believes the CAP will be accepted. Of course, because a request for a CAP must be filed within 30 days of the date of the revocation notice,[242] and because a provider or supplier has 60 days from the revocation notice to seek request reconsideration,[243] in most cases, a provider or supplier will know whether the CAP has been accepted prior to the time to file a request for reconsideration has lapsed.

6. **Contact CMS only in appropriate cases.** The authors' experience has been that CMS is sometimes willing to rectify mistakes made by the contractor or the provider or supplier without the necessity for an appeal, but bring only meritorious situations to CMS's attention and try to resolve the problem first at the contractor level.

7. **The DMEPOS supplier should sign the surety bond.** Despite the fact that there is no requirement per se at 42 C.F.R. 424.57(d), in the Program instructions or in the CMS-855S that the surety bond be signed by the principal (the DMEPOS supplier), the NSC has revoked billing numbers for DMEPOS suppliers because the bonds were not signed by the suppliers. Although the revocations of at least some of these suppliers were reversed by CMS, it is risky to depend on CMS reversing the NSC or on being successful on appeal when ensuring that the forms are signed is a relatively simple task.

8. **The name and address on the surety bond should match the name and address on the CMS-855S.** If there is even a slight discrepancy between the name and/or address between what is listed on the surety bond and the CMS-855S, the supplier runs the risk of having the bond rejected and its billing number revoked. If necessary, update the CMS-855S and submit it with the surety bond.

9. **Check to determine that the supplier is actually accredited for all**

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products and services it has listed on its CMS-855S. If an entity enrolling as a DMEPOS supplier is not accredited for all products and services it has listed on the enrollment application, its application will be delayed. If there will be a delay in receiving accreditation for certain products or services, the applicant would be advised to apply in a two-step process: first, submit a CMS-855S listing those products or services for which the applicant has received accreditation, and, after it has received accreditation for the remaining products or services, submit an updated CMS-855S.

10. **If the application for reassignment is delayed or denied, resulting in a later effective date, but the physician or practitioner is already enrolled, have the physician or practitioner submit claims and forward Medicare payment to the reassignee.** In the past, it was not crucial that the CMS-855R—allowing a physician or other practitioner to reassign payment to a medical group—be completed before the physician or other practitioner began furnishing services on behalf of the group. However, with limits on retroactive billing for services, the CMS-855R must be completed prior to the furnishing of the services, or Medicare will not pay the group for services furnished prior to the effective date of the CMS-855R. Obviously, the preferred course of action is to ensure that a conforming CMS-855R (*i.e.*, one that can be processed to completion) is submitted before the physician or other practitioner begins furnishing services on behalf of the group. If this is not possible (or the contractor wrongly refuses to accept the CMS-855R), however, there is still a way for the group to receive payment for the services. Medicare's rules on reassignment[244] dictate to whom Medicare can and will make payment – they do not affect private agreements between the parties. Medicare's policy has always been that once an individual or entity receives payment from Medicare, the individual or entity can forward the Medicare payment to whomever it wishes, regardless of whether the individual or entity could have received direct payment from Medicare. Therefore, the physician or other practitioner and the group can enter into an agreement by which the physician or other practitioner will turn over Medicare receipts to the group in the event that Medicare does not pay the group directly. Of course, this will work only if the physician or other practitioner is currently enrolled in Medicare.

11. **Make sure there is coverage of the premises during all business hours.** Suppliers that are small operations may be tempted not to have someone on the premises during all business hours. Regardless of whether a supplier needs personnel to be on location during all business hours in order to provide patient care or operate the business, a supplier that does not maintain a presence during all business hours is at risk of having its billing number revoked.

12. **Utilize Internet-based PECOS to enroll or make a change in enrollment information.** Providers and suppliers should review the CMS "Getting Started" guide (which can be found on the CMS website[245]) prior to using Internet-based PECOS, and should review their enrollment information in PECOS at least once a year. Using PECOS to make changes can take the worry out of whether the changes are received and implemented by the contractor.

Conclusion

Due to CMS's increasing focus on a supplier's or provider's Medicare billing privileges, it is becoming even more important for attorneys representing healthcare clients to be apprised of all changes in the enrollment process. The February 2011 Final Rule is further evidence of the paramount importance CMS places on the enrollment process and its increasing power to deny or revoke billing privileges to protect the Program. For those representing HHAs and DMEPOS suppliers, it is crucial to remember that those categories are under even greater scrutiny due to the high number of fraudulent claims as compared to other categories of providers and suppliers. By familiarizing themselves with the enrollment rules and the appeals procedures, attorneys representing healthcare clients will be better equipped to protect their clients' interests as CMS becomes stricter on its current and future enrollees.

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Endnotes

1 Pub. L. No. 111-148 (Mar. 23, 2010).

2 Pub. L. No. 111-152 (Mar. 30, 2010).

3 CMS itself has recognized that "[h]istorically, Medicare has permitted the enrollment of providers and suppliers whose qualifications for meeting all of [the] enrollment standards were sometimes questionable." 75 Fed. Reg. 24437, 24438 (May 5, 2010).

4 Medical Equipment Suppliers: Assuring Legitimacy, OEI-04-96-0240 p. i (Dec. 1997) http://oig.hhs.gov/oei/reports/oei-04-96-00240.pdf.

5 *Id.*

6 *Id.*

7 *Id.*

8 *Id.* at ii.

9 Pub. L. No. 104-134 (Apr. 26, 1996).

10 Pub. L. No. 105-33 (Aug. 5, 1997).

11 The term "provider" (abbreviated from the statutory term "provider of services") is defined in 42 C.F.R. §400.202 as including a hospital, a critical access hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

12 The term "supplier" is defined in 42 C.F.R. §400.202 as including a physician or other practitioner, or an entity other than a provider that furnishes healthcare services under Medicare. The term "supplier" is also defined in 42 C.F.R. §488.1 to mean an independent laboratory, portable x-ray supplier, physical therapist, ESRD facility, rural health clinic, federally qualified health center, or chiropractor.

13 *See* 61 Fed. Reg. 37278 (July 17, 1996). In lieu of submitting the paper CMS-855 application, most providers and suppliers can use the Internet-based Provider Enrollment, Chain and Ownership System (Internet-based "PECOS") to submit an initial Medicare enrollment application. The Internet-based PECOS can be used to submit an initial enrollment application as well as to view or change an application, track an application, add or change a reassignment of benefits, submit changes to existing enrollment information, reactivate an existing enrollment record, or to withdraw from Medicare. The Internet-based PECOS has been made available for suppliers of DMEPOS as of October 2010.

14 New contract entities—MACs—are replacing all of Medicare's current claims payment contractors known as fiscal intermediaries and carriers, on a phase-in basis.

15 There are five CMS-855 forms as follows: (1) CMS-855A for Institutional Providers; (2) CMS- 855B for Clinics, Group Practices, and Certain Other Suppliers; (3) CMS-855I for Physicians and NPPs; (4) CMS-855R for Reassignment of Medicare benefits; and (5) CMS-855S for DMEPOS. The CMS-855 can be accessed at www.cms.gov/MedicareProviderSupEnroll/02_EnrollmentApplications.asp.

16 *See* 42 C.F.R. §424.510.

17 *See* 42 C.F.R. §424.510 (d) (3).

18 *See* 42 C.F.R. §424.516 (d). With respect to independent diagnostic testing facilities ("IDTFs"), the reporting requirements are specified in 42 C.F.R. §410.33 (g) (2). With respect to DMEPOS suppliers, the reporting requirements are specified in 42 C.F.R. §424.57 (c) (2).

19 *See* 42 C.F.R. §424.510 (d) (3) (ii).

20 *See* 42 C.F.R. §424.515.

21 DMEPOS suppliers must continue to renew enrollment information in accordance with the requirements of 42 C.F.R. §424.57(e). Requirements for ambulance suppliers are set forth in 42 C.F.R. §410.41 (c) (2).

22 *See* 42 C.F.R. §424.515.

23 *See* 42 C.F.R. §424.515 (c).

24 For example, prior to 2000, there were 11 DMEPOS suppliers' standards; now the number of supplier standards has more than doubled, with 30 standards. The 2000 supplier standards were published at 65 Fed. Reg. 60366 (Oct. 11. 2000).

25 68 Fed. Reg. 22064 (Apr. 25, 2003). .

26 Pub. L. No. 108-173, §936(a)(2) (Dec. 8, 2003).

27 71 Fed. Reg. 20754 (Apr. 21, 2006).

28 *See* 42 C.F.R. §424.505.

29 42 C.F.R. §424.510.

30 42 C.F.R. §424.515.

31 42 C.F.R. §424.530.

32 42 C.F.R. §424.525.

33 42 C.F.R. §424.535.

34 42 C.F.R. §424.545.

35 42 C.F.R. §424.540.

36 *See* Medical Equipment Suppliers: Assuring Legitimacy, OEI-04-96-0240 p. i (Dec. 1997).

37 42 C.F.R. §424.525 and §424.530.

38 42 C.F.R. §424.525.

39 42 C.F.R. §424.525 (d).

40 42 C.F.R. §424.530.

41 *Id.*

42 42 C.F.R. §424.530 (c).

43 42 C.F.R. §424.530 (d).

44 42 C.F.R. §424.535.

45 71 Fed. Reg. at 20761.

46 42 C.F.R. §424.535.

47 42 C.F.R. §424.535 (a) (1).

48 42 C.F.R. §424.535 (b).

49 42 C.F.R. §424.535 (e).

50 42 C.F.R. §424.535 (d) (2).

51 42 C.F.R. §424.535 (f).

52 42 C.F.R. §424.535 (g).

53 42 C.F.R. §424.535 (c).

54 42 C.F.R. §424.535 (a) (1).

55 42 C.F.R. §424.540 (b) (3).

56 73 Fed. Reg. 69726 (Nov. 19, 2008).

57 Of note is that this new prohibition on retroactive billing does not apply to physical therapists or occupational therapists, as they are not considered NPPs.

58 73 Fed. Reg. 69766.

59 *See* 42 C.F.R. §489.13.

60 42 C.F.R. §489.13 (b).

61 42 C.F.R. §489.13(c) (2).

62 The effective date of the provider agreement is not delayed where CMS requires the SNF to submit a plan of correction for the requirements it does not fully meet, but if the SNF requires a waiver, the effective date is delayed until CMS receives an approvable waiver request. 42 C.F.R. §489.13(c) (1); 62 Fed. Reg. 43931, 43932 (Aug. 18, 1997).

63 This certificate is issued under 42 C.F.R. Part 493.

64 The NSC is responsible for enrollment of all DMEPOS suppliers nationwide.

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65 42 C.F.R. §424.57 (b).

66 *Id.*

67 42 C.F.R. §410.33 (i).

68 42 C.F.R. §424.535 (h).

69 75 Fed. Reg. 52629 (Aug. 27, 2010).

70 CMS Transmittal 1493 (April 18, 2008) https://www.cms.gov/transmittals/downloads/R1493CP.pdf.

71 42 CFR §424.57 provides the following: (29)

(i) Except as specified in paragraph (c)(29)(ii) of this section, is prohibited from sharing a practice location with any other Medicare supplier or provider.

(ii) The prohibition specified in paragraph (c)(29)(i) of this section is not applicable at a practice location that meets one of the following:

(A) Where a physician whose services are defined in section 1848(j)(3) of the Act or a nonphysician practitioner, as described in section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(B) Where a physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(C) Where a DMEPOS supplier is co-located with and owned by an enrolled Medicare provider (as described in §489.2(b) of this chapter). The DMEPOS supplier—

(1) Must operate as a separate unit; and

(2) Meet all other DMEPOS supplier standards.

72 Specifically, the final rule revises current supplier standards to ensure that the DMEPOS supplier maintains a physical facility on an appropriate site that must (1) measure at least 200 square feet (except for state-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice); (2) be in a location that is accessible to the public, beneficiaries, CMS and the NSC (*i.e.*, not in a gated community or other area where access is restricted); (3) be accessible and staffed during posted hours of operation, maintain a permanent visible sign in plain view and post hours of operation; and (4) contain space for storing business records, including the supplier's delivery, maintenance, and beneficiary communication records.

73 *See* Section 1834(a)(17) of the Act.

74 63 Fed. Reg. 2926 (Jan. 20, 1998).

75 65 Fed. Reg. 60366 (Oct. 11, 2000).

76 *Id.*

77 72 Fed. Reg. 42001 (Aug. 1, 2007).

78 74 Fed. Reg. 166 (Jan. 2, 2009).

79 42 C.F.R. §424.57 (d) (1).

80 42 C.F.R. §424.57(d)(3).

81 42 C.F.R. §424.57(a).

82 The terms "owner", "authorized official", and "delegated official" are defined in 42 C.F.R. §424.502.

83 42 C.F.R. §424.57 (d) (11).

84 42 C.F.R. §424.57 (d) (15).

85 42 C.F.R. §424.57 (d) (15)(ii). If a supplier changes its surety during the term of the bond, the new surety is responsible for any overpayments, civil monetary penalties ("CMPs"), or assessments incurred by the DMEPOS supplier beginning with the effective date of the new surety bond, and the former surety is responsible for any overpayments, CMPs, or assessments that occurred up to the date of the change of surety. If there is any gap in coverage by a surety, the supplier may have its billing privileges revoked and CMS will not pay for any services furnished during the gap.

86 Anecdotal evidence suggests that it may be especially difficult for a supplier that is subject to the elevated surety bond requirement to find a surety company that is willing to issue a bond due to the perception of added risk.

87 *See* Section 6402 of PPACA which amends Section 1834 (a)(16)(B) of the Act.

88 Section §1834(a)(20)(E) of the Act, states that the quality standards shall be published on CMS's website. Accordingly, the DMEPOS quality standards are available at www.cms.hhs.gov/medicareprovidersupenroll.

89 CMS has approved 10 entities as accrediting organizations. The accrediting organizations are listed under the Medicare Provider Enrollment website at www.cms.hhs.gov/medicareprovidersupenroll. The regulation for the accreditations procedures appears at 42 C.F.R. §424.58.

90 Section 1847(b)(2)(A)(i) of the Act requires DMEPOS suppliers to meet the quality standards before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program.

91 Excepted items are medical supplies furnished by home health agencies, drugs used with DME (inhalation drugs and drugs infused with a DME pump), immunosuppressive drugs, and anti-emetic drugs.

92 42 C.F.R. §424.57(c)(22); *see also* 42 C.F.R. §424.57(c)(23) – (25).

93 Pub. L. No. 111-72, §1 (Oct. 13, 2009).

94 Pub. L. No. 111-148, §3109 (Mar. 23, 2010). Section 3109 of PPACA also exempted certain pharmacies from the accreditation requirements.

95 Pub. L. No. 110-275 (July 15, 2008).

96 *See* section 1848(k)(3)(B) of the Act.

97 See Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Accreditation Fact Sheet, available at http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationMIPPA-FactSheet.pdf.

98 Medicare Financial Management Manual (CMS Pub. 100-06), Chapter 3, Section 130.

99 Note that a transfer of stock is specifically excepted from the definition of a CHOW at 42 C.F.R. §489.18.

100 42 C.F.R. §424.550(b)(1).

101 74 Fed. Reg. at 58118-19.

102 Transmittal 318 was available at http://www.cms.hhs.gov/transmittals/downloads/R318PI.pdf). This link informs the reader that "Change Request 6750, Transmittal 318, dated December 18, 2009, is being rescinded and will not be replaced at this time." In fact, CMS issued a Joint Signature Memorandum to its contractors rescinding Transmittal 318. Transmittal 318 added new section 5.5.2.6 to Chapter 10 of the Medicare Program Integrity Manual, CMS Pub. 100-08, but that section has since disappeared from the Manual.

103 MLN article MM6750, no longer available, but rescinded due to rescission of associated Transmittal 318.

104 74 Fed. Reg. at 58118 (Nov. 10, 2009).

105 75 Fed. Reg. 70372 (Nov. 17, 2010).

106 75 Fed. Reg. at 70464, amending 42 C.F.R. §424.502 to add definition of "change in majority ownership."

107 75 Fed. Reg. at 70464, amending 42 C.F.R. §424.550(b).

108 *See*, *e.g.*, 65 Fed. Reg. 60366 (October 11, 2000) addressing DMEPOS supplier standards; 71 Fed. Reg. 20754 (April 21, 2006) addressing enrollment requirements for providers and suppliers; 71 Fed. Reg. 69624 (December 1, 2006) addressing IDTF performance standards; 72 Fed. Reg. 17992 (April 10, 2007) addressing competitive acquisition for certain DMEPOS; 72 Fed. Reg. 66222 (November 27, 2007) addressing clarifications to IDTF performance standards; 73 Fed. Reg. 36448 (June 27, 2008) addressing appeals of determinations with respect to Medicare billing privileges; 73 Fed. Reg. 69726 (November 19, 2008) addressing enrollment bars; 74 Fed. Reg. 166 (January 2, 2009) addressing DMEPOS surety bond requirements; and 74 Fed. Reg. 58117 (November 10, 2009) addressing the prohibition against the sale or transfer of billing privileges for home health agencies.

109 The PPACA provisions also apply in some measure to the Medicaid and CHIP programs, but in keeping with the scope of this article, only the Medicare aspects of the PPACA provisions will be discussed.

110 *See*, *e.g.*, PPACA Sections 6401, 6402, 6405, 6406, 6407, 6001, 6002, 6003, 6004, 6101, and 6106.

111 75 Fed. Reg. 58204 (Sept. 23, 2010).

112 76 Fed. Reg. 5862 (February 2, 2011).

113 *Id.* at 5865.

114 This article discusses only Medicare; the changes for Medicaid and CHIP enrollment procedures can be found at 76 Fed. Reg. 5895.

115 Currently, MAOs generally use database checks to verify licensure and licensure sanctions and limitations with state licensing

boards and the federation of state medical boards; Drug Enforcement Agency ("DEA") certificates with the National Technical Information Service ("NTIS"); history of adverse professional review actions and malpractice with the National Practitioner Data Bank ("NPDB"); accreditation status of institutional providers and suppliers with national accrediting boards such as The Joint Commission ("TJC"); and search for HHS OIG exclusions using the HHS OIG website *http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp*. (76 Fed. Reg. 5866 (Feb 2, 2011).

116 *Id.* at 58206-07.

117 *Id.* at 5867.

118 75 Fed. Reg. 58208, 76 Fed. Reg. 5894.

119 *Id.* at 58209.

120 As defined in Section 1861(ss)(1) of the Act.

121 *Id.* at 5963-64. Although the following providers and suppliers were originally included in the limited risk category, in the February 2011 Final Rule, they were re-categorized to the moderate risk category: physical therapists and physical therapist groups; all ambulance suppliers, regardless of whether they are government or public affiliated; and portable x-ray suppliers.

122 *Id.*

123 75 Fed. Reg. 58210.

124 76 Fed. Reg. 5869.

125 75 Fed. Reg. 58210.

126 76 Fed. Reg. 5964.

127 *Id.*

128 75 Fed. Reg. 58209.

129 76 Fed. Reg. 58212.

130 *Id.* at 5964, 42 CFR §424.518(c)(2).

131 76 Fed. Reg. 5964, 42 CFR §424.518(c)(3).

132 76 Fed. Reg. 5964, 42 CFR § 424.518(c)(3)(iii).

133 75 Fed. Reg. 58217.

134 76 Fed. Reg. 5907.

135 *Id.*

136 *Id.*

137 *Id.*

138 *Id.* at 5964-65, 42 CFR §424.525(a)(3).

139 Section 6401(a)(2)(C)(iii) of PPACA provides for a hardship waiver for certain Medicaid providers. Note that Section 6401 of PPACA also provided for an entrance fee of $200 on "individual" suppliers and providers ("individual" was not defined), but this provision was repealed in section 10603 of the Reconciliation Act.

140 76 Fed. Reg. 5965, 42 CFR § 424.570(a).

141 76 Fed. Reg. 5965, 42 CFR § 424.570(b).

142 76 Fed. Reg. 5918.

143 *Id.* at 5965, 42 CFR §424.570(a)(2).

144 76 Fed. Reg. 5965, 42 CFR §424.570(a)(1)(iii).

145 76 Fed. Reg. 5965, 42 CFR §424.570(a)(1)(iv).

146 76 Fed. Reg. 5970, 42 CFR § 498.5(*l*)(4).

147 76 Fed. Reg. 5965, 42 CFR 424.550(d).

148 76 Fed. Reg. 5965, 42 CFR §§424.570(a)(1)(ii) and (d).

149 Section 1886(d) (10) of the Act, 42 U.S.C. §1395ww (d) (10).

150 *See* PPACA Section 6401 (a) (3) which adds Section 1866(j) (3) to the Act.

151 Section 1874A(h)(2) provides that a MAC may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error. Although section 1874A(h)(2), as added by Section 934 of the MMA, does not so limit Zone Program Integrity Contractors ("ZPICs"), which are responsible for overseeing program integrity for all Medicare-related claims, CMS has extended the limitation to all of its contractors performing non-random prepayment complex medical review, including ZPICs. *See* 73 Fed. Reg. 55753 (Sept. 26, 2008); 42 C.F.R. §421.505.

152 *See* PPACA Section 6401 (a) (3) which adds Section 1866 (j) (4) (A) to the Act.

153 *See* PPACA Section 6401(a) (3) which adds Section 1866 (j) (5) to the Act.

154 42 C.F.R. §405.371.

155 42 C.F.R. §405.371(d). The time limits for a suspension do not apply in certain circumstances. *See* 42 C.F.R. §405.371(d)(3).

156 42 C.F.R. §405.371(a)(1).

157 76 Fed. Reg. 5961, 42 CFR §405.370(a).

158 *Id.*

159 *Id.*

160 76 Fed. Reg. 5961, 42 CFR §450.371(b).

161 76 Fed. Reg. 5961, 42 CFR §450.371(b)(1)(i)-(ii).

162 76 Fed. Reg. 5961-62, 42 CFR §405.371(b)(1)(iii)-(iv).

163 76 Fed. Reg. 5961, 42 CFR 405.371(b)(2).

164 76 Fed. Reg. 5961-62, 42 CFR 405.371(b)(3).

165 The OIG has issued a number of compliance program guidance documents for various segments of the healthcare industry in which OIG encourages the adoption of compliance programs. *See, e.g.*, 73 Fed. Reg. 56832 (Sept. 30, 2008). Some states have mandatory compliance program requirements. For example, effective October 1, 2009, New York State healthcare organizations for which Medicaid constitutes $500,000 or more of the provider's annual business operations (considered "substantial" and defined as ordering, providing, billing or claiming $500,000 or more from Medicaid in a 12-month period), must have an "effective" compliance program and certify on an annual basis that the compliance program meets related statutory requirements (New York Social Services Law §363-d). The effective compliance program requirement is also applicable to any New York State provider subject to the provisions of Articles 28 or 36 of the New York Public Health Law or Articles 16 or 31 of the New York Mental Hygiene Law, regardless of the amount of Medicaid business.

166 *See* PPACA Section 6401 (a) (3) which implements a new Section 1866 (j) (7) of the Act.

167 *Id.*

168 76 Fed. Reg. 5942-43.

169 75 Fed. Reg. at 58228. The seven elements of an effective compliance and ethics program as described in the US Federal Sentencing Guidelines Manual are as follows:

(1) The organization shall establish standards and procedures to prevent and detect criminal conduct.

(2) (A) The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.

(B) High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program….Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.

(C) Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.

(3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct consistent with an effective compliance and ethics program.

(4) (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.

(B) The individuals referred to in subparagraph (A) are the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents.

(5) The organization shall take reasonable steps—

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(A) to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct;

(B) to evaluate periodically the effectiveness of the organization's compliance program; and

(C) to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees an agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.

(6) The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

(7) After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.

The Federal Sentencing Guidelines Manual is available online at http://ftp.ussc.gov/guideline.htm.

170 A CIA is entered into by a provider or supplier that has been investigated by the OIG and that wishes to settle potential liability and avoid the risk of exclusion.

171 *See* Section 1304 of the Reconciliation Act.

172 *See* 75 Fed. Reg. 24437 (May 5, 2010) implementing provisions contained in PPACA Sections 6402, 6405, and 6406.

173 75 Fed. Reg. at 24448, amending 42 C.F.R. §424.506 (c) (3).

174 75 Fed. Reg. at 24440 (May 5, 2010).

175 42 C.F.R. §424.506(b) (2).

176 42 C.F.R. §424.506 (c) (2).

177 "Eligible professional" is defined in 42 C.F.R. §424.506(a) as any of the professionals specified in Section 1848 (k) (3) (B) of the Act (*i.e.*, a physician, a practitioner described in Section 1842(b)(18)(C) of the Act, a physical or occupational therapist, a qualified speech-language pathologist, and a qualified audiologist).

178 42 C.F.R. §§424.507 (a) and 424.507(b).

179 75 Fed. Reg. at 24443.

180 42 C.F.R. §§424.507 (a) (1)(ii) and 424.507 (b)(1) (ii).

181 42 C.F.R. §424.507 (c)

182 42 C.F.R. §§424.516 (f) (1) and (2).

183 42 C.F.R. §424.535 (a) (10).

184 42 C.F.R. §424.515 (d).

185 42 C.F.R. §424.515 (d) (1).

186 42 C.F.R. §424.535 (a) (6).

187 *See*, *e.g.*, Medicare Change Requests ("CRs") 6486 and 6665 (revalidation of select Medicare Part A providers); CR 6755 (providers not in PECOS, in order to fully populate the PECOS system); CR 6669 (HHAs that are not in PECOS); CR 6666 (portable X-ray suppliers); CR 6486 (the top 50 SNF billers within each state for each Medicare contractor); CR 6485 (the top 50 Part B organizational supplier billers in each state for each Medicare contractor); CR 6574 (the top 50 Part B individual practitioner supplier billers in each state for each Medicare contractor); CR 6494 (all slide preparation facilities); CR 6517 (all radiation therapy centers); CR 5738 and 5903(HHAs in high-risk areas); CR 6421 (DMEPOS suppliers).

188 The website for CMS's provider and supplier enrollment page is http://www.cms.gov/MedicareProviderSupEnroll/.

189 42 C.F.R. §405.874.

190 The Final Rule implementing the appeals regulations codified at 42 C.F.R. Part 498 can be found at 73 Fed. Reg. 36448 (June 27, 2008). Note that the enrollment appeals process is codified at 42 CFR Part 498. This process is distinct from the Medicare Part A and Part B claims appeals process, codified at 42 CFR Part 405 Subpart I.

191 42 C.F.R. §498.20 (a).

192 *See* 42 C.F.R. §498.3 (b). The regulations outline numerous additional actions that qualify as "initial determinations."

193 *See* 42 C.F.R. §498.3 (d) (1). The regulations outline numerous additional administrative actions that do not constitute initial determinations. *See generally*, 42 C.F.R. Section 498.3 (d).

194 Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 15, Section 25.

195 42 C.F.R. §498.5 (l).

196 42 C.F.R. §498.10. *See also* 42 C.F.R. §498.11, which sets forth the authority of appointed representatives.

197 Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 15, Section 25.

198 *Id.*

199 42 C.F.R. §498.22 (b).

200 42 C.F.R. §498.22 (d). *See also* Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 15, Section 25.

201 42 C.F.R. §498.22 (b).

202 42 C.F.R. §§405.874(c), 498.56(e).

203 73 Fed. Reg. 36452 (June 27, 2008).

204 *Id.* at 36451.

205 42 C.F.R. §498.24.

206 42 C.F.R. §498.25 (a).

207 42 C.F.R. §498.40(c)(2).

208 42 C.F.R. §498.42.

209 42 C.F.R. §§498.47, 498.48 and 498.49.

210 42 C.F.R. §498.60.

211 42 C.F.R. §§498.62 and 498.63.

212 42 C.F.R. §498.68.

213 42 C.F.R. §498.69.

214 42 C.F.R. §498.70.

215 42 C.F.R. §§498.71(b), 498.83(a).

216 42 C.F.R. §498.78. Previously, an affected party was given the opportunity to concur in writing or on the record with a CMS request for remand. In deleting the provision that an affected party concur in writing or on the record with a CMS request for remand, CMS stated: "We contend that the appeals process is enhanced by allowing an ALJ to remand a provider enrollment case to the Medicare FFS contractor when CMS requests a remand Further, we believe that a remand could result in either a favorable decision to the appellant or in the administrative record being complete." 73 Fed. Reg. 36458 (June 27, 2008).

217 42 C.F.R. §§498.74.

218 42 C.F.R. §498.79.

219 42 C.F.R. §498.76.

220 42 C.F.R. §498.80.

221 42 C.F.R. §498.82.

222 42 C.F.R. §498.83(a) and (b).

223 42 C.F.R. §498.88 (g).

224 42 C.F.R. §498.95.

225 42 C.F.R. §498.3 and 498.5.

226 62 Fed. Reg. at 43934 (August 18, 1997).

227 73 Fed. Reg. at 36452 (June 27, 2008).

228 *Mikhail Paikin, DO*, DAB CR2064 (2010) (ALJ Sickendick). *See also Margaret J. Prewitt, CRNA*, DAB CR 2079 (2010) (ALJ Sickendick).

229 *Mobile Vision, Inc.*, DAB CR2124 (2010) (ALJ Sussan); *See also Andrew J. Elliot, M.D.*, DAB CR2103, at 3 (2010) (ALJ Kessel); *Victor Alvarez, M.D.*, DAB CR 2070 (2010) (ALJ Kessel); *Romeo Nillas, M.D.*, DAB CR 2069 (2010) (ALJ Kessel); *Jorge M. Ballesteros, CRNA*, DAB CR 2067 (2010) (ALJ Hughes); *Vincent Pirri, M.D.*, DAB CR 2065 (2010) (ALJ Smith).

230 *Eugene Rubach, M.D.*, DAB CR 2125 (2010) (Board Member Sussan).

231 Of course, providers and suppliers that challenge the effective date of their enrollment may still face the regulatory bar on retroactive enrollment. Thus, in some cases, the ability to bring an appeal on the issue of the effective date of enrollment may be an empty right, as ALJs are bound by CMS's regulations.

232 42 C.F.R. §498.2.

233 *See*, 42 C.F.R. §498.10 (regarding appointment of representatives).

See also Romeo Nillas, M.D., DAB CR2069 (2010) (ALJ Kessel) (finding that a provider's employer had no standing to file a hearing

request, either on its own behalf, or as the employer of the provider. However, the court did not dismiss the hearing request, as the court found that the employer was acting as the representative of the provider in the appeal. Specifically, the court stated, "Petitioner is the affected party in this case and he, and he alone, has a right to a hearing. However, [Employer] and Petitioner have clarified that [Employer] is serving as Petitioner's representative in this case.").

See also Victor Alvarez, M.D., DAB CR 2070 (ALJ Kessel) (finding, "CMS is correct in asserting that an employer of an affected provider has no right to a hearing. The right to a hearing in this case extends uniquely to [Provider]. However, [Provider] has offered evidence showing that [Employer] is serving only as [Provider's] representative and not seeking relief in its own right. For that reason I conclude that it is [Provider], and not [Employer], who seeks a hearing and decision in this case.").

234 42 C.F.R. §498.56(e)(2)(i).

235 *See* 42 C.F.R. §498.86(a).

236 42 C.F.R. §498.68.

237 42 C.F.R. §498.69.

238 42 C.F.R. §§498.68, 498.69 and 498.70.

239 42 C.F.R. §498.69.

240 If the revocation is based on federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational. 42 C.F.R. §424.535(g).

241 *See* 42 C.F.R. §498.22(b).

242 CMS Program Integrity Manual, Pub. 100-08, Ch. 15, §15.24.15.

243 42 C.F.R. §498.22(b) (3).

244 *See* Section 1842(b) (6) of the Act, 42 U.S.C. §1395u (b) (6), and 42 C.F.R. §424.80.

245 The "Getting Started" guide can be found at www.cms.gov/MedicareProviderSupEnroll/downloads/.