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**“Halt! Who Goes There?”  
Coping with the Continuing Crackdown on Medicare Enrollment**

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**“An ounce of prevention is worth a pound of cure.” – Benjamin Franklin**

**1 Introduction**

In recent testimony before the House Energy and Commerce Subcommittee on Health, in discussing the impact of provider and supplier fraud on the Medicare Trust Fund, the Inspector General of the Department of Health and Human Services (DHHS or HHS) stated, "Anyone who wants to keep their home safe begins by doing something very simple, locking the front door. We need to do the same with Medicare."<sup>1</sup> Towards that end, the Centers for Medicare and Medicaid Services (CMS) continues to use the Medicare enrollment process as the gateway through which health care providers must pass before gaining access to Medicare Trust Fund dollars, weeding out those deemed a potential threat to the fund.

The enrollment process itself – including maintaining enrollment after initially receiving billing privileges – remains difficult, and is growing more cumbersome. Following the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA -- hereinafter, "Health Reform"), CMS has considerably strengthened its ability to scrutinize the enrollment process. At the same time, applicants for and those already possessing billing privileges face efforts by CMS contractors to deny or strip them of such billing privileges based on often nuanced, technical details. In light of these mounting challenges, health care providers need to understand the dangers they face.

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<sup>1</sup> Inspector General Levinson's September 22, 2010 testimony, lines 982-985, <http://energycommerce.house.gov/documents/20100922/transcript.09.22.2010.he.pdf>.

This chapter focuses on recent developments in the enrollment process, examining changes and implications from Health Reform and its implementing regulations, provides a description of the appeals process with respect to enrollment denials and revocations of billing privileges, and explores recent decisions on enrollment actions (such as revocations and denials of billing privileges) and the common problems faced by physicians, durable medical equipment (DME) suppliers, and independent diagnostic testing facilities (IDTFs), and how to avoid them.<sup>2</sup>

## **..2 Recent Developments**

The Medicare enrollment process has undergone many changes in the last twenty years, and continues to evolve.<sup>3</sup> The most recent changes took embryonic form in the passage of Health Reform and were further developed in two sets of regulations published in May, 2010, and \_\_\_\_\_, 2010. These regulations impose additional burdens on those applying for initial or renewed billing privileges, subjecting them to screening requirements, potential pre-payment reviews on claims, or even outright enrollment moratoria.

### **..2.1 Statutory Changes**

The new Health Reform law grants CMS and its contractors authority to perform background checks on applicants for billing privileges.<sup>4</sup> The new screening process includes licensure checks across state lines, criminal background checks, fingerprinting, “database

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<sup>2</sup> For purposes of this article, these specific types of entities will be collectively referred to as “suppliers,” in keeping with the way they are categorized under the enrollment regulations. The term “providers” generally refers to institutional health care providers, such as hospitals, nursing homes, and other entities required to enroll using the CMS-855A enrollment form.

<sup>3</sup> For an in-depth examination of the history of changes to the enrollment process, see: Shay, “Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?”, Health Law Handbook, Alice G. Gosfield, ed., West Group, 2009, pp. 1-34.

<sup>4</sup> See generally, PPACA § 6401.

checks,” and “other screening.”<sup>5</sup> New applicants became subject to the screening process beginning March 23, 2011 (one year after the passage of Health Reform). Previously enrolled providers and suppliers will be subject to screening after March 23, 2012. However, any provider or supplier that was already enrolled when Health Reform was signed, and was subject to a revalidation<sup>6</sup> became subject to background checks on *[September 19/26, 2010.]*<sup>7</sup> By March 23, 2013, all providers and suppliers will face background checks.

Similar to the newly imposed background checks, Health Reform introduced increased disclosure requirements for applicants. Effective *[September 19/26, 2010]*, the statute requires that applicants for enrollment and for revalidation disclose whether the prospective enrollee (1) itself has “uncollected debt,” (2) was previously or is currently affiliated with an entity with “uncollected debt,” (3) is subject to a payment suspension, or (4) has been excluded or had billing privileges revoked or denied.<sup>8</sup> This change requires providers and suppliers to engage in a significant degree of inquiry with respect to their “affiliated” entities. While denial of enrollment frequently occurs when a provider or supplier represents a genuine danger to the Medicare Trust Fund (such as those convicted of felonies or tax fraud), providers and suppliers may be denied billing privileges merely because they failed to timely submit additional requested information on an enrollment form.

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<sup>5</sup> These last two terms are not defined in the statute.

<sup>6</sup> “Revalidation” is a process by which already-enrolled Medicare providers and suppliers are required to update their enrollment information. This process usually requires the completion of a full CMS-855 enrollment form. It is also separate from the reporting requirements with which providers and suppliers must comply on an ongoing basis. Revalidation must generally occur once every five years, but the process has been in place since 2006, so some providers are already subject to revalidation. See, 42 CFR 424.515.

<sup>7</sup> One hundred eighty days after passage of Health Reform.

<sup>8</sup> “Uncollected debt” currently is undefined.

The statute requires providers and suppliers to report if any “affiliated” entity has had Medicare billing privileges denied.<sup>9</sup> Against this currently nebulous background, this necessarily means at a minimum that providers and suppliers must inquire as to whether any such denials have ever occurred with respect at least to entities they own, share common control with, or are in joint ventures with, and hope that the “affiliated” entity answers honestly.

For example, given how vague the term "affiliated" is, a cardiology practice contracting with an IDTF to purchase technical components of diagnostic studies might be required to report whether the IDTF has ever been denied billing privileges. Similarly, if it is in a joint venture for a catheter lab with entrepreneurs, it could be required to ask the same of the entrepreneurs. Without a definition of "affiliated," it is impossible to know whose information must be reported. Certainly a joint venturor seems a more likely "affiliate" than an independent contractor, but there is no way to know. Moreover, it is unclear how long a period of time is relevant, and there is no distinction among grounds for denial. Based on the plain language of the statute, a supplier who was denied privileges on the basis of tax fraud and is not currently enrolled is treated identically to a supplier who was denied privileges for failing to timely correct enrollment form deficiencies ten years in the past, but later reapplied and was granted privileges. In the eyes of the statute, the two are equally nefarious.

The statute also instructs the Secretary to establish procedures whereby new enrollees may be subject to pre-payment review for a period of thirty days up to one year. While not necessarily directly related to the enrollment process, this change represents an intermediate step between outright denial of billing privileges and full access to Medicare Trust Fund dollars.

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<sup>9</sup> At present, there is no clear indication of what constitutes “affiliation.” The statute does not make clear whether “affiliation” applies to any type of ownership interest, common control, joint ventures, W-2 employment, or 1099 independent contractors, nor is it clear how many degrees of separation require reporting.

However, pre-payment review can impose a significant burden on providers and suppliers, given its detrimental impact on cash-flow, and the amount of additional work the process may require of providers or suppliers and their staffs to substantiate services rendered. The pre-payment review process occurs when a Medicare contractor determines that there is a sustained or high level of improper billing by a particular provider or supplier. While they may ultimately be paid for their services, health care providers and suppliers subject to pre-payment review usually are required to submit documentation to substantiate the services they provided, depending on the level of review undertaken.<sup>10</sup> The process of gathering and sending such documentation within the timeframes required by the local Medicare contractor can be burdensome and time-consuming. Moreover, if supporting documentation is not submitted within the required timeframe, the claims may be denied, even if the supporting documentation shows valid charges. There is also no mechanism by which to challenge the pre-payment review, nor have it lifted; there are no appeal rights that apply until the Medicare contractor makes a final determination about a specific claim. In essence, the provider or supplier can be kept in limbo, with no cash flow, while awaiting judgment on its claims. At present, there are no regulations governing this section, so it is unclear how and when such pre-payment review will be applied.

#### 2.2 Regulatory Changes Related to Health Reform

On May 5, 2010, CMS published regulations expanding upon the changes in Health Reform § 6401. Enrollment status now connects even to the ordering of certain types of services. Any provider or supplier that orders durable medical equipment, prosthetics, and orthotics (DMEPOS) must be listed in Medicare's online enrollment system (know as the

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<sup>10</sup> Automated, "routine" review, or "complex" review – with complex review requiring clinical determinations regarding claims. See, Medicare Program Integrity Manual, Ch. 3 § 3.4.5.

Provider Enrollment, Chain, and Ownership System, or PECOS). In other words, any provider or supplier that orders imaging services – from an individual physician to an institutional provider – must be identified on the claim form by name and NPI, and must appear in the PECOS database.<sup>11</sup> This requirement also applies to providers and suppliers that order laboratory studies, imaging services, and specialist services. CMS has stated that “[The] Medicare contractor will reject claims from providers and suppliers for [these services] if the legal names and NPIs are not reported in the claims, or...if the ordering or referring supplier does not have an approved enrollment record in PECOS.”<sup>12</sup>

Fortunately, all providers and suppliers who have submitted an enrollment or revalidation, or an information update within the past six years are already listed in PECOS. If the provider or supplier enrolled more than six years ago, however, they will need to submit a new application to be listed in PECOS. This may be done using one of the paper enrollment forms,<sup>13</sup> or online using PECOS itself.<sup>14</sup> The stated goal in this endeavor is that “these requirements may lead to a reduction in inappropriate Medicare payments.”<sup>15</sup>

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<sup>11</sup> 42 CFR §424.507(a).

<sup>12</sup> 75 FR 24443, May 5, 2010.

<sup>13</sup> Such as the CMS-855A for providers, the CMS-855B for groups and IDTFs, the CMS-855I for individual practitioners, and the CMS-855S for DMEPOS suppliers.

<sup>14</sup> Still further, any provider or supplier that opted out of Medicare in the last six years will be listed in PECOS. With respect to teaching physicians, the teaching physician whose name appears on the claim form must be listed in PECOS, not the resident or intern. These requirements also apply to dentists. As a separate concern, CMS also states “Our requirements will enable us to know the identity of the individual who ordered or referred and, if appropriate, we could establish edits to check for over-ordering specific items or services, over-referring specific services, *and/or over-ordering or over-referring to specific providers of services and suppliers.*” 75 FR 24444, emphasis added. However, CMS does not provide any further comment on what “over-ordering or over-referring” means.

<sup>15</sup> 75 FR 24444, May 5, 2010.

The new regulations also permit the Secretary of DHHS to revoke enrollment for up to one year for each act by physicians and other suppliers if they fail to maintain and provide access upon request to documentation relating to written orders or requests for payment for DMEPOS, home health, labs, imaging studies, home health, and specialists services. Such documentation must be maintained for seven years, including both written and electronic documents.<sup>16</sup> These changes signify a shift by CMS towards expanding the function of enrollment. Rather than simply using enrollment as a tool to deny bad actors access to the Medicare Trust Fund, enrollment is now being used as a means to deny improper claims.

***[The discussion below is based on the proposed enrollment regs, which were published 9/23/2010. I'm keeping an eye on the federal register to see when final regs get published. It's possible that this will happen after Dec. 1, so I thought I should at least put something down here that can be revised when the final rule hits. The regs take effect 3/23/2011.]***

Further elaboration on Health Reform provisions was provided with the release of the ***[Date Pending]*** regulations. These new regulations provide considerably more detail on the screening measures to be used and on enrollment moratoria, as well as outlining a new mechanism for enrollment application fees. Again, the underlying goal appears to be to reduce the outflow of money from the Medicare system, and to safeguard the Trust Fund.

Prior to the publication of these regulations, certain screening measures in the enrollment process were already in effect. For example, CMS already required applicants to hold a current state license, and required Medicare contractors to review licensing board data on a monthly basis<sup>17</sup> to ensure that providers and suppliers are in compliance with such requirements, with

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<sup>16</sup> See 42 CFR § 424.516(f); 75 FR 24445.

<sup>17</sup> 75 FR 58206, September 23, 2010.

billing privileges to be revoked when the provider or supplier has their license suspended or revoked. Similarly, CMS already employed site visits for certain provider types as a means of ensuring compliance with Medicare enrollment requirements. Independent diagnostic testing facilities (IDTFs) and DMEPOS suppliers already were subject to pre-enrollment site visits, for example. The databases checked include the Social Security Administration's database to verify applicant Social Security numbers (including to check when an applicant has died), the National Plan and Provider Enumeration System to verify an applicant's National Provider Identifier number, and state licensing boards to verify that the applicant has the required licenses. CMS contractors also check the HHS OIG's List of Excluded Individuals/Entities. Finally, CMS contractors employ monthly checks against the Medicare Exclusions Database.<sup>18</sup> All these requirements remain in place.

Medicare contractors are also instructed to periodically check databases, and to verify information about prospective provider and supplier enrollees. However, many of the new screening processes, such as criminal background checks, fingerprinting, and mandatory (as opposed to discretionary) site visits have not been used before. The regulations considerably enhance the screening measures available, establishing three levels of screening, based on the potential risk posed by the provider or supplier type: (1) limited risk, (2) moderate risk, and (3) high risk. Given recent news regarding Medicare suppliers who would "be the envy of many traditional mafia families,"<sup>19</sup> it is understandable why CMS is developing such screening measures.

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<sup>18</sup> 75 FR 58207, September 23, 2010.

<sup>19</sup> Rothfield, Michale, "Dozens Arrested in Medicare Scheme," Wall Street Journal Online Edition, October 14, 2010, <http://online.wsj.com/article/SB20001424052748703673604575550002841068546.html>.

Limited risk provider and supplier types include physicians, non-physician practitioners, medical clinics, group practices, and providers or suppliers publicly traded on the New York Stock Exchange or NASDAQ.<sup>20</sup> These provider and supplier types will be subject to screening processes that (1) verify that the provider or supplier meets applicable Federal regulations or state requirements for the provider or supplier type before making an enrollment determination, (2) verifying licensure status, and (3) database checks on a pre- and post-enrollment basis “to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.”<sup>21</sup>

Moderate risk providers and suppliers include: nonpublic and non-government owned or affiliated ambulance service suppliers, community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, IDTFs, and independent clinical laboratories, as well as currently enrolled (or revalidating) DMEPOS suppliers. These providers and suppliers are subject to the same screening procedures as low risk providers and suppliers, but also are subject to unannounced and unscheduled pre- and post-enrollment site visits.<sup>22</sup>

High risk providers and suppliers include: newly enrolling home health agencies and DMEPOS suppliers, as well as physicians and non-physician practitioners about whom CMS has discovered evidence that another individual is using their identity, any provider or supplier that has been placed on a previous payment suspension, excluded by the HHS OIG or had its

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<sup>20</sup> The full list also includes ambulatory surgical centers, end-stage renal disease facilities, federally qualified health centers, histocompatibility laboratories, hospitals – including critical access hospitals, Indian Health Services facilities, mammography screening centers, organ procurement organizations, mass immunization roster billers, portable x-ray suppliers, religious nonmedical health care institutions, rural health clinics, radiation therapy centers, public- or government-owned or affiliated ambulance service suppliers, and skilled nursing facilities. 75 FR 58209.

<sup>21</sup> 75 FR 58209, September 23, 2010.

<sup>22</sup> 75 FR 58210, September 23, 2010

Medicare billing privileges denied or revoked by a Medicare contractor within the past ten years, as well as those providers that have been terminated or precluded from billing Medicaid. These providers and suppliers will be subject to the same degree of scrutiny as low risk and moderate risk providers and suppliers, but will also be subject to criminal background checks and will be required to submit fingerprints.<sup>23</sup>

In addition to these burdens, certain types of providers and suppliers are subject to an application fee.<sup>24</sup> The application fee does not apply to physicians, non-physician practitioners, physician groups, or medical clinics; instead, it applies to “institutional providers.”<sup>25</sup> The application fee is not required to reassign the right to payment using the CMS-855R form (since it would create no new enrollment); but the fee is required for all institutional provider initial applications, new practice locations added, and voluntary or requested revalidations.

Applications that do not include the application fee, and which do not include a request for a hardship exception are rejected without further review. In cases where a provider or supplier requests a hardship exception which is rejected, the provider or supplier has thirty days from the date when the Medicare contractor sends the rejection letter to send in the required application fee and forms. In addition, Medicare contractors may revoke billing privileges if an institutional provider does not submit an application fee or hardship exception that meets regulatory requirements and which is rejected, or if the application fee cannot be deposited into a

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<sup>23</sup> 75 FR 58211, September 23, 2010.

<sup>24</sup> The fee is \$500 for CY 2010, and is adjusted by the percentage change in the consumer price index for all urban consumers for the 12-month period ending with June of the previous year. 75 FR 58217, September 23, 2010.

<sup>25</sup> Defined to include “Any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (but not physician and nonphysician practitioner organizations), or CMS-855S or associated Internet-based PECOS enrollment application.” 42 CFR § 424.502. Physicians and nonphysician practitioner organizations are explicitly exempted from the application fee by PPACA § 10603.

government-owned account. In general, there will be no refunds of the application fee, although Medicare contractors may choose to refund the fee if an application is rejected for certain grounds. For example, CMS contrasts a scenario where the fee would be returned because the application was rejected due to a failure to sign an Internet-based PECOS form, whereas a denial of an application based on non-compliance would not result in a return of the application fee. In such circumstances, a subsequent application would require a second application fee.

Lastly, CMS is now permitted to impose six-month long Medicare enrollment moratoria by provider type, among other options.. This may occur when (1) CMS identifies data indicating trends associated with a high risk of fraud, waste, or abuse; (2) a state has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type (or both); or, (3) when, after consulting with the HHS OIG or the Department of Justice, CMS identifies either a particular provider or supplier type or a particular geographic area as having a significant potential for fraud, waste, or abuse. Moratoria will only apply to initial enrollment applications and applications to add new locations to an existing account. The moratoria will not apply to changes of ownership, mergers, or consolidations, nor to changes in practice location that do not expand a provider's or supplier's operations. There is no judicial review for temporary enrollment moratoria, but CMS explicitly permits administrative law judges and the Departmental Appeals Board to hear administrative appeals to the moratoria. The regulations do not establish any limit on how long a moratorium may remain in place, although it will require periodic renewal at six-month intervals.

Given the increasing obstacles facing providers and suppliers attempting to obtain or maintain billing privileges, and the potential for disaster if they fail to meet these requirements, it is crucial to understand (1) the practical effect of a loss of billing privileges, (2) the nature of

the appeals process itself, and (3) the types of problems that suppliers typically face. The remainder of this chapter examines these issues.

### **3 Denials vs. Revocations**

Before examining the types of problems that suppliers commonly face regarding enrollment, it is important to understand the difference between revocation and denial of billing privileges. While both lead to a similar outcome (the inability to be paid), the long-term effects on practitioners differ and may lead to different arguments on appeal.

#### **3.1 Denial**

Denial of Medicare billing privileges can occur both when a prospective enrollee has its application denied prior to obtaining privileges, and upon revalidation or updating of enrollment information.<sup>26</sup> There are many bases for denial. If an applicant fails to comply with the enrollment requirements<sup>27</sup> on the application itself, and has not submitted revised documentation, the application will be denied. Denials may also occur based on the conduct of the applicant, such as when an owner, manager, or other similar individual has been excluded, debarred, or suspended from participating in any other Federal programs.<sup>28</sup> Similarly, applicants who, within the ten years prior to enrollment or revalidation, have been convicted of a federal or state felony that CMS has determined to be detrimental to the best interests of the program, will be denied.<sup>29</sup> The Medicare contractor will also deny an application when false or misleading information has

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<sup>26</sup> 42 CFR § 424.530.

<sup>27</sup> Such as completing required fields and including required additional documentation.

<sup>28</sup> The full list of entities includes owners, managers, authorized or delegated officials, medical directors, supervising physicians, “or other personnel.”

<sup>29</sup> The list of felonies include felonies against people (such as rape, murder, and assault), financial crimes (such as extortion, embezzlement, tax evasion, and insurance fraud), and any other felony that CMS determines is a risk to the Medicare program. Denial on the basis of a felony may last up to ten years from the date of conviction.

been included on the enrollment form, when an on-site review determines that the enrollee is either non-operational or does not meet the enrollment requirements, when an overpayment exists at the time of filing for enrollment, or when the enrollee is currently under a payment suspension.

With the exception of the ten-year denial based on a felony conviction, the ultimate effect of a denial of enrollment simply means that the application is denied. The applicant for billing privileges may merely apply again once either its appeal rights have lapsed, or it has appealed and the denial is upheld. While there is no guarantee that CMS will accept a subsequent application, a denial carries no further penalty.

Revocation, by contrast, occurs when CMS has previously granted billing privileges, but those privileges are later taken away.<sup>30</sup> As with denial of enrollment, revocation may occur for multiple reasons. Many of these reasons mirror those applicable to denial.<sup>31</sup> However, revocation may also occur for reasons such as providing inaccurate information or failing to provide information at all upon request by CMS for a “reverification.”<sup>32</sup> Revocation may also occur for misuse of a provider or supplier’s billing number – such as selling or otherwise permitting another entity to use the number.<sup>33</sup> Likewise, if a provider or supplier abuses their billing privileges – such as submitting claims for services to deceased patients, or services rendered

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<sup>30</sup> 42 CFR § 424.535.

<sup>31</sup> Such as improper conduct – like felonies, filing false or misleading information, or a determination of non-operational or non-compliant status based on an on-site review. 42 CFR § 424.535.

<sup>32</sup> The regulations often use unclear terminology, using the terms “reverification” and “revalidation” interchangeably. See 42 CFR § 424.515. [*The proposed 9/23/10 regulations, however, fix this and only use the term “revalidation.”*]

<sup>33</sup> The regulations, however, explicitly permit reassignment of right to payment, which itself is accomplished via the CMS-855R form.

when the provider or supplier was not physically in the jurisdiction where the patient was treated – the provider or supplier may be subject to revocation. A provider or supplier’s failure to report certain information within required timeframes will also result in revocation<sup>34</sup>, as will a failure to document and/or provide HHS with documentation relating to the ordering of DMEPOS, home health, imaging, laboratory, and/or specialist services. Finally, providers and suppliers may have billing privileges revoked for noncompliance when they fail to submit a “corrective action plan” (CAP).<sup>35</sup> However, providers and suppliers are granted an opportunity to correct such noncompliance and submit a CAP before a final determination to revoke billing privileges, and CMS may request additional documentation to determine compliance, which must be submitted within sixty days.

Unlike a mere denial, revocation of billing privileges results in the provider or supplier being barred from re-applying for billing privileges for a period of not less than one and not more than three years. Upon re-applying, the provider or supplier must submit a complete new application, and must be resurveyed or recertified by state survey agencies, as applicable. In some cases, a revocation may be reversed, such as when the revocation was for an adverse action by an entity with which the provider or supplier terminated its relationship within thirty (30) days of the notice of revocation. Once a revocation is imposed, providers and suppliers may submit claims for services rendered prior to the effective date of revocation for up to 60 days

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<sup>34</sup> Providers and suppliers must report adverse actions and changes of location and/or ownership within thirty days, or other changes within ninety days. See 42 CFR § 424.516(d).

<sup>35</sup> A CAP is often used to correct errors in the application form itself which previously were highlighted by the Medicare contractor. CAPs may also be used in circumstances where the provider fails to properly report required information (such as failing to report the ending of a reassignment via a CMS-855R form). A CAP is not permitted in cases of a felony conviction, an onsite review determining that the provider or supplier is non-operation, or other cases relating to conduct.

from the effective date. However, where revocation is premised on a suspension or loss of licensure, or other similar event, the effective date is the date on which CMS determines that the suspension was in effect. In other words, the day CMS discovers a physician has lost his license is the effective date for revocation – even if this date occurred prior to notifying the physician of the revocation. If the sixty-day period tolled within that time, no claims may be submitted.

The nature of the final determination of denial or revocation can have a substantial impact on a practitioner, and may require different strategies on appeal, as well as different considerations relating to the provider's or supplier's cash flow. Further, while in most cases it is clear when CMS has revoked or denied billing privileges, there may be situations where such a determination is less clear. For example, in US Ultrasound v. CMS<sup>36</sup>, an IDTF claimed that CMS had *revoked* its billing privileges, whereas CMS claimed it had *denied* billing privileges. The IDTF's calculation was that, if the ultimate determination was for a revocation, then the \$11,600 of claims the IDTF had accumulated could be submitted during the sixty-day period from the effective date of revocation. By contrast, a denial would mean that none of the claims could be submitted. The IDTF was, apparently, untroubled by the one to three year bar on re-application for privileges, and more concerned with getting paid.<sup>37</sup>

#### **4. Appeals.**

Both prospective enrollees and current enrollees may appeal (1) initial determinations, (2) reconsideration determinations, (3) administrative law judge (ALJ) hearing decisions, and (4)

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<sup>36</sup> CR1982 (July 31, 2009).

<sup>37</sup> The decision to deny privileges rather than revoke them was made by CMS on the theory that a denial would be the least burdensome outcome for the practitioner – given that it would be able to reapply for privileges immediately thereafter

departmental appeals board (DAB) decisions.<sup>38</sup> The appeal of an initial determination is also referred to as a request for reconsideration. A request for reconsideration allows for reconsideration of the initial determination by a Medicare contractor hearing officer. The request itself must state the issues or findings of fact in the initial determination with which the “affected party” disagrees and the reasons for such disagreement.<sup>39</sup> The request must be submitted within sixty days of receipt of the initial determination, unless a time extension is requested.<sup>40</sup>

If the reconsideration returns an unfavorable decision, the provider or supplier may request a hearing in front of an ALJ. The request for a hearing must specify the issues, findings of fact, and conclusions of law with which the requestor disagrees, and must specify the basis on which such findings and conclusions are being challenged. A request for an ALJ hearing must be made within sixty days of receipt of the notice of receipt of the hearing determination, unless an extension is granted.<sup>41</sup> If a hearing is granted, an affected party may waive its right to appear and present evidence at a hearing, although CMS or the OIG may force an in-person hearing if it can show good cause for requiring the presentation of oral evidence.<sup>42</sup> This waiver may be withdrawn at any time prior to the ALJ mailing notice of the hearing decision.<sup>43</sup>

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<sup>38</sup> 42 CFR § 498.5.

<sup>39</sup> “Affected party” is defined as “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 the rules governing the appeals process.]” 42 CFR 498.2.

<sup>40</sup> 42 CFR § 498.22. The notice of the initial determination is presumed to have been received five days from the date on the notice itself, unless it can be shown that the notice was received later or earlier. An extension will be granted if good cause for missing a deadline can be shown.

<sup>41</sup> 42 CFR § 498.40. Again, additional time will be granted if good cause can be shown.

<sup>42</sup> 42 CFR § 498.66.

<sup>43</sup> 42 CFR § 498.66.

If a party is dissatisfied with the ALJ's decision or dismissal of a hearing request, they may file a request for review by the DAB within sixty days of receipt of the notice of decision or dismissal from the ALJ.<sup>44</sup> As with the ALJ hearing request, a DAB review request must specify the issues, findings of fact, or conclusions of law with which the party disagrees, as well as the basis for challenging the findings and conclusions.<sup>45</sup> Suppliers and prospective suppliers who are dissatisfied with a DAB decision may seek judicial review.<sup>46</sup>

While the discussion above provides a useful timeline, there are some practicalities to consider in approaching the appeals process. One key problem that prospective applicants may face is when they attempt a "self-help" solution. Upon receipt of the initial notification letter, applicants may attempt to call the Medicare contractor directly to resolve the problem, without regard to the time-sensitive nature of their appeal rights. As a result, they may find an eventual appeal time-barred because they were under the impression that the Medicare contractor was working with them to resolve the matter (and thus, assumed the timeliness requirements would be waived). Moreover, the advice given by the Medicare contractor's staff on how to resolve the matter will be of no avail should the applicant rely on such advice and still receive a negative result.<sup>47</sup> Attorneys may only discover such facts after they have transpired, and applicable

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<sup>44</sup> 42 CFR § 498.82. The same rules regarding time extensions for ALJ hearing requests also apply to DAB review requests.

<sup>45</sup> 42 CFR § 498.82.

<sup>46</sup> 42 CFR § 498.5.

<sup>47</sup> Another variant of this scenario is where the applicant calls the Medicare contractor, which simply instructs the applicant to "submit another application." After completing and submitting a subsequent application, the applicant fails to direct the application to the specific contact who is handling their enrollment matter, which results in the application being denied by other enrollment staff who are unaware of the ongoing contact between the Medicare contractor and the applicant.

deadlines have passed. It may, however, still be worth submitting appeals requests, depending on how the arguments on appeal are structured.

A related issue is the basis for the appeal. As will be seen below in section \_\_.5 of this chapter, arguments premised on an estoppel claim often fail. Typically, these claims are premised on bad advice received from the Medicare contractor, upon which the applicant relied to their detriment. Then the argument goes, had the Medicare contractor's representative not provided incorrect information, the applicant would not have been denied, had their privileges revoked, or received a later effective date for billing privileges than requested. When filing an appeal, it is therefore essential to premise the appeal on proper grounds. Rather than make a substantive argument based on estoppel, it is better to use the improper advice provided by the Medicare contractor to, for example, request a time extension based on good cause.<sup>48</sup> In essence, the "bad advice" argument is simply used to get the applicant's "foot in the door" and avoid being time-barred; the "bad advice" argument is not the basis for the substantive challenge.

In terms of increasing the odds of a successful appeal, it is important to bear in mind CMS' own timeliness requirements. Typically, an ALJ pre-hearing order will give the Medicare contractor's counsel thirty days to submit a brief and exhibits. If the Medicare contractor's counsel is unable to meet this deadline, they may ask for an extension with the permission of the applicant's counsel. In some situations, it may be in the applicant's interest to permit the time extension in the hopes of convincing the Medicare contractor's counsel to abandon its defense altogether. This, however, will depend heavily on the circumstances of each case.

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<sup>48</sup> For example, in the scenario where the applicant relied on bad advice, and found their appeal rights time-barred, the "good cause" could be argued to be the bad advice offered by the Medicare contractor.

## **\_.5 Common Problems and Potential Arguments<sup>49</sup>**

While understanding the appeals process itself is helpful, the ideal appeals strategy is to not need one in the first place. With a better understanding of how “the other side” sees the situation, their authority and scope of power, and the impact of a supplier’s action and inaction in the enrollment process, suppliers and their counsel may be more able to navigate the enrollment process successfully – or at least be forewarned as to how things may go wrong. Towards that end, this section examines certain common themes in appeals to better understand how administrative law judges (ALJs) and the Departmental Appeals Board (DAB) interpret and apply Medicare’s enrollment regulations; as well as what arguments and regulatory interpretation CMS itself employs; the significance of the timing of both the enrollment application itself and responses to CMS, and requests for hearings; and the breadth of CMS’ authority to revoke or deny billing privileges, including reaching back in time.<sup>50</sup>

The cases discussed below were selected from enrollment appeals filed between 2008 and 2010 for which an ALJ or DAB issued a written opinion. Not every such case is discussed. Rather, while the specific facts giving rise to the appeals often differ from case to case, the cases below provide examples of common themes. The most common appeals are for denials, revocations, and applicable dates of billing privileges.

### **\_.5.1 Rigid Statutory and Regulatory Construction.**

ALJs rarely deviate from the precise letter of the law, and apply a very rigid approach to statutory construction. Where a regulation lists specific practitioner types as being eligible for

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<sup>49</sup> Many thanks to Caitlin Munley for her invaluable assistance in collecting the appeals decisions.

<sup>50</sup> In some instances, CMS may reach back ten years to revoke billing privileges, such as when the supplier was convicted of a felony.

Medicare billing privileges, the ALJ will not overturn a denial when the supplier is not explicitly among those on the list. If a regulation requires that certain conditions be satisfied before privileges can be granted, the ALJ will not overturn a revocation based on a failure to meet those requirements to the strict letter of the law. Where application of a regulation turns on a subsequent analysis of state law, the ALJ will usually take the most narrow view of the law.

In Salem Gastroenterology Associates, PA v. CMS,<sup>51</sup> following an internal review by the local Medicare contractor of all ambulatory surgical centers (ASCs) in the contractor's jurisdiction, a gastroenterology practice had its billing privileges revoked on the basis that the practice lacked a state license as an ASC. In fact, while the practice did not have a state license, it had a state *permit*, and was accredited by Accreditation Association for Ambulatory Health Care, Inc. According to the practice, the North Carolina law regarding ASC licensure was vague. They argued that state law allowed the performance of such procedures in a physician office when such office was not licensed as an ASC, although state law also licensed ASCs (described as "ambulatory surgical facilities" in North Carolina law). The practice claimed that CMS' manuals stated that licensure was not a requirement for enrollment purposes where state law did not require licensure to perform ambulatory surgical procedures.<sup>52</sup> North Carolina law permitted the performance of "limited ambulatory surgical procedures which do not constitute an ambulatory surgical program," but specifically stated that this "does not make that office an ASC."<sup>53</sup> The ALJ ultimately rejected the practice's arguments, and found that licensure was

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<sup>51</sup> CR1785 (May 7, 2008).

<sup>52</sup> Specifically, the practice cited to the CMS State Operations Manual, Appendix L, applying interpretive guidance to 42 CFR § 416.40, which stated "Where a State has no applicable licensure requirements, or where ambulatory surgical services may be provided without licensure, a facility will be eligible if it meets the definition of § 416.2 and all other applicable Medicare requirements." CR1785, P.7, emphasis in original.

<sup>53</sup> CR1785, P.7.

required by state law. Therefore CMS legitimately denied billing privileges. In upholding the revocation, the ALJ did not address the argument relating to the performance of ambulatory surgical procedures not requiring a license, and focused solely on the fact that the state did require a license to be considered an ambulatory surgical facility.

A similarly rigid approach to statutory construction has been applied to situations where a supplier's enrollment was denied or revoked due to a felony conviction. In Innes v. CMS,<sup>54</sup> a chiropractor was denied enrollment due to a past conviction for tax evasion. The chiropractor admitted the conviction, but argued that he should be allowed to reenroll because it was in the government's interest to permit him to earn a living so he could pay down his tax debt, and to provide service to Medicare beneficiaries in his area. The ALJ upheld the denial, on the basis that tax evasion was specifically described as a felony for which denial is appropriate.

In Cesar A. Rojas, MD v. CMS,<sup>55</sup> a physician had a "limited permit" to practice granted by New York state. The ALJ noted that CMS manuals stated that CMS contractors would deny on the basis of temporary *permits*.<sup>56</sup> The physician argued that he had a temporary *license*, not a temporary permit. The "limited permit" permitted the physician to practice at specific hospitals for a specific time, and only under supervision. The physician admitted that he also had not completed all of his exams. Based on these facts, the ALJ found that the physician was unlicensed and therefore denial was appropriate. Most interesting, however, is the fact that the ALJ specifically found that the limited permit did not qualify as a valid temporary license

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<sup>54</sup> CR2094 (March 18, 2010).

<sup>55</sup> CR1789 (May 16, 2008).

<sup>56</sup> The ALJ noted that "CMS instructs its contractors not to accept a temporary permit, defined as 'one in which the applicant is not yet fully licensed and must complete a specified number of hours of practice in order to obtain the license.' [Medicare Program Integrity Manual, Ch. 10, § 4.2.2].

because of the language of the applicable New York law. Specifically, the ALJ pointed out, “[New York law] is clear that the permit authorized is not a license and it is only available to those who do not qualify for a license for one of the reasons listed. I conclude that the permit Petitioner was issued was not a ‘license’ within the meaning of the New York statutes.”<sup>57</sup>

Likewise, in two cases relating to site visits resulting in a denial and a revocation, respectively, ALJs have, again, held to the strict letter of the law. In the denial case, an independent diagnostic testing facility (IDTF) had only registered as a single fixed-site IDTF, and had attempted to use mobile units in conjunction with the fixed-site registration.<sup>58</sup> Medicare regulations, however, explicitly require IDTFs to register each mobile unit separately. Accordingly, the ALJ found that denial was proper. In Promedics v. CMS,<sup>59</sup> a DMEPOS supplier had not opened itself to the public yet, while awaiting Medicare billing privileges. The DMEPOS supplier could not afford its overhead expenses without simultaneously being able to bill for delivery of DMEPOS. A site visit found the supplier to be not operational because the supplier had moved to a new location.<sup>60</sup> The supplier argued that it had telephoned the Medicare contractor to notify it of the move. When the Medicare contractor’s investigator finally visited the new location, the location was not open, due to the initial denial and inability to submit claims for services to ensure sufficient cash flow to cover overhead expenses. While the ALJ

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<sup>57</sup> The specific law, N.Y. Education Law § 6525, describes that a person eligible for a limited permit must have fulfilled their requirements for licensure as a physician except for those relating to examination and citizenship or permanent residence in the United States; foreign physicians holding standard certificates from the education council for foreign medical graduates, or who have passed an exam in accordance with state regulations; or foreign physicians or interns who are in the country on a non-immigration visa for continuing medical study as part of an exchange program. CR1789, P.9.

<sup>58</sup> Presbyterian Imaging Centers, LLC v. CMS, CR2190 (July 22, 2010).

<sup>59</sup> Promedics, Inc. v. CMS, CR2059 (January 19, 2010).

<sup>60</sup> Promedics, Inc. v. CMS, CR2059 (January 19, 2010).

accepted this as true, she stated that because no CMS-855 form was ever submitted to report the change of location, and because no supporting documentation had submitted,<sup>61</sup> denial was appropriate.

Certain categories of suppliers may also run afoul of rigid statutory construction. In Peter McCambridge, C.F.A. v. CMS, a “certified first assistant” claimed that she should have been given billing privileges. The certified first assistant did not fall squarely within the definition of applicable practitioner types to which Medicare billing privileges may be granted. Accordingly, the ALJ upheld the denial.<sup>62</sup> In Prokay v. CMS,<sup>63</sup> a “counselor of mental health services” applied for billing privileges and was denied. The counselor claimed to be the equivalent in terms of education and scope of practice to qualify as a social worker under Medicare. However, the definition of a “clinical social worker” under Medicare regulations required that the counselor have a masters degree in social work. Accordingly, even though the counselor was licensed under state law and granted an identical scope of practice as a clinical social worker, the ALJ upheld the denial.

Medicare contractors, however, can also find themselves on the losing end of rigid statutory construction. In West Norman Endoscopy Center, LLC v. CMS,<sup>64</sup> the DAB overturned a decision by an ALJ, on the basis of a strict reading of the enrollment requirements. West Norman Endoscopy Center (WNEC) submitted an enrollment application, which was rejected.

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<sup>61</sup> The DMEPOS supplier had not yet obtained a state license and had provided no evidence of insurance.

<sup>62</sup> DAB 2290 (December 17, 2009). The practitioner in this case also argued that they met the definition of a “provider” under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and therefore should have qualified under Medicare’s regulations. The DAB rejected this argument.

<sup>63</sup> CR1860 (October 31, 2008).

<sup>64</sup> DAB 2331 (September 23, 2010).

At issue in the case was WNEC's failure to submit a voided check with its CMS-855B enrollment application (and presumably with its CMS-588 electronic funds transfer form).<sup>65</sup> In its decision, the ALJ found that the voided check, in addition to the CMS-588 electronic funds transfer form, constituted "supporting documentation" which must be submitted with a CMS-855B application. The DAB rejected this argument, pointing out that, although the applicable regulation required submission of a CMS-588 form, the regulation did not state that supporting documentation for the CMS-588 itself was required.<sup>66</sup> Because TrailBlazer could not point to any document that indicated CMS' official interpretation that a voided check must be included with the CMS-588 in order for the enrollment application (the CMS-855B) to be complete, and because no notice of any such requirement was provided to WNEC, the DAB overturned the ALJ's determination that a voided check was required, and found in favor of WNEC.

These cases illustrate the fact that ALJs will strictly interpret the statutory and regulatory requirements. Even in a situation where there is ambiguity in the applicable CMS manual (as in Salem Gastroenterology), where regulatory or manual language exists to support the denial or revocation of billing privileges, the ALJ will typically narrowly construe the language and may find in favor of CMS. This leaves little "wobble room" to argue statutory and regulatory interpretation. Accordingly, where state law varies from Medicare regulations and requirements, suppliers applying for billing privileges must be certain to meet the letter of the law as well as its spirit.

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<sup>65</sup> The DAB noted that TrailBlazer only requested the voided check, and did not request a CMS-588. While there was no copy of a submitted CMS-588 form in the record, the DAB further noted that the CMS-588 application does require either a copy of a voided check or confirmation of account information on bank letterhead. DAB2331, fn.7.

<sup>66</sup> In fact, the DAB points out that 42 CFR § 425.510, the preamble to the final rule adopting Part 424, Section 17 of the CMS-855B application, and the Medicare Program Integrity Manual in effect at the time all failed to mention the voided check. DAB2331, pp.8-9.

### 5.3 Flawed CMS Counter Analysis

In recent cases, certain CMS contractors<sup>67</sup> have adopted a controversial argument to end-run the substance of an appeal. While the argument has found little favor among ALJs, understanding it can arm suppliers and counsel with an effective counter-argument, and provides insight into how CMS contractors construe Medicare regulations governing the appeals process.

The argument essentially states that Medicare suppliers (such as physicians, physician practices, IDTFs, and other entities that enroll using the CMS-855B or CMS-855I enrollment forms) are not entitled to a review of their effective date for billing privileges; only providers (such as hospitals and other entities using the CMS-855A enrollment form) and suppliers who must be accredited are afforded appeal rights for determinations of the effective date of billing privileges. The argument states that Medicare does not provide an appeals mechanism to challenge the effective date for billing privileges, per 42 CFR § 405.874. This argument has been rejected by ALJs, however, who have supported the counter-argument.

Under the counter-argument, although Part 424 does not explicitly grant appeal rights for challenges to a determination of effective date of billing privileges, it does grant appeal rights under Part 498. Specifically, 42 CFR § 498.3(b)(15) explicitly permits an appeal for effective date determinations, and is not explicitly carved out under Part 424. Thus, ALJs have found, an effective date determination is a “final determination” which can be appealed.

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<sup>67</sup> Both PalmettoGBA and TrailBlazer Medicare have used this line of argument. See, Albany Physical Therapy v. CMS, CR2184 (July 16, 2010); Tri-Valley Family Medicine, Inc. v. CMS, CR2179 (July 9, 2010); Anjali Sahai, M.D. v. CMS, CR2172 (July 1, 2010); Susanna West, CRNA v. CMS, CR2170 (June 30, 2010); Victor Alvarez, M.D. v. CMS, CR2070 (February 22, 2010).

The DAB has also rejected this line of argument in Victor Alvarez, M.D. v. CMS,<sup>68</sup> delving into the history of enrollment requirements and appeal rights. The DAB explained that, 42 CFR § 498.5(l) “sets out appeal rights for any ‘prospective supplier...dissatisfied with an initial determination or revised initial determination related to the denial...of Medicare billing privileges...’”<sup>69</sup> Although the language of this section does not explicitly state that “effective date” determinations are “related to” a denial, the DAB explained that even prior to 1997,

“it was well established that, by setting an effective date for a provider agreement later than the date sought by the prospective provider, CMS (then HCFA) was in essence refusing to enter into an agreement at an earlier date on the basis that the prospective provider did not qualify as a provider before that date.”<sup>70</sup>

Accordingly, the DAB found that the ALJ had properly rejected the argument made by the Medicare contractor and remanded the case to a hearing officer.

Understanding the ALJ and DAB lines of reasoning may prove critical to defending a case, if the CMS contractor raises such an argument. While certain ALJs have repeatedly addressed this argument, other ALJs may not be familiar with the line of reasoning. This argument also sheds light on CMS’ approach to arguing such cases. Even in the face of repeated rejections by ALJs, certain CMS contractors persist with this argument. If successful, the argument would essentially be a procedural end-run around any substance regarding the appropriate effective date. Rather than engage in a debate about when applications were mailed, whether they were lost by the contractor, and how far back a supplier can reach for an effective date, CMS could simply deny any challenge outright. The line of reasoning has been used by

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<sup>68</sup> DAB 2325 (July 23, 2010).

<sup>69</sup> Victor Alvarez, M.D. v. CMS, DAB 2325, pp.3-4 (emphasis in original).

<sup>70</sup> Victor Alvarez, M.D. v. CMS, DAB 2325, p.4. The DAB further noted that the language of the 1997 rulemaking specifically stated that it was adding an appeal mechanism for effective dates, and that such an effort, while not codified prior to 1997, had already been confirmed by court decisions. DAB2325, p.5.

Medicare hearing officers, so it may also be used to ease the administrative burden on contractors. While the argument has been rejected multiple times by ALJs, and now by the DAB, suppliers representing themselves as well as counsel unfamiliar with the counter-argument need to know that they should not give up when faced with this position.

#### 5.4 Timing

Much of the enrollment process – including appeals of decisions – turns on the timing of certain actions. Missing a deadline can prove fatal for an enrollment application, and the date of submission (which itself can be a topic of debate) is essential to determining the effective date of billing privileges, should an application be successfully processed. Deadlines are also critical to the appeals process. From the supplier’s perspective, issues of timing may play a practical role as well: namely, when the supplier can finally expect cash-flow from Medicare.

For example, in Professional Medical Center v. CMS,<sup>71</sup> a multispecialty clinic in Miami missed its deadline (sixty days) to file for reconsideration, when it filed more than one-hundred twenty days after the date of the decision. The ALJ upheld the denial based on the failure to timely respond, and ignored the factual basis for the denial. Of note was the discussion by the ALJ regarding the presumption of timeliness of the initial notice from the Medicare contractor. Unless either side can prove that notice was received earlier or later, the presumption is that the notice letter arrived five days from the date on the letter.<sup>72</sup> Generally, CMS contractors do not send such letters using any method of delivery confirmation (such as an overnight carrier, or certified return-receipt by the postal service); so, proving the late arrival of the letter could be extremely difficult. Moreover, an extension in time will only be granted when the supplier can

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<sup>71</sup> CR2052 (January 8, 2010).

<sup>72</sup> Professional Medical Center v. CMS, CR2052, P.4.

show “good cause.”<sup>73</sup> Such was not the case here, however, and the clinic made no effort to claim that the contractor had failed to send the letter when it said it had.<sup>74</sup> Similarly, in Arwinnah P. Bautista, M.D. v. CMS,<sup>75</sup> the supplier filed twenty-nine days late, claiming that he, as a layman, misunderstood the requirements of 42 CFR Part 498 and the appeals process. Again, the ALJ did not address the merits of his case, and found in favor of CMS based on the supplier’s failure to respond timely.

In some cases, a supplier may comply with Medicare’s deadlines, but still fail to effectively time its steps. For example, in A to Z DME, Inc. v. CMS,<sup>76</sup> a DMEPOS supplier was not operational at the time of its survey by the Medicare contractor. As part of the grounds for denial, the contractor noted that the supplier was answering customer requests using a fax machine, not a phone line. Accordingly, the surveyor found that the company was not actually open and serving the public. The supplier argued that it was in “start up mode,” and was merely planning to begin business. After the survey occurred, the supplier became compliant, but only complied *after* the surveys occurred. As with the Promedics case described above, suppliers must understand that they must meet all of the enrollment requirements before beginning to provide services. They cannot hope for Medicare to “let them slide” on certain requirements just so that they can start submitting claims.

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<sup>73</sup> Professional Medical Center v. CMS, CR2052, PP.4-5.

<sup>74</sup> Also of note is the clinic’s argument that the mere fact that they had received a response to the hearing request must have meant that its request was filed timely, since a hearing had been granted. This line of argument was unsuccessful.

<sup>75</sup> CR2185 (July 16, 2010).

<sup>76</sup> DAB2303 (March 2, 2010).

In Albany Physical Therapy v. CMS,<sup>77</sup> a physical therapy practice submitted an enrollment application to PalmettoGBA. Palmetto appeared to have lost the application. The practice resubmitted months later. When Palmetto granted billing privileges, it based the effective date on the resubmission, rather than on the initially submitted application. Naturally, the physical therapy practice challenged this decision. Unfortunately, the practice could not prove when it had sent the original, nor that Palmetto had received it. The practice did not send using any method involving delivery confirmation, and thus had no proof. However, even proof of delivery might not have been enough, since a supplier's "proof" might be insufficient to convince an ALJ.

In Tri-Valley Family Medicine v. CMS,<sup>78</sup> a physician practice submitted an enrollment application to CMS, which CMS returned because no signature page was included with the initial application. Tri-Valley resubmitted, and claimed it had provided the signature page in the second submission. However, the Medicare contractor sent the application back, stating that no signature page had been provided. From this point on, the case takes a turn for the surreal. The Medicare contractor claimed that it had never received, nor sent back any signature page. Yet Tri-Valley claimed it had received the returned application *with* the supposedly-missing signature page, highlighting the signature itself. In other words, the Medicare contractor had claimed no signature page had been included, and then returned the application with the signature page! The case ultimately turned on Tri-Valley's inability to prove that the signature page had been returned to them. The Medicare contractor, upon receipt of applications, stamped each page of the application using an internal numbering system. However, the signature page

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<sup>77</sup> CR2184 (July 16, 2010).

<sup>78</sup> CR2179 (July 16, 2010).

bore no such stamp. The ALJ determined that the fact that the signature page lacked this stamp, but the other pages had sequential stamps with no indication of a “missing” page, meant that it was likely that the practice had simply highlighted its own signature page, not one sent to or returned by the Medicare contractor.

This case is particularly troubling with respect to proving the timeliness of submission. The ALJ stated that he did not believe the Medicare contractor to be covering up having received the signature page, and found it far more likely that Tri-Valley had either mistakenly or maliciously claimed the highlighted page had been returned by the contractor. If this is the case, it poses a substantial burden for enrollees to prove the full content that a Medicare contractor receives. Even if an application is sent using delivery confirmation, how can one prove the contents of said packet? If prospective enrollees are viewed as likely to claim that they have submitted a full application when they have not, and no similar skepticism is applied to the Medicare contractor, how are suppliers ever to prove that they properly submitted? Thus, delivery confirmation methods seem useful, but only to prove that *something* was delivered, not the full contents of the package.

Providers and suppliers often think about enrollment only in terms of their business needs. They may hurry to finish the enrollment forms to ensure cash-flow. However, providers and suppliers – and especially their counsel – should take CMS’ rigidity and timing requirements into account. Providers and suppliers should ensure that they have met all of the enrollment requirements the first time, including providing all supplemental documentation, and actually beginning operations where required (such as for IDTFs and DMEPOS suppliers) in case an on-site investigator happens to visit. Doing so can speed the processing of the application, and can help create a smoother path to obtaining billing privileges. Incomplete or improper filings will

only lead to delays and headaches with local Medicare contractors. Lastly, even though the Tri-Valley case seems to suggest an impossible standard of proof, suppliers should make sure they can establish a paper trail to prove when they submitted information, and what was submitted as best as possible.<sup>79</sup>

#### 5.5. *Post Hoc, Ergo Propter Yank*

As inflexible and bureaucratic as this process may seem, based on the examples cited above, the best and most incredible is saved for last. While Medicare contractors will naturally deny or revoke billing privileges in circumstances such as when providers have been convicted in the past, or engaged in misconduct in the present, there are some cases when privileges are initially granted, and then subsequently withdrawn, not as a revocation, but as part of the *initial* enrollment process.

In Barnett v. CMS,<sup>80</sup> a physician had been convicted in 2005 of illegally selling prescription drug samples. The supplier subsequently applied for Medicare billing privileges in April, 2006, which were granted in May, 2006. Following this, he applied for Medicaid billing privileges, which caused Medicaid to ask CMS about his Medicare billing privileges in light of his conviction. Consequently, CMS revoked his billing privileges on August 9, 2007 – even though they had been aware of the conviction from the outset. The supplier challenged this action, claiming both that CMS had *de facto* decided that his conviction did not require denial of billing privileges, and claiming that CMS should be estopped from retroactively denying him his billing privileges. The ALJ ultimately found in favor of CMS, noting the permissive nature of

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<sup>79</sup> Sending applications via certified return receipt mail, retaining photocopies of what is sent and checking that against CMS' correspondence if documents are returned may help. Internal practices may help as well, such as a practice checklist for completing the enrollment forms.

<sup>80</sup> CR1786 (May 8, 2008).

the revocation provisions, and noted that ALJs have no authority to review CMS' exercise of discretion in such matters. Put simply, the supplier had been convicted of a felony within the previous ten years. Thus, CMS was within its statutory and regulatory authority to revoke or deny billing privileges on this basis, even if it had previously granted such privileges. The ALJ explained that the equitable doctrine of estoppel does not generally apply to the federal government.

Similarly, In Rojas v. CMS,<sup>81</sup> a supplier was convicted for false tax claims in March, 1998. The supplier was enrolled in Medicare on January 18, 2007. The Medicare contractor revoked the enrollment on February 17, 2007. As with the Barnett case, the supplier made no denial of the fact of his conviction. Instead, he argued that the revocation violated the *ex post facto* clause of the U.S. Constitution. The ALJ held that there was no way to equitably estop the federal government. Moreover, the *ex post facto* argument was denied, because the clause in question only applies to criminal law.

Finally, in US Ultrasound v. CMS,<sup>82</sup> an ultrasound IDTF was informed by the local CMS contractor that it had been granted billing privileges. The IDTF was registered using two separate billing numbers, one in Kansas and the other in Missouri, and provided ultrasounds in a nursing home setting. Included with enrollment application was a copy of a contract between the IDTF and a company known as Alliance Radiology, whereby Alliance owned the equipment, and employed the technicians, and physicians. Prior to submitting its enrollment application, the IDTF consulted with representatives of the Medicare contractor regarding the permissibility of this arrangement, and was informed that there would be no problem. Following the processing

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<sup>81</sup> CR1797 (June 2, 2008).

<sup>82</sup> CR1982, discussed above in §.3.1.

of its application, the IDTF was sent its billing number, with an effective date of June 18, 2008. On November 20, 2008, the IDTF was informed that, upon further review, its privileges were being denied. The analysis from the Medicare contractor was that the entity that should be billing was, in fact, Alliance Radiology, since Alliance had all the equipment and employed the personnel. On the face of this argument, the ALJ found for CMS. The IDTF had not challenged CMS' authority to deny its privileges, nor had it challenged the factual basis of denial. Instead, it argued that CMS was, required to revoke its privileges, rather than deny them.<sup>83</sup> The ALJ disagreed, and the Departmental Appeal Board found no grounds for equitable relief. Although it was an unfortunate set of circumstances, the DAB was forced find that CMS had properly denied the IDTF's billing privileges.<sup>84</sup> The DAB explained that equitable relief is only available in circumstances where the government engaged in "affirmative misconduct," such as where the government acted fraudulently. Because U.S. Ultrasound had not proven any such misconduct, the DAB was required to find in favor of CMS.

Compare this scenario to that of Heckler v. Community Healt Services of Crawford Count,<sup>85</sup> wherein an applicant for federal funding relied on the advice of a fiscal intermediary and improperly included certain costs which resulted in an overpayment. When the intermediary then attempted to recoup the money, the defendant claimed that the intermediary's actions should be estopped, on the grounds that it had relied on the intermediary's erroneous advice. The U.S. Supreme Court ruled against the applicant, noting that "As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements [in these

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<sup>83</sup> As discussed above, the IDTF intended to retroactively bill claims for services performed, whereas a denial would effectively render those claims unbillable.

<sup>84</sup> Heckler, at 64.

<sup>85</sup> 467 U.S. 51 (1984).

circumstances.]” The Court also noted that the applicant’s reliance on the bad advice was insufficient to support estoppel because the advice was given orally, and not written. The need for written evidence of bad advice from a Medicare contractor is therefore paramount; bad advice given in a telephone conversation is insufficient to challenge a Medicare ruling.

“Unfairness” is clearly insufficient to save an enrollment denial or revocation which is legitimate on its face. As long as CMS is enforcing its legitimate authority granted by statute and regulation, and as long as the facts support CMS’ position, the supplier will find no solace in an argument that it is effectively having its privileges denied after already having them granted. In short, an error by CMS will not compel an ALJ or the DAB to overturn a revocation or denial, as long as such revocation or denial is based on uncontested facts and legitimate authority. In light of this, prospective enrollees must be certain to properly complete their applications, and – if they find themselves faced with an appeal – must attempt to challenge the factual basis and/or legitimate authority of the Medicare contractor in the specific circumstances.

## **\_.6 Conclusion**

“In the modern era, too often, the government doesn’t know who it’s working with...It would be hard to exaggerate the importance of strengthening [the Medicare enrollment standards.]”<sup>86</sup> These words from Health and Human Services Inspector General Levinson are unequivocal. Already previously burdensome and complicated, the obstacles placed in the path of both the already enrolled and those attempting to enroll for the first time are only likely to

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<sup>86</sup> Inspector General Levinson's September 22, 2010 testimony, lines 1215-1216; 1222-1224, <http://energycommerce.house.gov/documents/20100922/transcript.09.22.2010.he.pdf>.

increase in difficulty and number. Potential consequences can range from a loss or denial of billing privileges to overpayments to potential Federal False Claims Act exposure.

The process for appealing unfavorable enrollment actions likewise presents a thorny path. Hearing officers, ALJs, and the DAB are often constrained to strict interpretations of statutory and regulatory language, and lack the power to provide equitable relief despite provider or supplier reliance on the incorrect advice of Medicare contractor staff. Even in situations where the ALJ or DAB rejects a Medicare contractor argument premised on an incorrect interpretation of regulatory language, providers and suppliers caught in the appeals process must bear the dual burdens of attorney fees and freezing of revenue streams until the matter is resolved. Even if the provider or supplier ultimately prevails, how long will it have taken to obtain a favorable result? What loans may have been taken out to pay ongoing financial obligations?

This chapter has attempted to present both the potential pitfalls of the enrollment appeals process, and provide some practical guidance on how to avoid or at least navigate such pitfalls. However, there is no substitute for simply not needing to engage in such activities in the first place. Towards this end, providers and suppliers need to understand the difficulty involved in the enrollment process, the need to maintain ongoing vigilance with respect to matters such as notification requirements for enrollment information, and the potential harm they face if they fail to properly enroll or maintain their enrollment.

Providers and suppliers should eschew “self-medicating” by attempting to complete applications without a review by health care counsel, and should not attempt to resolve denials, revocations, or disputes about the effective date of billing privileges on a *pro se* basis. Rather, they should seek the services of health care attorneys familiar with the enrollment process and/or

the appeals process, and should work side by side with such legal counsel in the completion of enrollment applications.