Pre-Publication Draft

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THE MEDICARE PART-B ENROLLMENT OBSTACLE COURSE: IT HASN'T GOTTEN ANY EASIER

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Accepted for publication in the Health Law Handbook, 2019 Edition.
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Introduction

A demographic crisis faces the Medicare program. In its annual 2018 report to Congress, the Board of Trustees for the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds stated that "Medicare expenditures represented 3.7 percent of GDP in 2017. Under current law, costs increase to 5. percent of GDP by 2042, largely due to the rapid growth in the number of beneficiaries."[1] The Medicare Part-A Trust Fund is currently projected to be depleted by 2026.[2] In recent years, efforts have been made to stanch the flow of money out of the Medicare system, including the first shifts towards value-based payment, the Medicare Incentive Payment System (MIPS)[3], and the recent change to how evaluation and management services will be compensated in the coming years.[4] Part of the framework for controlling the outflow of Medicare funds is controlling who has access to the funds in the first place through Medicare's credentialing process (hereinafter referred to as "enrollment," in accordance with Medicare's own terminology), and the concomitant enforcement of Medicare's enrollment requirements.

These issues were last examined in the Health Law Handbook eight years ago. Since that time, there have, unsurprisingly, been changes that warrant a revisit. This article focuses primarily on physician enrollment requirements, but also examines issues relating to independent diagnostic testing facilities (IDTFs) and durable medical equipment, prosthetic, orthotic, and supplies (DMEPOS) suppliers.[5] The article reviews the current regulatory landscape and requirements for obtaining Medicare billing privileges. It examines regulations, current enrollment forms, and CMS manual instructions that provide additional guidance. It then explores problematic aspects of the Medicare enrollment process for suppliers. Finally, the article considers practical methods to avoid some of these problems, or to navigate them more effectively where they arise.

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[1] Report, p. 19.

[2] Report, p. 5.

[3] For more on MIPS, see, Shay, Daniel, "To Quality And Beyond! The Present and Future of Medicare's Physician Quality Reporting Programs," Health Law Handbook, 2016 ed., pp. 31-66.

[4] 83 Fed. Reg. 59452 (November 23, 2018).

[5] Physicians, IDTFs, and entities that provide DMEPOS are all referred to as "suppliers" throughout this article, and in Medicare's statutes and regulations themselves. Although these entities are often colloquially referred to as "providers," the term "provider" has a specific meaning in the Social Security Act and its regulations, and is meant to refer primarily to institutions such as hospitals and nursing facilities. "Supplier" is the more accurate term for Part-B enrolled entities. See, 42 USCA § 1395x(u).

The Rules

The Medicare enrollment process has undergone multiple changes over the lifetime of the program. What began with a simple one-page application form has morphed into a complex set of interrelated data that may be reported using multiple paper applications, or through the use of a website provided by the Centers for Medicare and Medicaid Services (CMS).[6] In the eight years since this book last examined Medicare enrollment, there have been both regulatory changes and changes in the specific issues that seem to bedevil suppliers. The general trend has been towards greater intrusiveness by CMS, heightened enforcement, and increasing requirements for reporting of information.

The Present State of Affairs

1. Enrollment Generally, Revalidations, Reporting Changes, and Billing Privileges

Initial enrollment[7] must be done through the Provider Enrollment, Chain, and Ownership System (PECOS) website,[8] or through the CMS-855 series of forms.[9] Current copies of the CMS forms may be found on CMS' website.[10] Suppliers must submit a range of information, much of which has not changed since 2011.[11] The information includes data such as corporate name, "doing business as" name, copies of necessary licenses, as well as a certification statement signed by an "Authorized Official."[12] IDTFs must report

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[6] For a more in-depth review of the history of the Medicare enrollment process, see Shay, "Enrolling in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" Health Law Handbook, 2009 ed., pp. 1-35; Shay, "Halt! Who Goes There?" – Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, 2011 ed., pp. 71-103.

[7] Governed by regulations at 42 CFR § 424.510.

[8] Located at, https://pecos.cms.hhs.gov/pecos/login.do#headingLv1.

[9] For purposes of this article, the primary important forms are the CMS-855I for individual physicians and solely owned corporations; the CMS-855B for physician groups, IDTFs, [Add the rest]; the CMS-855S for DMEPOS suppliers; and the CMS-855R whereby a supplier may reassign their right to receive payment for services to another enrolled supplier or provider. Interestingly, institutional providers are required to pay an application fee of at least $500. 42 CFR § 424.514. Failure to pay or submit a hardship exception will result in rejection of the enrollment application for newly-enrolling institutions, or revocation of billing privileges for currently enrolled providers. This, however, does not apply to suppliers. 42 CFR § 424.514(g).

[10] Located at, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.html.

[11] See, CMS-855B, 855I. Details of information required are discussed more fully in Shay, "Enrolling in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" Health Law Handbook, 2009 ed., pp. 1-35.

[12] 42 CFR § 424.510. "Authorized Official" is defined in accordance with 42 CFR § 424.502 to mean an appointed official, such as a CFO or CEO, who is granted the legal authority to make changes to Medicare enrollment data. Typically, an "authorized official" is someone who is an owner or executive in the business itself.

information such as their supervising physician(s), the range of services they perform, any physicians who will perform interpretations to be billed by the IDTF, and a list of technicians and their identifying information (including birth dates, Social Security Numbers, etc.).[13] Suppliers of DMEPOS must report a range of other information, including their business structures, the list of products and services the supplier provides, and information about their liability insurance and their surety bond (when required to obtain one).[14]

One recent change comes in the form of the signature requirement for the certification statement that must be submitted with all applications. In years past, enrolling and revalidating suppliers and providers (explained more fully below) who used PECOS were unable to submit electronic signatures for the certification form. In 2012 PECOS added the functionality, but still permitted providers and suppliers to submit a hard copy of the signed certification statement. However, in September, 2018, the Medicare Program Integrity Manual was revised to state that, "If the provider submits its application online and chooses to submit its certification statement via paper rather than through e-signature, it shall do so via PECOS upload functionality. The provider shall not mail in its paper certification statement as it will not be accepted."[15]

This change resolves a potential problem for providers and suppliers enrolling using the PECOS system, by shortening the time it takes to submit a complete application, thereby allowing an earlier effective date of billing privileges, as discussed further below. Previously, the enrolling entity would have to mail a copy of the signed certification statement to the Medicare Administrative Contractor (MAC), which risked it being lost in transit, or misplaced somewhere within the MAC, which in turn could lead to additional development requests (i.e., seeking additional information) and/or delays in effective dates of billing.

The effective date of billing privileges depends on the type of provider or supplier seeking such privileges. Surveyed, certified, and accredited suppliers and providers (e.g., hospitals, ASCs, etc.) are granted effective dates based on their having met certain health and safety standards.[16] If such standards have been met on the date when CMS surveys the provider or supplier, then the effective date of billing privileges is the latest of the dates on which CMS determines that each applicable requirement is met.[17] If the

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[13] See generally, CMS-855B enrollment form, Attachment 2.

[14] See generally, CMS-855S enrollment form.

[15] Medicare Program Integrity Manual, Chapter 15, Section 15.5.14.4(B), emphasis added.

[16] 42 CFR § 489.13.

[17] 42 CFR § 489.13(b).

provider or supplier has not met the health and safety standards, then the effective date of billing privileges vary by provider or supplier type.[18]

For DMEPOS suppliers, the effective date of billing privileges is specified as the date it meets the requirements covered in 424.57(b).[19] Although these requirements include that the supplier has submitted a completed enrollment application to CMS, they also address unrelated matters regarding the DMEPOS supplier's eligibility to receive payment for Medicare-covered items, such as whether the date on which the item was furnished was on or after the date CMS issued a DMEPOS supplier number for billing privileges, that CMS had not revoked or excluded the DMEPOS supplier's billing privileges when the item was furnished, and that all documentation necessary to process the claim was submitted to CMS.[20] No actual effective date of billing privileges is specified in the regulations themselves; there is no statement, for example, that the date of billing privileges is the latter of the date on which the supplier complies with the requirements listed in 424.57(c) and (d), and the date on which it submitted a complete enrollment application to CMS that could be successfully processed.

Physicians, non-physician practitioners (NPPs), and ambulance suppliers are all granted an effective date of billing privileges based on the later of (a) the date of filing an enrollment application that was subsequently approved by a Medicare administrative contractor (MAC), or (b) the date the supplier first began furnishing services.[21]

Since 2009, CMS has permitted physicians and NPPs (and groups thereof) to bill for services rendered not more than thirty days prior to their effective date of billing privileges.[22] However, prior to 2009, suppliers could reach back in time much farther -- back to the date of "approval" rather than the date of "enrollment."[23] In 2014, CMS published a final rule revising certain enrollment regulations which modified provisions of the regulations to apply specifically to ambulance suppliers.[24]

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[18] 42 CFR § 489.13(c).

[19] 42 CFR § 424.520(c).

[20] 42 CFR § 424.57(b).

[21] 42 CFR § 424.520(d).

[22] 42 CFR § 424.521. See also, Medicare Program Integrity Manual, Chapter 15, Section 15.17(B).

[23] Previously, CMS described that a supplier enrolled in Medicare in December 2008, with an approval date reaching back to October 2006 could retrospectively bill for claims rendered as early as October 1, 2006. 73 Fed. Reg. 38535, July 7, 2008. For a longer discussion on this specific issue of supplier back-billing, see Shay, "Enrolling in Medicare: Fraternity Hazing or Keeping Out Bad Actors?" Health Law Handbook, 2009 ed., pp. 1-35.

[24] 42 CFR § 424.521(a); 79 Fed. Reg. 72500, December 4, 2014.

Effective dates of billing privileges (and related retroactive billing dates) are critical to suppliers of this type. Additional development requests (i.e., MAC-requested corrections or additional documentation for a submitted enrollment application) increase the time between the date of submission and the potential effective date of billing privileges (often referred to as a "gap period"). In practice, most suppliers are already operating by the time they submit an enrollment application; few apply prior to opening for business and providing services to Medicare beneficiaries. All providers and suppliers must be operational before being granted billing privileges, although providers and suppliers subject to on-site review are particularly vulnerable on this ground.[25] If the site is not actually in operation, that can serve as a basis to reject an application or revalidation, or to revoke billing privileges.[26] Effective dates of billing privileges – as tied to submission dates of enrollment applications – can also prove critical for reactivation of billing privileges following a deactivation for technical noncompliance, as discussed further below.

Revalidation is a process of recertification of the accuracy of enrollment data. Suppliers are required to recertify this information at least every five years (described as a five year "cycle"), although CMS may request "off cycle" revalidations.[27] An "off cycle" revalidation may be triggered by "random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements."[28] The process itself essentially requires that the supplier resubmit an entire enrollment application in accordance with the requirements of 42 CFR § 424.510. This may also include a site visit by a CMS surveyor, depending on the type of provider or supplier. Also permitted is an "additional off-cycle revalidation."[29] This process, changed in 2011, now permits CMS to conduct more than one off-cycle revalidation.[30] Prior to the 2011 changes, CMS was limited to performing a single off-cycle revalidation. In making the change, CMS explained,

> Section 424.515(e) was added for a specific purpose and we could not require a provider or supplier to revalidate off-cycle pursuant to § 424.515(e) more than once. The application fee was included in the statute to cover exactly the type of screenings that will be performed during the revalidations, and we do not believe it is appropriate or necessary to exempt the revalidations from the fee.[31]

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[25] 42 CFR §424.510 (6).

[26] 42 CFR §§ 424.530(a)(5); 424.535(a)(5).

[27] 42 CFR § 424.515. The exception to this rule is DMEPOS suppliers, who must submit a revalidation every three years. 42 CFR § 424.57(g).

[28] 42 CFR 424.515(d)(1).

[29] 42 CFR § 424.515(e).

[30] Institutional providers may also be charged an application fee as part of the process.

[31] 76 Fed. Reg. 5894, February 2, 2011.

A failure to revalidate effectively will result in the deactivation of billing privileges (discussed in greater detail below).[32]

Most suppliers must report most changes to their enrollment information within ninety days.[33] However, the following three changes must be reported within thirty days: (a) changes in ownership; (b) adverse legal actions; or (c) changes in practice location.[34] The actual impact of reporting these changes is discussed in greater detail below. In addition to the above requirements, IDTFs must also report changes to their general supervising physician,[35] and DMEPOS suppliers are instructed to report all changes to their information within thirty days.[36]

Interestingly, there is no definition for an "adverse legal action" provided in the regulations. Instead, reference is made to "final adverse actions" in the definitions section: (1) Medicare-imposed revocation of any Medicare billing privileges; (2) suspension or revocation of a license to provide health care by any State licensing authority; (3) revocation or suspension by an accreditation organization; (4) conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or (5) an exclusion or debarment from participation in a Federal or State health care program.[37] However, CMS "closes the loop" on this apparent definitional gap by making clear in its manuals that its instructions on "final adverse actions" apply explicitly "to the adverse legal action sections of the Form CMS-855."[38]

Many providers still submit paper applications, although more are using the PECOS website and electronic applications. For some time, CMS has "incentivized" the use of the PECOS website by requiring MACs to process enrollment applications submitted electronically faster than paper applications. For example, for initial enrollment applications and revalidations submitted by paper which do not require a site visit, MACs are instructed to process 80% of applications within 60 days, 90% within 120 days, and

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[32] 42 CFR § 424.540.

[33] 42 CFR § 424.516(d)(2).

[34] 42 CFR § 424.516(d)(1).

[35] 42 CFR § 410.33(g)(2).

[36] 42 CFR § 424.57(c)(2). The specific language reads, "The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change."

[37] 42 CFR § 424.502.

[38] Medicare Program Integrity Manual, Ch. 15, Section 15.5.3.

95% within 180 days.[39] For paper applications requiring a site visit the timelines are 80 days, 150 days, and 210 days, respectively.[40] By contrast, for "web-based" applications (meaning those submitted through the PECOS website), CMS instructs that 90% must be processed within 45 days, 95% within 60 days, and 99% within 90 days.[41]

The implication of the above provisions are that CMS far prefers web-based applications to paper applications. Web-based applications will be processed much faster, will be harder to lose or misplace, and with the addition of electronic submission of the signed certification statement, the delay between submission date and a potential effective date of billing privileges (and thus, retroactive billing date) is considerably lessened.

2. Denial, Revocation, and Deactivation

Denial occurs when an initial application or revalidation is rejected by CMS or the MAC. Revocation is when the provider or supplier has already applied for and been granted billing privileges, and those billing privileges are subsequently revoked. The regulations specify multiple grounds for denial and revocation, several of which were modified in the 2014 rulemaking.[42]

For example, denial or revocation may occur when the supplier is not in compliance with enrollment requirements or the supplier's application for its supplier type, and the supplier has failed to submit a plan of corrective action.[43] A provider or supplier also may find its application denied or its billing privileges revoked on conduct grounds, such as when the provider, supplier, or an owner, managing employee, authorized or delegated official, medical director, supervising physician, or other personnel providing Medicare reimbursable services and who are reported on an enrollment application is (1) excluded from the Medicare program; or (2) debarred, suspended, or otherwise blocked from

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[39] Medicare Program Integrity Manual, Chapter 15, Section 15.6.1.1.2.

[40] The percentages remain the same as for applications not requiring a site visit. Medicare Program Integrity Manual, Chapter 15, Section 15.6.1.1.1. This language actually deviates substantially from the regulatory requirements themselves, as described in 42 CFR § 405.818. The regulations state that CMS must process initial enrollment and revalidation applications within 180 days of receipt, and change-of-information and reassignment of payment requests within 90 days of receipt. No mention is made of allowing for "slippage." The discrepancy between the regulatory language and CMS' own internal instructions is apparently known to CMS. In fact, the Medicare Program Integrity Manual states, "Even though the provisions of 42 CFR § 405.818 contain processing timeframes that differ than those in sections 15.6.1 through 15.6.3, the contractor shall adhere to the standards specified in sections 15.6.1 through 15.6.3."

[41] Medicare Program Integrity Manual, Chapter 15, Section 15.6.1.3.

[42] 79 Fed. Reg. 72500 (December 5, 2014).

[43] 42 CFR §§ 424.530(a)(1), 424.535(a)(1).

participating in any other Federal procurement or non-procurement activity under the Federal Acquisition Streamlining Act.[44]

Similarly, a denial or revocation may occur if the provider, supplier, or an owner, managing employee was, within the past ten years, convicted[45] of a federal or state felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.[46] The types of offenses for which such a denial or revocation may occur include: (1) crimes against persons (such as murder, rape, assault, or other similar crimes, including guilty pleas and adjudicated pretrial diversions; (2) financial crimes (such as extortion, embezzlement, income tax evasion, or insurance fraud); (3) felonies that place the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct); or, (4) felonies that would result in mandatory exclusion under Section 1128(a) of the Social Security Act.[47] Denials and revocations based on these grounds last for a minimum period of ten years from the date of the conviction if the individual has been convicted on one previous occasions for one or more offenses.[48]

This basis for denial and revocation was revised in the 2014 rulemaking, which made several modifications, including adding "managing employees" as individuals whose conviction could serve as a basis for denial or revocation, and defining "conviction" in relation to 42 CFR § 1001.2. CMS also provided some insight into the underlying bases for this category of exclusion. For example, in response to commentary that a supplier's enrollment should not be denied or revoked when it exercised a good faith effort to determine whether an owner or managing employee had been convicted, CMS explained, "...It is the felony conviction itself -- not whether the organization screened for such convictions -- that is the relevant matter."[49] In other words, CMS is more concerned with protecting Medicare funds from those individuals convicted of felonies it deems risky

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[44] 42 CFR §§ 424.530(a)(2), 424. 535(a)(2).

[45] "Convicted" as defined in accordance with 42 CFR § 1001.2 – which defines the term to mean "(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether (1) there is a post-trial motion or an appeal pending, or (2) the judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed; (b) a Federal, State or local court has made a finding of guilt against an individual or entity; (c) a Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or (d) an individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

[46] 42 CFR §§ 424.530(a)(3), 424.535(a)(3).

[47] 42 USCA § 1320a-7.

[48] 42 CFR §§ 424.530(a)(3); 424.535(a)(3).

[49] 79 Fed. Reg. 72511 (December 5, 2014). CMS also included adjudicated pretrial determinations as falling into the same category as "felonies," as discussed later in this article.

than it is with efforts expended by the enrolling entity that has chosen to associate with such an individual.

Other grounds for both denial and revocation include: (1) submitting false or misleading information on an enrollment application;[50] or failing an on-site review, meaning that the site itself is not operational to provide Medicare services or items to the public or failing to satisfy any other enrollment requirement.[51]

More recent grounds for denials were added to include where the supplier or provider has outstanding Medicare debt, or where the supplier or provider was previously an owner of a provider or supplier with Medicare debt that existed when its enrollment was either voluntarily or involuntarily terminated or revoked, and (1) the owner left within a year of termination or revocation, (2) the Medicare debt has not been repaid, and (3) CMS decides that the uncollected debt poses an undue risk of fraud, waste, or abuse.[52] Other grounds include when the provider or supplier is under a payment suspension[53] or when CMS has instituted a temporary moratorium.[54]

Grounds for revocations include when the supplier or provider misuses their billing number by knowingly selling the number or allowing someone else to use the number;[55] or when the provider or supplier abuses their billing number, such as by submitting claims for deceased beneficiaries, claims when the rendering practitioner was not in the same state and could not have provided the services, claims where necessary equipment was not present, or whenever there is a pattern or practice of submitting claims that fail to meet Medicare requirements.[56] Another ground for revocation is a failure to report enrollment data that must be reported in accordance with Medicare's reporting

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[50] 42 CFR §§ 424.530(a)(4); 424.535(a)(4). This can also lead to a referral to the Office of Inspector General (OIG) for criminal, civil, or administrative sanctions. Moratoria on enrollment means that the CMS contractor is no longer accepting enrollment applications. Moratoria can be imposed for certain provider types and/or for certain geographic areas.

[51] 42 CFR §§ 424.530(a)(5); 424.535(a)(5).

[52] 42 CFR § 424.530(a)(6). Added in the 2014 rulemaking. Previously, CMS based this ground for denial or revocation on the existence of an "overpayment," but revised the language to apply to any "Medicare debt," although CMS has declined to define what "Medicare debt" actually means, and prefer that it be "interpreted broadly." 79 Fed. Reg. 72506 (December 5, 2014).

[53] 42 CFR § 424.530(a)(7).

[54] 42 CFR § 424.530(a)(10).

[55] 42 CFR § 424.535(a)(7). This does not apply to valid reassignments, however.

[56] 42 CFR § 424.535(a)(8). In determining whether there is a pattern or practice of submitting claims that fail to meet Medicare requirements, CMS looks at the percentage of claims that were denied; the reason for denials; whether the provider or supplier has a history of final adverse actions and the nature of such actions; the length of time during which the pattern continued; how long the provider or supplier has been enrolled in Medicare; and any other information that CMS deems relevant.

requirements, such as failing to report a change of location within thirty days of the change.[57] Finally, revocation may be imposed if the provider or supplier has been terminated by a state Medicaid program.[58]

With respect to revocations, in practice, they are often the result of a combination of the above-mentioned grounds. For example, a revocation might be imposed based on the submission of false information or failing to submit information, such as failing to report a felony conviction of a managing employee or the suspension of an owning practitioner's state license.

For denials arising from the adverse activity of an owner, managing employee, or authorized or delegated official, the denial may be reversed if the supplier terminates the adversely affected individual and submits proof of termination of its business relationship with the individual or organization within thirty days of the notification of denial.[59]

Finally, both denials and revocations confer appeal rights under Medicare's regulations, meaning that they can be appealed to a hearing officer, up to an administrative law judge (ALJ), the Departmental Appeals Board (DAB), and eventually to a federal court if necessary.[60]

In contrast to a revocation or denial, a deactivation of billing privileges is described by CMS as "an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any condition of participation."[61] There are multiple grounds for deactivation. These include: (1) failure to submit claims for twelve consecutive calendar months;[62] failure to report changes of information within required timeframes;[63] and failure to timely (within ninety days) provide complete and accurate information and supporting documentation for a revalidation, whether on- or off-cycle.[64]

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[57] 42 CFR § 424.535(a)(9).

[58] 42 CFR § 424.535(a)(12).

[59] 42 CFR § 424.530(c).

[60] 42 CFR § 498.3.

[61] 42 CFR § 424.540(c).

[62] 42 CFR § 424.540(a)(1).

[63] 42 CFR § 424.540(a)(2).

[64] 42 CFR § 424.540(a)(3).

Once a supplier's billing privileges have been deactivated, the supplier may apply for a reactivation of billing privileges and have them restored. When the deactivation has occurred for any reason other than non-submission of claims, the supplier attempting to reactivate must submit a complete, new enrollment application. Alternatively, if it is deemed appropriate by CMS, the supplier may recertify that their current enrollment information is accurate.[65] As is discussed further below, the deactivation period begins what is known as a "gap period" in the supplier's billing, representing claims that are simply lost revenue. When a supplier successfully reactivates their billing privileges, ALJs generally do not permit them to reach back to the date of deactivation and begin billing for services rendered during the period between the date of deactivation and the date of reactivation. Instead, the date of reactivation – specifically the date when the supplier submitted an enrollment application that was processed to completion becomes the first date on which the supplier may submit claims, Unlike a denial or revocation, there are no appeal rights for a deactivation.[66]

Current Problem Areas and Procedural Hurdles

Today, Medicare suppliers seem to fall prey to the difficulties of the enrollment system in several areas. One can review both ALJ and DAB opinions for examples of the types of pitfalls that suppliers face. This section explores those common problems that have arisen in the previous two years, and several procedural and legal hurdles that result from these issues.

1. Failed Revalidations and Their Impact

One of the most common problems is the impact of a failed revalidation. The scenario usually plays out as follows: first, the supplier is contacted by the local MAC, often at a now-out-of-date address found in the supplier's enrollment information. The supplier is either unaware of the attempted contact (because it was sent to a defunct address), or receives the communication and ignores it or fails to file timely the revalidation.[67] Based on the lack of response (and without regard to the reason why no revalidation was submitted), the MAC deactivates the supplier's billing privileges. At this point -- finding their billing privileges, and thus their stream of Medicare income cut off -- the supplier submits an application to reactivate billing privileges. In some circumstances, the MAC makes additional development requests -- seeking corrected information or additional information -- which prolong the process of reactivating billing privileges. As a result, a multi-week to multi-month "gap period" stretches on, during which the supplier cannot submit claims for otherwise valid services rendered during the "gap period." Eventually, the supplier appeals the deactivation, but finds no relief upon appeal; the "gap period"

[65] 42 CFR § 424.540(a)(3).

[66] See, 42 CFR § 498.3.

[67] In most cases, a MAC will send a revalidation notice, and a subsequent notice if the first one receives no response.

stands and the supplier has to swallow the cost of the care.

Recently, suppliers have tried to advance several different arguments -- each unsuccessfully -- to try to mitigate the impact of a deactivation and the resultant "gap period." In denying the appeal, the DAB and ALJs alike currently rely on Willie Goffney, Jr. M.D. v. CMS.[68] Goffney, the physician, had allegedly not filed a Medicare claim since 2008. On October 31, 2012, Goffney was informed by CMS that his billing privileges would be deactivated for failure to submit claims for a twelve month consecutive period (obviously longer, in this case). Goffney then claimed to have sent an initial enrollment application packet to CMS on August 31, 2015, which was subsequently approved by CMS (meaning that the first date on which Goffney could bill would be July 31, 2015).

Goffney requested a reconsideration by a hearing officer, which was granted, but in which the hearing officer found against Goffney and permitted the deactivation to stand. Goffney then appealed to an ALJ, which granted summary judgment to CMS, upholding the date of billing privileges at August 31, 2015. Before the DAB, Goffney argued that he never should have been deactivated in the first place, because he never had a twelve month period during which he failed to submit claims.[69] Goffney claimed that the MAC's representatives had even told him that he was not, in fact, deactivated after he had received the 2012 letter. In essence, Goffney was appealing the deactivation itself.[70]

In issuing its analysis of the Goffney case, the DAB relied on the intersection of several regulatory provisions. First, the DAB noted the definition of a "deactivation" itself, noting the language that states "The provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information."[71] Second, the DAB stated that the grounds for deactivation were proper (in this case, a failure to submit a claim for a twelve month period).[72] Third, the DAB noted the explanation of the purpose for deactivation, specifically that the process is used "to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments."[73] The DAB also noted that deactivation does not itself

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[68] DAB 2763 (January 23, 2017).

[69] Confusingly, Goffney had been unable to receive reimbursement since at least 2008. His claims began to be rejected beginning in 2005 for reasons that Goffney did not understand, and for which the MAC was unable to provide a clear explanation. Goffney, at 2.

[70] Goffney's actual claims and argument were not well pleaded. For example, dates were inconsistently referenced: Goffney stated that he had begun billing Medicare in 1989, but later claimed it was in 1991; he stated that his claims had stopped being paid in 2005 and then later noted that it was in 2006,but the DAB ultimately found these discrepancies irrelevant. Goffney, at 3.

[71] 42 CFR § 424.502.

[72] 42 CFR § 424.540(a).

[73] 42 CFR 424.540(c).

terminate the underlying supplier agreement.[74] Finally, the DAB noted that denial and revocation are appealable, but deactivation is not.[75] Based on this, the DAB explained that Goffney had no right to appeal the deactivation, since no such rights had been granted by regulation. In support of this, the DAB cited to federal regulations which grant appeal rights to "initial determinations" only, and noted that deactivation of enrollment was not on the list of eligible acts.[76] The DAB stated that "the only action in the reconsidered determination which is appealable...is the initial determination of the effective date of the enrollment application reinstating [Goffney]."[77] Thus, the only available option for a supplier who had been deactivated is a "rebuttal" as described at 42 CFR § 424.545(b).[78]

The Goffney decision has been used at the ALJ level to reject multiple cases brought under different theories, all attempting to overturn deactivations. For example, in Hieu Ball, M.D., Inc. v. CMS,[79] the supplier failed to properly revalidate. This, in turn, led to a deactivation of the supplier's billing privileges, after which the supplier sought to reactivate its billing privileges. The supplier's argument was that the effective date for reactivation should be changed to the date of deactivation, because the letter from CMS notifying the supplier of the request for a revalidation had been sent to an incorrect address.[80] In support of Ball's assertion that Ball had properly filed an update to Ball's address information, Ball submitted email correspondence from customer service at CMS indicating that Ball's billing agent had submitted a Medicare enrollment application (although the DAB noted that no information was provided to prove the contents of such application).[81] The ALJ stated that Ball had failed to establish that it had timely notified the MAC of its new address, but that the precise circumstances surrounding the deactivation were irrelevant, based on the Goffney precedent.[82] Specifically, the DAB

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[74] Goffney, at 3.

[75] 42 CFR § 498.3.

[76] Goffney, at 5. Specifically, the list of initial determinations at 42 CFR § 498.3(b).

[77] Goffney, at 5.

[78] The right to file a "rebuttal" is granted under 42 CFR § 424.545(b). The term "rebuttal," as the DAB pointed out in Goffney, at 5, is defined under CMS regulations as "an opportunity to submit a statement." 42 CFR § 405.374.

[79] ALJ CR5002, December 29, 2017.

[80] The supplier also argued that its billing agent had submitted an enrollment application on April 22, 2014 – one day after the notice – although the contents of the application were not included in the record of the case.

[81] Ball, at 4.

[82] Ball at 4.

quoted the following statement in Goffney, "Only facts relevant to the effective date resulting from the . . . application were material to the ALJ decision."[83]

Another example is Miguel Palos, M.D. v. CMS,[84] in which the ALJ dismissed the case, citing a lack of jurisdiction. Similar to the Ball case above, in Palos, the supplier had been notified on November 18, 2016 that its billing privileges were being deactivated retroactive to November 3, 2016. The basis for the deactivation was a failure to revalidate correctly. Palos filed a PECOS application, which was subsequently approved, on November 23, 2016, which became the supplier's effective date of billing privileges. The supplier appealed this date, seeking to reach back to the date of deactivation. Interestingly, the ALJ took note of a policy change at CMS regarding the effective date of reactivation, indicating that at one time, CMS had actually permitted suppliers to reach back to the date of deactivation once the supplier reactivated billing privileges. Specifically, the ALJ stated,

> The CMS policy regarding reactivation and the reactivation effective date appears to be inconsistent with the Secretary's regulation, which provides that deactivation of Medicare billing privileges is to protect the provider or supplier from misuse of their billing privileges and the Medicare Trust Funds and does not have any effect upon the provider's or supplier's participation in Medicare...The [CMS policy] fails to cite any statutory or regulatory authority delegating to CMS or the MACs authority to declare a provider or supplier ineligible during a so-called "gap period" for reimbursement for care or services delivered to a Medicare-eligible beneficiary and otherwise reimbursable."[85]
> The ALJ also noted that the "gap period" resulting from deactivation and reactivation application dates "is clearly contrary to the Secretary's regulation that provides deactivation '**does not have any effect upon the provider's or supplier's participation agreement or conditions of participation.**'[86]

However, in spite of the ALJ's favorable treatment of the supplier's argument, the ALJ noted that it lacked the jurisdiction to resolve the discrepancy.[87]

In Trinidad v. CMS,[88] a revalidation request was again sent to a supplier at an incorrect address which had remained in the supplier's enrollment data, but where a revalidation request had not been sent to the correct address, which was also in the supplier's

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[83] Ball at 4, citing Goffney at 7.

[84] ALJ CR4967, November 15, 2017.

[85] Palos, at 8.

[86] Palos, at 8-9, emphasis in original.

[87] Palos, at 10.

[88] ALJ CR4989, December 13, 2017.

enrollment data. The supplier argued that CMS was required to send revalidation requests to all addresses listed in the supplier's enrollment data, but the argument found no purchase with the ALJ.[89] Instead, the ALJ stated that even if such a requirement existed (and no such requirement does), "I would still be without authority to overturn deactivation of Dr. Trinidad's Medicare enrollment. That is because my jurisdiction in this case is limited to reviewing the effective date of approval of Petitioner's reactivation enrollment application."[90] Again, the ALJ cited to Goffney in support of its position.[91]

The underlying position of the ALJs and the DAB appears to be consistent with Goffney; to wit, because Medicare's regulations governing the appeals process do not provide explicit grounds on which to appeal a deactivation (since it is not considered an "initial determination," the appellate apparatus has no authority to even consider the arguments advanced by petitioners, no matter how meritorious their arguments might otherwise be. Instead, it appears that, absent a regulatory change that recharacterizes deactivation as an "initial determination," even arguments highlighting what appear to be manifestly unfair and unauthorized practices by CMS (such as that noted by the ALJ in Palos) will be unanswerable. The DAB and ALJs may be able to highlight CMS' inappropriate action, but will have no authority to correct it.

2. *Revocations for Felony Convictions, Bad Billing, and "False" Information*

Suppliers facing revocations have not found any better luck with the ALJs or the DAB than those facing deactivations. In most cases, suppliers claim that the revocation in question is improper, usually due to some extenuating circumstances. However, if the revocation is proper on its face in accordance with the regulations, ALJs and the DAB tend to uphold them.

For example, consider revocations based on felony convictions. In the case of Sunsites Pearce Fire District v. CMS,[92] a question arose as to whether a managing employee had actually been convicted of a felony involving having threatened an individual with a firearm. The petitioner was a rural fire station in Arizona attempting to add a manager to its ambulance service. The manager had been charged with disorderly conduct for recklessly discharging a pistol in the presence of his former girlfriend. The manager entered into the county's "adult diversion program," with the court ordering that charges against him be suspended for two years while he participated in the program, and eventually with the court dismissing the charges upon completion of the program.[93]

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[89] Trinidad, at 5.

[90] Trinidad, at 5-6.

[91] Trinidad, at 6.

[92] ALJ CR5012, January 25, 2018.

[93] Sunsites, at 2.

When the fire department filed its enrollment, it neglected to list the manager's participation in the program in Section 6B of its CMS-855B application.[94] CMS requested that the petitioner correct the application and resubmit, after which the petitioner resubmitted another CMS-855B and asserted that the manager had not been subject to any adverse legal actions. CMS subsequently revoked the petitioner's billing privileges for failing to disclose an adverse legal action of an individual with an ownership interest and/or managing control.

In response, the petitioner argued that that the manager had not been "convicted" of a "felony offense"(as defined in 42 CFR § 1001.2) in accordance with the regulations at the time that the manager entered into the program.[95] However, the ALJ was unconvinced, and found that the regulation merely clarified what could constitute a "conviction" of a felony, rather than expanding the scope of the regulation itself.[96]

In Breton L. Morgan, M.D., Inc. v. CMS,[97] Dr. Morgan was convicted of a felony in 2007, and failed to list the conviction on his enrollment application when the application was submitted within ten years of the conviction.[98] Dr. Morgan had also been excluded from participation in Medicare for five years by the Office of Inspector General (OIG).[99] He was reinstated by the OIG on July 17, 2013, and then filed the application for billing privileges, on which he listed the exclusion, but did not list the felony conviction.[100] He was granted billing privileges in 2013, but these were later revoked for his failure to list the felony conviction. On appeal, Dr. Morgan argued that CMS was already aware of the conviction, and that therefore revocation was inappropriate. The ALJ, however, was unconvinced, and stated, "Whether or not CMS had records and was aware of Dr. Morgan's felony conviction in 2007 is not the issue. Petitioners had an affirmative duty under the regulations, of which they were advised by the CMS-855I, to submit a true,

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[94] Pertaining to the final adverse legal action history of individuals with ownership interests and/or managing control of the supplier.

[95] The petitioner's argument turned on the timing of a regulatory change which added clarifying language to 42 CFR § 424.535(a)(3), stating that a person is considered convicted of a felony offense when they have "entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld." 42 CFR § 424.535(a)(3). The language was added to the regulations in 2015, and the manager had entered participated in the county program between 2011 and 2013. The petitioner argued, therefore, that the regulations did not reach back in time to make the deferred adjudication into which the manager entered a conviction going forward. Sunsites, at 3-4.

[96] Sunsites, at 4.

[97] CR 5014, January 30, 2018.

[98] Morgan, at 7. The application itself was submitted and signed on July 17, 2013.

[99] Morgan, at 8.

[100] Morgan, at 8.

complete, and accurate application. Petitioners violated that affirmative duty. Petitioners offer no explanation for the failure."[101] The ALJ then explained that, having found a basis for revocation of Dr. Morgan's billing privileges, the ALJ had no authority to review the exercise of CMS' discretion in choosing to revoke them.

In Premier Integrity Solutions, Inc. v. CMS,[102] a supplier had relied on a credentialing company to properly submit and maintain data for its enrollment, and to report a previous revocation of billing privileges when the credentialing company submitted a new enrollment application. However, the company mistakenly neglected to report the previous revocation. As a result, the petitioner's billing privileges were revoked, once the previous revocation was discovered. The petitioner argued to the ALJ that it had begun pursuing damages against the credentialing company for the credentialing company's negligent failure to disclose the information, and that the petitioner should not be penalized for the credentialing company's failure. Unfortunately, the ALJ rejected the petitioner's argument, and noted that the petitioner had an obligation to monitor and manage its own enrollment data, even if it chose to outsource the work. The ALJ specifically noted that the petitioner's chief financial officer -- the Authorized Official for the petitioner in its enrollment information -- electronically signed its application indicating that the petitioner had not been the subject of any adverse legal action (which was demonstrably false).[103] The ALJ stated,

> A supplier is bound by any false or misleading information that a third party lists on its enrollment application, and false or misleading information may ultimately be submitted to the Medicare administrative contractor if a supplier does not carefully review all sections of an enrollment application. By signing a certification statement attesting to the accuracy of the content of an application, the supplier adopts any false or misleading statements in the application. There is simply no provision under law that absolves a supplier when its authorized official signs an incorrect enrollment application, regardless of who prepares the application for that person's signature.[104]

In the end, it is the certification by the Authorized Official that binds the provider or supplier to the submission of information by an agent; however negligent the agent may be, such negligence will not absolve the provider or supplier of their duty to review the agent's information prior to submission.

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[101] Morgan, at 10-11.

[102] CR5018, February 1, 2018.

[103] Premier, at 6.

[104] Premier, at 6-7.

In Scanameo v. CMS,[105] a supplier had its billing privileges revoked for submitting claims for deceased patients. In total, at least eighty-one claims had been submitted for services rendered to patients who were deceased at the time the supplier claimed to have rendered the services.[106] The supplier also argued that it had not received payment for any of the claims.[107] The supplier claimed that the submissions were due to clerical errors in billing, rather than abuse of the billing supplier's billing privileges.[108] The ALJ determined, however, that the supplier's intent was irrelevant to determining whether abuse had occurred. The mere fact that the supplier had engaged in a pattern of greater than three instances of billing for deceased patients was enough to support the revocation.[109] In other words, because the regulations themselves did not include a discussion of the intent of the entity submitting claims, intent was not within the scope of the ALJ's review. The ALJ explained,

> CMS is not required to show that Petitioners intended to either defraud or abuse billing privileges, and accidental or inadvertent billing errors have been found to be a sufficient basis for revocation…CMS is not required to show that Petitioners intended to defraud Medicare before it revokes their enrollment and billing privileges. The regulation only requires the existence of claims for services that could not have been delivered. It is irrelevant whether or not the claims were actually paid by CMS. Petitioners' implied argument that they should not be held responsible for innocent staffer clerical errors is without merit. Petitioners are ultimately responsible as a matter of law for ensuring that their claims for Medicare reimbursement are accurate and for any errors in those claims. Petitioners cannot avoid responsibility for their claims by the simple expedient of shifting responsibility and liability to staff or others…Petitioners, as the enrolled suppliers, are responsible to ensure compliance with Medicare requirements…To the extent that Petitioners' arguments…may be construed as a request that I grant equitable relief, I have no authority to do so. I am required to follow the Act and regulations and have no authority to declare statutes or regulations invalid.[110]

The overall takeaway from these cases is that ALJs and the DAB are unsympathetic to attempts by petitioners to argue beyond the scope of the regulatory language if the underlying regulatory requirements to support CMS' action (e.g., revocation or

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[105] CR5001, February 6, 2018.

[106] Scanameo, at 6. CMS asserted that ninety-four such claims had been submitted, although the supplier disputed the total number. Scanameo, at 5.

[107] Scanameo, at 6.

[108] Scanameo, at 9.

[109] Scanameo, at 8, quoting the language of the preface to the 2008 final rule modifying Medicare's enrollment regulations, at 73 Fed. Reg. 36448 (June 27, 2008).

[110] Scanameo, at 10-11, internal quotations and citations omitted.

deactivation of billing privileges) were met. If a felony was committed, if more than three claims for deceased patients were submitted, if an adverse action was not reported, the mere occurrence of these facts is sufficient to support the revocation. Arguments surrounding intent, or arguments that try to shift responsibility for maintenance of enrollment data to third parties fall on deaf ears. At best, petitioners might try to advance an argument that the event that would trigger a revocation itself did not occur, but that would likely require either an error by the MAC, or a technicality in the definitions of terms that underlie the triggering events. Even in the case of reliance on a technicality, the ALJ and DAB may still find in favor of CMS.

3. *Deceased Suppliers*

In some cases, suppliers have run afoul of the regulations when the supplier has died, which in turn presents thorny questions surrounding deactivation of billing privileges. For example, our firm represented a solo physician practice, where the owning physician had died, and the physician's estate had taken control of the practice. Unfortunately, the jurisdiction where this occurred also adhered to the "corporate practice of medicine" doctrine, whereby an unlicensed individual or entity may not own a professional medical practice, nor employ a physician. As a result, the estate was seeking to transfer the interest in the practice to the deceased physician's son, who was himself a physician. That process, however, raised additional tax-related concerns, which led to a delay in the transfer itself. Meanwhile, the practice had neglected to inform the local MAC of the physician's death, and as a result found its billing privileges deactivated. However, the deactivation itself was made retroactive from the date that CMS discovered the physician's death to the date the physician actually died.

This is arguably improper conduct by CMS, and could be argued to be an unconstitutional taking under the 5th Amendment. In essence, deactivation is meant to be prospective, not retrospective. In other words, CMS should only apply a deactivation to a supplier's billing privileges upon a specific date of notice, rather than attempt to reach back in time to the date of a triggering event for deactivation. It is arguably this reason – the prospective nature of the deactivation – that serves as the grounds for why deactivation itself is not considered an "initial determination" for purposes of the appeals process. For CMS to therefore reach back in time and deactivate billing privileges (as opposed to retroactive revocation which is permissible) represents an unconstitutional taking.

Consider the case of Urology Group of NJ, LLC v. CMS.[111] In this case, the CMS contractor learned in December, 2015 from a monthly file from the Social Security Administration that one of the group's physician owners had died on October 18, 2015. The local MAC then submitted a letter requesting a change to the CMS-855B enrollment data to remove the deceased physician owner from the group's records, and informed the

[111] DAB 2860, March 23, 2018.

group that it had to respond to the request within ninety days.[112] The group failed to respond, and a subsequent letter was sent four months later, stating that the group's billing privileges were deactivated as of the date of the subsequent letter (April 5, 2016), due to the fact that the MAC had not received the requested CMS-855B change to delete the deceased physician from the practice's enrollment record within the allotted ninety day timeframe. The supplier then submitted a CMS-855B enrollment application that deleted five partners, including the deceased physician, from the practice's records on April 28, 2016, which was subsequently approved by the MAC, and resulted in a new effective date of billing privileges of April 28, 2016. The supplier then requested a redetermination, arguing that the effective date should be the date of deactivation of billing privileges, to avoid the "gap period."[113]

The group also argued that the effective date of billing privileges had been based on instructions in the Medicare Program Integrity Manual[114] which contradicted the language of the regulations that stated "the deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement."[115] The reconsideration determination was unfavorable, and the supplier appealed to the ALJ, which also found against the supplier. The DAB once again relied upon the Goffney decision to state that it would only review the reactivation effective date, because the regulations do not provide suppliers with a right to appeal deactivations.[116] The DAB characterized the group's arguments as follows:

> (1) The deactivation regulations, as promulgated in 2006, do not authorize a 'gap period' for the reimbursement of covered services; (2) a valid participation agreement binds CMS to reimburse a supplier for services rendered during the deactivation period; and (3) CMS' refusal to retroactively reimburse a supplier for services rendered during the deactivation period without the opportunity to appeal constitutes a deprivation of property without due process.[117]

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[112] Urology, at 3.

[113] The group also claimed that it had not received either the initial letter requesting that the group update its enrollment record, nor the subsequent letter informing it of its deactivation. At the ALJ level, the ALJ noted that "Petitioner's allegations that it has been unable to locate either letter are insufficient to rebut the presumption that Novitas mailed each letter to the address listed on the letter." Urology, at 6. The DAB likewise stated "We need not address this argument, as whether or not Petitioner was notified of the deactivation of its Medicare billing privileges is outside the Board's authority to review." Urology, at 7.

[114] Specifically, the Medicare Program Integrity Manual, Chapter 15, Section 15.27.1.2.

[115] 42 CFR § 424.540(c).

[116] Urology, at 6.

[117] Urology, at 6-7.

However, the DAB stated that such arguments were not "cognizable in this forum," and that they could be appealed only after submitting a claim and only through the process set forth in 42 CFR Part 405.[118]

The supplier also advanced challenges based on the language of the Medicare statute, and on the Constitution itself. In addition, the supplier argued that the regulations at 42 CFR § 424.520(d)[119] only discuss the effective date of billing privileges with respect to the initial enrollment date, and do not address reactivations.

Practical Solutions

1. The Best Defense is a Good Offense

The best way to avoid most of these problems is to actively manage enrollment data on a proactive basis, rather than a reactive one. Instead of waiting for a revalidation request to update enrollment information, suppliers should periodically check their enrollment information to make corrections and additions as necessary.

For example, a key takeaway from the cases involving a failed revalidation, deactivation, and subsequent reactivation is that in almost every instance, the supplier claimed to have never received the communications from the MAC regarding the need to revalidate. As a result, the supplier failed to respond in a timely fashion, the supplier's billing privileges were deactivated, and the supplier was forced to reactivate its billing privileges and grapple with the financial impact of however long the "gap period" was between the supplier's submission of a reactivation packet and the date of deactivation.

In most cases, these problems arose as a result of the supplier maintaining an outdated address for long periods within the supplier's enrollment data. Typically, the supplier noted that the MAC had sent correspondence to an address that the supplier had not used for several years, but which the supplier had failed to remove from its enrollment record. As noted in the ALJ opinions, the responsibility lies with the supplier to ensure that their enrollment data is up-to-date; the supplier cannot rely upon other systems, such as the National Plan & Provider Enumeration System (NPPES) to communicate with the CMS enrollment system; all data within PECOS is provided by the suppliers themselves.[120] Changes to a supplier's address must be reported within thirty days, in accordance with the regulations.[121] This includes both the addition of a new location, and the removal of an old address. From a practical perspective, the reason to promptly remove an outdated

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[118] Urology, at 7, citing Goffney, at 6.

[119] Pertaining to the effective date of billing privileges for physicians, nonphysician practitioners, and nonphysician practitioner and physician groups.

[120] Notwithstanding MACs' receipt of periodic Social Security reports indicating deceased providers.

[121] 42 CFR § 424.516(d)(1).

address is obvious, after reading the various ALJ and DAB decisions: doing so eliminates a possible address to which CMS might erroneously send time-sensitive communications. By removing all old addresses, suppliers can avoid the scenario where CMS sends a request for revalidation or notification of a change in billing privileges to the old address. As discussed above, CMS has no obligation to send copies to every location listed in a supplier's record; it need only send to one valid (as in, currently listed) address. Therefore, if the only address(es) on record are ones where the supplier is currently active, the chance that a supplier might miss a communication are reduced considerably.

Similar advice applies with respect to those suppliers who have reassigned their right to payment, or who have accepted a reassignment. Several years ago, our firm represented a physician practice that had its billing privileges revoked as a result of an final adverse legal action against a former physician who had reassigned his right to payment to the practice. The physician in question had his license in another state revoked, and the practice had neglected to report the adverse action to its MAC, since the physician had not worked for the practice for more than five years. In our case, the supplier was lucky in that the matter was resolved without the need for a hearing. We and the client were able to produce records of paystubs that had ceased many years previously, and the client signed an affidavit that the physician had not work for them for years. Critical to getting the revocation lifted, however, was the fact that the enrollment forms from the time the client had terminated its relationship with the physician did not require the client to report the termination of the reassignment.[122] However, had the physician left the practice's employ after the requirement to report a termination of enrollment, the client would likely have had no recourse, especially in the current environment. At the very least, the client would have had to file a reapplication for billing privileges.[123]

2. Use Experts, but Check Their Work -- Remember Where the Buck Stops

Medicare suppliers often task supplier staff with the responsibility of maintaining Medicare enrollment information. Any staff member given the responsibility for maintaining enrollment information should be exquisitely familiar with the content of the enrollment forms themselves, including what information must be reported, and the

[122] Where possible, it is advisable to retain copies of previous iterations of Medicare manuals and CMS-855 enrollment forms. The author retains much of this information, and is happy to share such documentation, including enrollment forms that date back to 2006 in some cases.

[123] It is worth noting another key difference between the environment in the past, and the current environment with respect to navigating enrollment disputes. Part of what our firm was able to do was to speak on the telephone to the hearing officer, who included their contact information – including direct phone number – in their communications. In later cases in which we have assisted clients navigating a revocation or deactivation of billing privileges, communications from the MAC have not included such contact information in all cases. As a result, resolving these matters typically takes longer, and often requires going through the appeals process.

timelines for reporting deadlines. They should likewise be comfortable with using the PECOS website and/or completing CMS-855 forms.[124]

If the supplier chooses to use a billing agent or a credentialing company, however familiar such agent or company may be with the enrollment requirements and the type of data that must be reported and when, the supplier should always check any data to be submitted before it is sent. As a result, someone in the supplier's office should have some familiarity both with the general requirements for what information must be submitted in an enrollment application, and with the actual data that the supplier will report. In other words, it is not enough to simply know that a supplier has a general obligation to report adverse legal events; one must also know what types of events must be reported, and must have available the actual information that will be reported on an enrollment application. Familiarity with this information is essential in ensuring that any agent submitting an enrollment application on the supplier's behalf is submitting accurate information.

3. *The Appeals Process Is Not a Silver Bullet*

From reviewing the ALJ and DAB decisions, the Medicare appeals process for enrollment-related matters is extremely rigid, inflexible, and tied to the precise language of the regulations themselves. The authority of the ALJs and the DAB alike is circumscribed by Medicare's enrollment regulations, and neither is able to deviate from the regulations, regardless of the merits of an otherwise unaddressable argument. Moreover, the appeals process has a decided thumb on the scale in favor of CMS, with respect to claims of MAC misconduct.

Absent clear evidence that the MAC has acted improperly, the ALJs and DAB are unlikely to find against the MAC. Even if improper conduct can be shown, there is no guarantee that the ALJs or the DAB will be authorized to rule on such conduct. In the Urology case, the petitioner claimed to have not been notified by the MAC, and offered evidence to rebut the presumption that it had, in fact, been notified. When the ALJ rejected the argument, the petitioner appealed to the DAB, claiming that the ALJ's determination that the evidence was insufficient to rebut the presumption was itself improper. However, the DAB declined to address the argument substantively, and simply stated that such a determination was outside of the DAB's authority to review. "Petitioner's Medicare billing privileges were deactivated beginning April 5, 2016, a fact that is supported by the evidence…Petitioner may not now challenge the effectuation of the deactivation through an appeal that solely concerns the effective date of reactivation."[125]

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[124] Although, based on the CMS requirements for processing times for applications, it is preferable to be familiar with and to regularly use the PECOS website, it can be helpful to be familiar with the CMS-855 forms, and suppliers and their staff may choose to use them to collect and prepare information for submission to the PECOS website itself.

[125] Urology, at 7. In fact, the petitioner appears to have appealed on multiple grounds, but the DAB only reviewed the effective date in the Urology case.

These factors only emphasize the importance of ongoing compliance and review efforts. Suppliers must ensure that the data they have submitted is accurate and current, and should plan, at the very least, to check enrollment data on an annual – if not more frequent – basis. Similarly, suppliers should consider the enrollment implications of factors such as hiring decisions, space leases, changes in ownership, changes in management, and even changes in billing agents and plan in advance to report such information in a timely fashion.

One final aspect of the appeals process that suppliers should consider is the current backlog of cases at the ALJ level. Currently, Medicare is anticipating that its backlog of cases will finally be cleared in 2022.[126] This, however, will run beyond the deadline previously ordered by a federal judge to clear the backlog by 2020.[127] It has been estimated that the Office of Medicare Hearings and Appeals "receives more than a year's worth of appeals work every 24 weeks at the third level of appeals."[128] Therefore, a supplier cannot count on the appeals process to proceed swiftly. As a result, monies in dispute, such as potential reimbursement from claims that fall within a "gap period," will likely remain in dispute for several years as the claims wend their way through the appeals process and the related logjam. The better approach is to avoid the process on the front end by taking a proactive stance towards ensuring compliance with enrollment reporting requirements.

4. The Value of a Current Compliance Plan

Most enrollment issues boil down to a question of remaining vigilant with respect to maintaining the current status of enrollment data. Towards this end, it is essential for providers and suppliers to have a well established, regularly consulted compliance plan which incorporates their obligations with respect to maintaining Medicare enrollment data. The plan should clearly delineate who is assigned the duty of maintaining such enrollment data, including who a provider's or supplier's authorized and/or delegated official is, and who is responsible for preparing enrollment documents or gathering enrollment information prior to submission. More than one individual may be involved in the process, but one person with knowledge of the requirements, the nature of the information that must be reported, and the deadlines for reporting such information and responding to CMS requests for information or revalidation should be in charge of the overall process. The same way a provider or supplier might have a Compliance Officer

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[126] https://www.healthleadersmedia.com/finance/medicare-eliminate-appeals-backlog-within-4-years-hhs-tells-judge.

[127] https://www.healthleadersmedia.com/finance/medicare-eliminate-appeals-backlog-within-4-years-hhs-tells-judge. See also, Memorandum Opinion of Judge Boasburg, December 5, 2016, available as item #48 at https://www.courtlistener.com/docket/4212741/american-hospital-association-v-sebelius/.

[128] http://www.hmenews.com/article/brief-hhs-details-status-appeals-backlog-supplier-dropped-lawsuit.

or a HIPAA Privacy and Security Officer, it should have a Medicare Enrollment Officer who is tasked with coordinating the maintenance of Medicare enrollment data.

Any compliance plan document should make it clear that maintaining enrollment data is an ongoing process. It should also likely include in them the type of information that must be reported and when (e.g., changes in reassignments must be reported within ninety days; adding or removing practice locations must be reported within thirty days). Naturally, the nature of information that must be submitted and maintained will vary between provider and supplier types, but the underlying obligation to report such information proactively should be stressed in the document; by remaining proactive in its duty to report, a provider or supplier can avoid the potential negative impact of a revocation or deactivation of billing privileges, and the subsequent loss of revenue in the time that the provider or supplier must then take to reactivate billing privileges.

Attorneys can and should assist in the development of compliance plans. Such efforts will help ensure both that the plan is not an off-the-shelf "compliance plan in a box," which may not address the practice's needs, but also will improve the likelihood that the plan directly confronts the legal risks the practice faces and the potential impact on fraud and abuse risks. Enrollment should not be treated as a separate issue from these larger, thornier concerns, since failure to properly maintain enrollment credentials can raise questions about potential False Claims liability, which must be analyzed by legal counsel.

Conclusion

The Medicare enrollment process is a detail-oriented, time-consuming one, which requires continual maintenance by suppliers, and the navigation of complicated regulations. The volume of information that must be submitted is extensive, but the difficulty of resolving issues after a violation is an exercise in corralling horses after they have already left the barn. Instead, suppliers should put in place structures that assist them in maintaining compliance on an ongoing basis. Regular enrollment data checks – to ensure that information is complete and accurate – should be part of the compliance-minded supplier's repertoire. Likewise, suppliers should be mindful of the timelines for reporting data, and how they can differ, depending on the type of information being reported, and the type of supplier reporting the data. Corrections and additions – as well as removing outdated information where appropriate – should be undertaken as soon as possible. Requests for revalidation should also be responded to promptly, to avoid potential loss of billing privileges. The assistance of knowledgeable legal counsel can help with this process and, ideally, avoid the impact of a denial, deactivation, or revocation of billing privileges.