Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Tri-Valley Family Medicine, Inc.
Docket No. A-10-98
Decision No. 2358
December 30, 2010

FINAL DECISION ON REVIEW OF HEARING OFFICIAL DECISION

Tri-Valley Family Medicine, Inc. (Tri-Valley) appealed the decision of Board Member Leslie A. Sussan (Board Member).[1] *Tri-Valley Family Medicine, Inc.*, DAB CR 2179 (2010) (DAB CR2179). The Board Member ruled in favor of the Centers for Medicare & Medicaid Services (CMS), holding that the effective date of approval for Tri-Valley's participation in the Medicare program is July 8, 2009 because Tri-Valley had not submitted a signed, fully complete Medicare enrollment application prior to that date.

As explained below, we conclude the Board Member erred in analyzing whether an enrollment application Tri-Valley submitted in November 2008 could have been subsequently approved by the CMS contractor, Palmetto GBA (Palmetto). The Board Member based her analysis on her misreading of a regulatory provision that was not in effect at the time and on the related preamble, rather than examining what Palmetto should have done under the regulatory enrollment process in effect at the time the November 2008 application was submitted.

Accordingly, we reverse the Board Member's decision and conclude that Tri-Valley is entitled to an effective enrollment date of November 20, 2008, which is the date Palmetto received Tri-Valley's enrollment application that could have been processed to approval had Palmetto properly requested from Tri-Valley any information that was missing. We further conclude that Tri-Valley is entitled to receive payment for covered Medicare services retroactively to November 1, 2008, which is the date it first began providing medical services to Medicare beneficiaries.

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[1] Pursuant to 42 C.F.R. § 498.44, Board Member Sussan was designated as the hearing official to hear provider supplier enrollment appeals under 42 C.F.R. Part 498, Subpart P and was assigned this case to issue an initial decision.

Background

Tri-Valley is a physician practice that began providing services to Medicare beneficiaries in November 2008. The physician, who is the owner and authorized representative of Tri-Valley, had previously been part of a different physician group and has been licensed since 1996. Tri-Valley initially submitted an enrollment application which Palmetto returned on October 20, 2008. CMS Ex. 1. Tri-Valley submitted a second application, which was received by Palmetto on or about November 20, 2008. Palmetto returned the second application to Tri-Valley on November 26, 2008. CMS Ex. 3. Palmetto's stated reason for returning each of these applications was that Section 15 of the enrollment application (CMS-855I), the certification statement section, was not signed. It is undisputed, however, that the November 2008 application was signed by the authorized physician in two places in Section 17. CMS Ex. 2, at 28, 33.

In July 2009, Tri-Valley submitted an enrollment application that was approved by Palmetto with an effective date of July 8, 2009 based on the date of receipt of the application. CMS Ex. 6. In determining this date, Palmetto applied 42 C.F.R. § 424.520(d) (2009). Thereafter, Palmetto permitted Tri-Valley to bill Medicare retroactively to June 8, 2009, based on 42 C.F.R. § 424.521(a) (2009). CMS Ex. 8.

Tri-Valley requested a hearing on the effective date assigned and made numerous factual assertions that CMS, via its contractor, made various mistakes handling its enrollment applications submitted prior to July 2009. Among other things, Tri-Valley contended that the application submitted in November 2008, which was identical to the approved July 2009 application, was in fact signed and should have been processed to approval. This would have entitled Tri-Valley to retroactively bill to November 1, 2008, which is the date Tri-Valley first furnished Medicare covered services. The Board Member issued a decision on the written record, denying Tri-Valley's appeal for an effective date earlier than June 8, 2009.

In analyzing the question of the appropriate effective date in this case, the Board Member noted that she first must consider as a matter of law what Tri-Valley must show in order to demonstrate entitlement to an earlier effective date under section 424.520(d), which refers to the "date of filing" of an application "that was subsequently approved by a Medicare contractor" for determining an appropriate effective date. *Id.* at 10. The Board Member considered only two possible interpretations of section 424.520(d). First, she considered that the language could "mean that the effective date must be the date on which the contractor received the actual application that it approved." DAB CR2179, at 10. The second interpretation she identified was that the effective date was the "date on which a complete application is first received which is subsequently processed to approval." *Id.* In deciding which of these two interpretations to follow, the Board Member observed that the preamble to the final rule adopted "the 'date of filing' of an application as the date a Medicare contractor receives a signed provider enrollment

application that the Medicare contractor is able to process to approval." 73 Fed. Reg. 69,725, 69,769 (Nov. 19, 2008). She noted that in the preamble, the emphasis "appears to be [the date] on when the contractor first received an approvable application." DAB CR2179, at 10 (emphasis in original). The Board Member then concluded that this "explanation is consistent with the interpretation that the receipt of a *signed, fully complete application* by a contractor triggers the effective date, which would not be defeated by subsequent filing of additional copies of the application." *Id.* at 10-11 (emphasis added).

Based on this legal conclusion, the Board Member addressed the factual issue of whether Palmetto had received a "complete signed application" in November 2008 because, if so, then it would have been "approvable since it was identical to the one which was resubmitted and processed to ultimate approval in July 2009." *Id.* at 11. The Board Member then analyzed the evidence and found that, even if the submitting physician had signed the November 2008 application, Palmetto had not in fact *received* a signed Section 15, and, therefore, that application could not be processed to approval. Accordingly, the Board Member concluded that Tri-Valley had not met the requirements of section 424.520(d) until Palmetto received a resubmitted, signed application on July 8, 2009.

Analysis

On appeal, Tri-Valley raises two primary arguments. First, it contends that the Board Member's finding that the November 20 application was unsigned is not supported by substantial evidence in the record. Second, Tri-Valley contends that it is entitled to an effective date of November 20 (with billing privileges as of November 1) because Palmetto could have ultimately processed the November application to approval by requesting the purportedly missing signature. We do not need to address the Board Member's factual finding that the November application received by Palmetto was not signed and complete because we find that the Board Member erred in analyzing whether the November 2008 application was an application capable of being processed to approval based upon her misreading of section 424.520(d) (which was not in effect in November 2008) and its related preamble language, rather than examining what Palmetto should have done in November 2008 under the regulatory process that was in effect at the time. Thus, this case raises a narrow issue regarding how to apply a revised effective date regulation to an enrollment application that had been submitted before that regulation was in effect.

To help the reader understand our analysis and why it differs from the decision below, we first review the regulatory provisions in effect in November 2008 and their history, and then examine Palmetto's action in light of that history, as well as the subsequent regulatory changes and their consequences.

1. Section 1866(j) of the Social Security Act (Act) requires the Medicare enrollment process to be governed by regulation.[2]

Title XVIII of the Act governs the healthcare program for the aged and disabled known as Medicare. In 2003, Congress enacted section 1866(j) of the Act, which specifically directed the Secretary to "establish *by regulation* the process for the enrollment of providers of services and suppliers" in Medicare. Section 936(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173 (emphasis added). Congress noted that CMS had previously established provider and supplier enrollment processes in instruction manuals issued to the contractors. *See* H.R. CONF. REP. 108-391, at 786 (Nov. 21, 2003). The instructions to the contractors provided a physician the right to appeal to a fair hearing officer under 42 C.F.R. § 405.874. However, unlike providers and some other suppliers, physicians were not entitled to further appeal a denied Medicare enrollment application or revoked Medicare billing privileges to an Administrative Law Judge (ALJ) or the Board under 42 C.F.R. Part 498. MMA, however, provided that a provider or supplier whose enrollment was denied would have a right to a hearing under the procedures that apply under section 1866(h)(1)(A) of the Act, that is, the Part 498 procedures.

2. The Secretary promulgated regulations establishing a Medicare enrollment process in 2006.

In 2003, prior to the enactment of MMA, the Secretary had proposed that all providers and suppliers be required to complete an enrollment form and submit specified information. 68 Fed. Reg. 22,064 (April 25, 2003). If the information submitted on an initial application was determined to be incomplete, invalid, or insufficient to meet Medicare requirements, billing privileges could be rejected or denied. *Id.* The Secretary proposed that rejection of an enrollment application would not occur if the provider or supplier was actively communicating with CMS to resolve any issues. *Id.* at 22,070. Denial of the enrollment application was proposed if the provider or supplier was found not to be in compliance with Medicare enrollment requirements. *Id.*

In 2006, the Secretary issued implementing regulations at 42 C.F.R. Part 424, subpart P, setting out the enrollment process Medicare uses to establish eligibility to submit claims for Medicare covered items and services.[3] To receive payment for items and services covered by Medicare, "a provider or supplier must be enrolled in the Medicare program." 42 C.F.R. § 424.505. "Once enrolled, the provider or supplier receives billing privileges . . . ." *Id.* To enroll, "[p]roviders and suppliers must submit enrollment information on

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[2] The current version of the Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

[3] Unless as noted here, the regulations cited in this decision were in effect as of November 2008.

the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process . . . CMS enrolls the provider or supplier into the Medicare program." 42 C.F.R. § 424.510(a). In addition, a prospective "provider or supplier must submit a complete enrollment application and supporting documentation to the designated Medicare fee-for-service contractor." 42 C.F.R. § 424.510(d)(1). The application must include "[c]omplete, accurate, and truthful responses to all information requested within each section as applicable to the provider or supplier type." 42 C.F.R. § 424.510(d)(2)(i). The "certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier both legally and financially." 42 C.F.R. §§ 424.510(d)(3), 424.510(d)(3)(i)(A).

The regulations define an enrollment "application" to be the CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by the Office of Management and Budget (OMB). 42 C.F.R. § 424.502. The approved form for physicians is the CMS-855I. 71 Fed. Reg. 20,754, 20,756 (Apr. 21, 2006).

Recognizing that the application process was complex, the regulations established criteria for CMS, or its contractor, to reject or deny an enrollment application, in two places – section 424.525 and section 424.530. Section 424.525 requires a Medicare contractor that receives an enrollment application with missing information or supporting documentation to request the information or documentation from the provider or supplier and to give the provider or supplier at least 30 days to respond with the missing information in order to cure any deficiencies in the application. *See* 42 C.F.R. § 424.525.[4] The regulatory history of section 424.525 makes it clear that applicants will be given an opportunity to cure any deficiencies or supply any missing documentation before an application will be rejected. *See* 71 Fed. Reg. at 20,754, 20,759 ("if a provider or supplier enrolling in the Medicare program for the first time fails to furnish complete information on the CMS [form] 855, or fails to furnish missing or any necessary supporting documentation as required by CMS under this or other statutory or regulatory authority within 60 calendar days of our request to furnish the information, we would reject the provider or supplier's 855 application."); 68 Fed. Reg. at 22,070. Indeed, the preamble to the final rule shortening the time period for submitting information or supporting documentation to 30 days specifically states that "[r]ejection would not occur if the provider or supplier is actively communicating with us to resolve any issues regardless of any timeframes." 73 Fed. Reg. at 20,759.

Section 424.530 provided authority for CMS to deny an enrollment application if the provider was not in compliance with all Medicare enrollment requirements (which

[4] The 2006 regulation provided for at least a 60-day period to correct deficiencies before an application could be rejected, which was subsequently reduced to 30 days in 2008. *See* 73 Fed. Reg. 36,448, 36,455 (June 27, 2008); *see also* 73 Fed. Reg. at 69,769 ("During the application review process, contractors notify applicants about missing information and documentation and afford the applicant at least 30 days to correct deficiencies.").

include the requirement for a signature on the certification statement), *and* had not submitted a corrective action plan. 42 C.F.R. § 424.530(a)(1).

Nothing in the regulations or their preamble specifically addressed what process would be followed if an application was not signed in all places where a signature was required. But the only two process options the regulation established were that the contractor could either treat the missing signature like any other missing information and request it within the regulatory deadline or treat the failure as noncompliance and deny the application, after giving the provider or supplier an opportunity to submit a corrective action plan, and then affording a right to appeal. Under either option, the regulations clearly provided applicants with an opportunity to cure any deficiencies in an application before any adverse action could be taken.

Prior to January 1, 2009, "depending on their effective date of enrollment, [physicians were permitted to] retroactively bill the Medicare program for services that were furnished up to 27 months prior to being enrolled to participate in the Medicare program." 73 Fed. Reg. 69,726, 69,766 (Nov. 19, 2008); 42 C.F.R. §§ 424.44, 424.510; *Andrew J. Elliott, M.D.*, DAB No. 2334, at 3 (2010). Thus, a physician could retroactively bill Medicare for up to 27 months during the application process so long as he or she remained licensed and submitted claims in a timely manner.

3. The Secretary promulgated amended regulations governing the Medicare enrollment process, effective January 1, 2009.

Effective January 1, 2009, the Secretary re-designated 42 C.F.R. § 424.520 as 42 C.F.R. § 424.516 and added a new section 424.520 entitled "Effective date of Medicare billing privileges." *Elliott* at 3. Under the new section 424.520(d), the effective date for billing privileges for physicians is "the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor or the date an enrolled physician . . . first began furnishing services at a new practice location." 42 C.F.R. § 520(d) (2009). The preamble for the new section 424.520(d) stated that the "date of filing" is the date that a Medicare contractor receives a "signed" application that the contractor is "able to process to approval."[5] 73 Fed. Reg. at 69,769. This was the first indication that lack of a signature on an application might affect the timing of when a physician could get paid for covered services.

Under the new provisions, moreover, a physician could bill retroactively only 30 days from the effective date of billing privileges, rather than 27 months as previously had been the case. Finally, the preamble noted that physician applications would not be rejected if deficiencies were not cured within 30 days, but instead would be denied, thereby

[5] Tri-Valley's enrollment application was signed November 1, 2008, and Tri-Valley said it was mailed November 3 (which CMS did not deny). P. Hearing Request at 1. Thus, Tri-Valley did not have timely notice of the regulatory changes published on November 19, 2008 and their concomitant effects.

triggering appeal rights. However, the amended regulations did not change any of the provisions previously set forth in sections 424.525 and 424.530 regarding an opportunity to cure any deficiencies in a timely manner.

4. The Board Member erred in interpreting and applying new section 424.520(d) and the related preamble language.

Although there are no appeal rights for a rejected enrollment application, a provider or supplier may appeal an assigned effective date after CMS has made an effective date determination. *Victor Alvarez, M.D.*, DAB No. 2325, at 15 (2010).

In the present case, to determine the effective date of Tri-Valley's Medicare enrollment, the Board Member focused on interpreting and applying the standards set forth at the new section 424.520(d). DAB CR2179, at 10-11. Relying on the regulation's interpretive preamble, the Board Member concluded that under section 424.520(d), "the receipt of a *signed, fully complete application* by a contractor triggers the effective date[.]" *Id.* at 10 (emphasis added). Based upon her factual finding that Palmetto did not receive a signed, complete application in November 2008, the Board Member concluded that Tri-Valley was not entitled to an effective date earlier than July 8, 2009. *Id.* at 15.

We disagree with the Board Member's conclusion, for several reasons. First, nothing in the regulations or in the preamble language on which the Board Member relied indicates that the effective date was to be determined by the submission of a *complete* application. Instead, the regulation refers to an application that is "subsequently approved" by the contractor. It does not require that the application be "approvable" as initially submitted. The regulatory process, which was unchanged, included provision for the contractor to request information or supporting documentation if an application was not complete. Thus, if the information or documentation was timely submitted and all other requirements were met, that application could be approved, and a provider or supplier was not required to submit an additional application. The preamble language cited by the Board Member recognizes this by referring to an application that a contractor is able to process to approval. Indeed, the preamble indicated agreement with the comment that the filing date should not be the date when the application is "deemed complete and ready for approval." 73 Fed. Reg. at 69,769.

Second, the preamble language indicating that the date of filing of an application is the date a *signed* application is received is not properly applied in deciding whether Palmetto was able to process the November 2008 application to approval. The new provisions were not effective until January 1, 2009. 73 Fed. Reg. 69,726. By relying on the preamble language in evaluating whether Palmetto was able to process the November 2008 application to approval, the Board Member impermissibly gave it retroactive effect.

Third, we note that the factual dispute in this case is only over whether Palmetto received a signed Section 15 in November 2008. It is undisputed that the authorized physician did sign the November 2008 application in two other places. The Board Member did not discuss why these signatures would not suffice under the preamble statement, which merely indicates that the date of receipt of a signed application is the date of filing.

5. The Board Member did not consider whether Palmetto followed the regulations in effect at the time of the Tri-Valley's November 2008 Medicare enrollment application.

In determining whether Palmetto was able to process the November 2008 application to approval, the key question is whether a missing physician signature on the certification section constitutes "missing information or supporting documentation" within the scope of section 424.525 or the type of noncompliance that should have resulted in the denial of application under section 424.530. The Board Member did not directly address these questions in her decision. Prior to the effective date of the amended section 424.520(d), neither the regulations nor their preamble directly addressed this question. As explained below, we conclude that, at the very least, a missing signature fell within the scope of section 424.525.

Section 424.525 specifically provides that an applicant will have at least 30 days to provide any missing information or supporting documentation before a contractor may reject an application. As noted above, the preamble indicated that an application would not be rejected if the applicant was actively communicating with contractor. Similarly, section 424.530 provides that a contractor is authorized to deny an enrollment application that fails to meet an enrollment requirement, only after the applicant is provided an opportunity to submit a corrective action plan to cure the deficiency. Thus, the regulations in effect at the time of the November 2008 application created a process in which a contractor was able to subsequently approve an application even if it was not *signed and fully complete* when it was first submitted.[6] Neither regulation treated a missing signature as different from other information or documentation to be handled through that process.

It is undisputed that Palmetto returned Tri-Valley's November 2008 enrollment application once it determined that the application did not contain the required physician's signature, without giving Tri-Valley the 30-day period to provide the information or an opportunity for a corrective action plan and without providing any appeal right. In a footnote, the Board Member suggested that "returning" the application was nonetheless authorized by CMS's instructions to contractors for processing

[6] Indeed, the amended regulations do not alter the process established by sections 424.525 and 424.530. Thus, even after the amended regulation became effective, an application need not be *fully complete* at the time of submission to be processed to approval.

enrollment applications. DAB CR2197 at n.1. The footnote quotes from a version of the instructions that was not in effect in November 2008. *See* Medicare Program Integrity Manual (PIM), chapter 10 (Rev. 286, issued 03-13-09, accessible at http://www.cms.gov/transmittals/downloads/R286PI.pdf). The manual instructions in effect at the time of processing the application did also instruct a contractor to "return" an application if there "is no signature on the CMS-855 application." *See* PIM, chapter 10, section 3.2.A (Rev. 218, issued 08-10-07, accessible at http://www.cms.gov/transmittals/downloads/R218PI.pdf). Unlike the Medicare statute and regulations, however, CMS's instructions to contractors do not have the force and effect of law and are not binding on the Board. *See Fady Fayad, M.D.*, DAB No. 2266, at 9 n.6 (2009), *citing Massachusetts Executive Office of Health and Human Services*, DAB No. 2218, at 12 (2008); *Foxwood Springs Living Center*, DAB No. 2294, at 8-9 (2009). In section 1866(j) of the Act, Congress specifically directed the Secretary to establish *by regulation* the procedures for actions on applications, rather than relying merely on instruction manuals. Neither the regulations nor the regulatory preamble reference the concept of "returning" an application as a part of the enrollment process. As previously discussed, the regulations authorize CMS only to reject or deny an enrollment application. *See* 42 C.F.R. §§ 424.525 and 424.530. Moreover, the manual instructions state that a "returned application is considered a non-application." Treating an approved CMS-855 form as a "non-application" merely because it is unsigned is inconsistent with the definition of an "application" at section 424.502.

In addition, the record does not support a conclusion that Palmetto was, in fact, treating the November 2008 submission as a "non-application" pursuant to the instructions. Instead, Palmetto's November 26, 2008 letter referred to the submission as an "application," which it clearly was. CMS Ex. 3.

In this case, Palmetto did not properly handle the processing of Tri-Valley's November 2008 application under the applicable regulatory process. Instead of requesting Tri-Valley to provide the missing physician signature within 30 days as required under section 424.525 or giving Tri-Valley a chance to submit a corrective action plan under section 424.530, Palmetto simply "returned" Tri-Valley's application on the basis that Section 15 was unsigned. Had Palmetto properly processed Tri-Valley's November 2008 application and requested the missing information within 30 days, Tri-Valley could have submitted the missing information, and the application would have been processed to approval because it was not deficient in any other way.

Thus, we conclude that the Board Member erred by not considering whether Palmetto had properly requested the missing signature from Tri-Valley in accordance with the regulatory process in effect at the time. Because the November 2008 application is identical in every respect to the approved July 2009 application, except that it may have been missing one signature, we conclude that Tri-Valley is entitled to an earlier effective date of November 20, 2008, with retroactive payment for Medicare covered services as of November 1, 2008.

Conclusion

For the reasons explained above, we reverse the Board Member's decision and grant an effective date of November 20, 2008 for Tri-Valley's enrollment in Medicare with billing retroactive to November 1, 2008, which is the date it first began providing medical services to Medicare beneficiaries.

/s/
Constance B. Tobias

/s/
Judith A. Ballard

/s/
Stephen M. Godek
Presiding Board Member