Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Premier Diagnostic Imaging, Inc.,
(NPI: 1750533469)

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-99

Decision No. CR2123

Date: April 26, 2010

DECISION

I grant summary judgment to the Centers for Medicare and Medicaid Services (CMS), sustaining its determination and that of its contractor, Wisconsin Physicians Service (WPS), to enroll Petitioner, Premier Diagnostic Imaging, Inc., in the Medicare program with an effective date of participation of April 28, 2009.

I. Background

Petitioner is a supplier of portable X-ray services in the greater Plymouth, Minnesota area. On October 14, 2008, Petitioner submitted its Medicare enrollment application to WPS, requesting that the facility be certified as a supplier of portable X-ray services under the Medicare program. CMS Ex. 11. By correspondence dated January 20, 2009, January 26, 2009, and March 30, 2009, Petitioner requested it be granted an exception to the CMS policy that surveys of existing Medicare providers and suppliers are given priority over initial Medicare certification surveys. CMS Exs. 3- 4. On April 16, 2009, CMS granted Petitioner's request for a priority exception. CMS Ex. 5. Subsequently, on April 28, 2009, the Minnesota Department of Health (state agency) completed Petitioner's initial Medicare certification survey, finding Petitioner in compliance with all applicable federal conditions, and recommended to CMS that the facility be certified as of that date. CMS Exs. 1, 12. By letter dated June 3, 2009, CMS notified Petitioner that

the effective date of its Medicare participation was April 28, 2009, the date the state agency surveyed Petitioner. CMS Ex. 6.

By letter dated October 24, 2009, Petitioner requested a hearing. Petitioner asserted that the effective date of its participation should be moved to October 14, 2008, the date of the enrollment application, arguing that Petitioner has long been in compliance with state and federal regulations and had not altered the high quality service provided from its inception through the time the state agency certified compliance. *Id*. Petitioner contended that circumstances beyond Petitioner's control, but within CMS's or the state agency's control, unreasonably delayed the survey and certification process. *Id*.

The case was initially assigned to Administrative Law Judge (ALJ) Alfonso J. Montaño. However, the case was transferred to me for a hearing and a decision pursuant to 42 C.F.R. § 498.44, which permits a Board Member to be designated to hear appeals taken under Part 498, which governs this appeal.

On January 11, 2010, CMS filed a Joint Notice of Issues for Summary Disposition (Joint Notice). On February 25, 2010, CMS filed a motion for summary disposition (CMS Br.) accompanied by fifteen proposed exhibits, which it identified as CMS Ex. 1 – CMS Ex. 15. Petitioner submitted a response brief (P. Br.) on April 12, 2010, accompanied by two proposed exhibits, which it identified as Premier Ex. 1 and Premier Ex. 2. I admit these exhibits to the record of the case.

II. Issues

The issues in this case are:

1. Whether summary judgment is appropriate;

2. Whether CMS properly determined, as a matter of law, Petitioner's effective date of participation in Medicare to be April 28, 2009; and

3. Whether I have authority to find 42 C.F.R. § 489.13(b) invalid or unconstitutional.

III. Discussion and conclusions of law

I make conclusions of law to support my decision in this case. I set forth each conclusion below as a separate heading.

1. The case can be decided on CMS's motion for summary disposition.

In *Senior Rehabilitation and Skilled Nursing Center*, DAB No. 2300 (2010), the Departmental Appeals Board (Board) recently reiterated the standards for summary judgment as follows:

> Summary judgment is appropriate when the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *Kingsville Nursing and Rehabilitation Center*, DAB No. 2234, at 3 (2009), citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986). While the Federal Rules of Civil Procedure (FRCP) are not binding in this administrative appeal, we are guided by those rules and by judicial decisions on summary judgment in determining whether the ALJ properly granted summary judgment. *See Thelma Walley*, DAB No. 1367 (1992) . . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. *Kingsville* at 3, citing *Celotex*, 477 U.S. at 323. If the moving party carries its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986) (quoting FRCP 56(e)). To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact - - a fact that, if proven, would affect the outcome of the case under governing law. *Id.* at 586 n.11; *Celotex*, 477 U.S. at 322. In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. *U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

Senior Rehab., DAB No. 2300, at 3. The Board has also noted that the role of an ALJ in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not be assessing credibility or evaluating the weight of conflicting evidence when resolving a summary judgment motion. *Holy Cross Village at Notre Dame*, DAB No. 2291, at 4-5 (2009).

The following material facts are not in dispute[1]:

On October 14, 2008, Petitioner submitted its Medicare enrollment application to WPS. CMS Ex. 11. On November 3, 2008, WPS recommended approval of Petitioner's application to the state agency, which then needed to arrange for a survey of Petitioner.

[1] These facts are drawn from CMS's Brief at pages 6-9, which Petitioner adopts as having "fairly and accurately synopsized the timeline from Premier's application to enrollment." P. Br. at 3. The exhibits are cited where relevant.

CMS Ex. 2. For a number of reasons, including limited resources and an increase in prospective providers, CMS directed states to prioritize certain investigations over initial surveys of prospective providers and suppliers. CMS Ex. 14. However, for suppliers in certain unique circumstances, CMS provided a process where these suppliers could request an exception in their priority assignment. *Id*. Petitioner requested such an exception by letter and email correspondence dated January 20, 2009, January 26, 2009, and March 30, 2009. CMS Exs. 3, 4.

On April 16, 2009, CMS notified Petitioner that it granted its request for a priority exception, noting that it authorized the state agency to place Petitioner in the queue for an initial survey, "contingent upon the accomplishment of the required recertification workload." CMS Ex. 5. On April 28, 2009, the state agency conducted a survey of the institution to determine whether it was in compliance with Medicare participation requirements for suppliers of portable X-ray services. CMS Ex. 12. The state agency found that Petitioner met all requirements for Medicare participation on the date of the survey, specifically finding that Petitioner was in compliance with 42 C.F.R. Part 486, Subpart C, the conditions for coverage for suppliers of portable X-ray services. CMS Exs. 1, 12.

On June 3, 2009, CMS notified Petitioner that its request to be a Medicare supplier of portable X-ray services was approved and that the effective date of participation was April 28, 2009. CMS Ex. 6. On June 15, 2009, WPS notified Petitioner that its Medicare enrollment application was approved with the effective date of participation beginning April 28, 2009. CMS Ex. 7. By letter dated July 1, 2009, Petitioner requested that CMS reconsider its initial determination and change the effective date to October 14, 2008. CMS Ex. 8. On August 24, 2009, CMS affirmed its prior determination, finding that the effective date could be no earlier than April 28, 2009. CMS Ex. 9.

For purposes of summary judgment, I also accept as true Petitioner's assertion that access to radiology and X-ray services was severely limited in and around rural Minnesota, and that Petitioner's mobile services, provided 24 hours per day, seven days per week, would directly address this problem. P. Br. at 3-4. CMS indeed found, in deciding to grant priority to scheduling a survey of Petitioner, that "beneficiaries in Hennepin County area would suffer serious, adverse health care access consequences should this portable X-ray facility not become Medicare certified." P. Br. at 3 (citing CMS Ex. 5, at 2). I also accept Petitioner's assertion that it suffered a substantial financial burden as a result of the six months from Petitioner's application for Medicare enrollment (and four months from the time it requested expedited priority exception status) before the survey was completed that found Petitioner in compliance. P. Br. at 4. Although Petitioner asserted that it sought a hearing "to develop the factual record in support of its legal position stated herein," Petitioner stated that its hearing exhibits would consist only of those I have already admitted. *Id*. at 1. Petitioner identified no witnesses it would present beyond the affidavit of Ms. Kim S. Algoo, Petitioner's Chief Executive Officer, which I have also admitted.

Petitioner's witness attested that CMS Exhibits 1 through 13 are accurate copies of documentation of Petitioner's efforts to seek certification. Premier Ex. 1, at 2. Petitioner does not object to, or challenge, the authenticity of CMS Exhibits 14 and 15, although Petitioner's witness states that she cannot personally attest to their accuracy (CMS Exhibits 14 and 15 are CMS policy guidance documents). *Id*. CMS proffered no witnesses and did not seek to cross-examine Ms. Algoo.

Petitioner argues that the regulations need not, and should not, be applied in a manner that results in delaying its billing privileges until April 28, 2009. P. Br. at 4-8. This argument goes, however, to the construction and application of the law. Petitioner has not identified any genuine dispute of material fact. Therefore, I conclude that summary judgment is appropriate.

2. CMS properly determined Petitioner's effective date of participation to be April 28, 2009.

The regulation governing the effective date of participation in Medicare of a portable X-ray supplier, such as Petitioner, states: "[t]he agreement or approval is effective on the date the survey . . . is completed, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter." 42 C.F.R. § 489.13(b). Petitioner argues that CMS "misconstrues 42 C.F.R. § 489.13(b) to constitute a ban that prevents state survey agencies from finding a date of compliance with federal requirements, which is earlier than the last day of the survey." P. Br. at 4. First, Petitioner suggests that certain CMS guidance indicates that the effective date should instead be "the date of *actual* compliance." P. Br. at 4 (emphasis in original) (citing CMS Ex. 15, at 13 (Excerpt from CMS's State Operations Manual (SOM))). Petitioner contends that this guidance supports an effective date in October 2008, because surveyors reviewed Petitioner's patient data from October 2008 and noted an inspection in October 2008. Second, Petitioner emphasizes that CMS agreed that its survey was entitled to priority status, apparently contending that it should have been surveyed more quickly and, hence, presumably obtained an earlier effective date. I explain below why I do not find either argument persuasive.

In addition, Petitioner makes arguments that section 489.13(b) conflicts with federal statutes or violates the United States Constitution. Petitioner expressly recognizes that I do not have authority "to ignore unambiguous regulations" on this basis, but presses them before me to comply with the requirement for exhaustion of administrative remedies and thus preserve the arguments on appeal. P. Br. at 2.

a. Section 489.13(b) does not permit an effective date earlier than the last day of the survey finding compliance.

The language of the applicable regulation at 42 C.F.R. § 489.13(b) is unambiguous and specifically requires that, for a supplier of portable X-ray services, the survey finding compliance with all applicable requirements is a condition precedent to an effective date. The earliest date that a supplier, such as Petitioner, can be approved is the date that the survey is completed.

In support of its argument that the regulation can be read to permit an earlier date, Petitioner points to the following statement in the SOM: "[a] . . . supplier cannot begin to have its services covered and reimbursed by Medicare until the date on which it is found, via the certification process, to be in compliance with all federal requirements, including compliance with . . . the [conditions for coverage] if it is a supplier . . . ." P. Br. at 4 (citing CMS Ex. 15, at 13). Petitioner suggests that this statement implies a "more lenient" view that a supplier may be paid for services once it actually achieves compliance, even if no survey confirming that has been completed yet. This suggestion is not supported by the wording of the statement, which dictates that a supplier cannot begin to have services paid before it is in compliance with all applicable conditions. Nothing in the statement suggests that a supplier is entitled to have all services paid from the date it first achieves compliance, contrary to the explicit requirement that coverage does not begin until the survey verifying compliance is completed. Moreover, the SOM specifically states that the supplier must be found to be in compliance thru the certification process, which is the survey, before the supplier may be paid for any services.

Furthermore, the SOM goes on to warn that because "it usually is impossible to schedule and complete a survey, i.e., ascertain actual compliance with all applicable requirements, on the date a new institution opens its doors[,] [t]he institution generally must operate for a short initial period without Medicare payment for its services." CMS Ex. 15, at 14. This explanation should have put Petitioner on notice that services provided prior to the completion of the survey would not be covered. Petitioner argues that six months is too long to be described as a "short initial delay." P. Br. at 6. While I recognize that the timing of the survey created difficulties for Petitioner, I cannot remedy those difficulties by ignoring the plain language of the regulation.

Petitioner, however, argues that the form reporting the results of its survey "contains not one but **two** inspection dates." P. Br. at 5 (emphasis in original). In addition to the entry of "4-28-09" as "date surveyed," Petitioner points to an entry of "10-08" as "Date of Last Inspection." *Id.* (citing CMS Ex. 12, at 1, 10). Petitioner suggests that I apply the regulation by concluding that the state survey agency therefore found that Petitioner "met all applicable federal requirements on the earliest date identified by [the state survey agency] on the Form 1882, which is October 2008." P. Br. at 7. The short answer is that the regulation does not provide for an effective date on the earliest date on which an

inspection took place or on which applicable requirements were met but on the "date the survey . . . is completed," if the applicable requirements were met on that date. 42 C.F.R. § 489.13(b). The documents establish, and Petitioner does not dispute, that the initial certification survey was completed on April 28, 2009. *See*, *e.g.*, CMS Exs. 1, 12.[2]

Petitioner also contends, however, that the surveyors found that Petitioner was actually in compliance as of October 2008 because they reviewed data from October 2008. P. Br. at 4-5. In her affidavit, Kim S. Algoo asserts (and I accept as true for these purposes) that she is familiar with the survey conducted on April 28, 2009 and that the surveyors "requested patient information and files dating back to [Petitioner's] first day of service, October 27, 2008, . . . in addition to the material [she] had previously provided . . . ." Premier Ex. 1, at 2. A compliance evaluation may logically require a review of records for prior services performed since the standards being evaluated include, for example, referrals for service and preservation of records (section 486.106). As with the equipment inspection standards, however, the record review addresses only some, but not all, of the standards which must be found to be met for the surveyors to conclude that compliance has been achieved.

It is true, as Petitioner argues, that a supplier must start operations prior to a survey to generate patient files to be reviewed for compliance. P. Br. at 9. As noted above, CMS recognized that the result is an interlude in which services are provided but are not eligible for payment.

Moreover, Ms. Algoo's affidavit only establishes that some of the records reviewed dated back as far as October 27, 2008. Ms. Algoo does not suggest that the surveyors concluded that Petitioner was in compliance based solely on the records from October 2008. On the contrary, she implies that they requested other, presumably more recent, information. I cannot therefore conclude that Petitioner was found in actual compliance as of October 2008. All that it is possible to conclude is that Petitioner was found to be in compliance as of April 28, 2009, when the surveyors completed their review of all the documentation and found that all the conditions were met.

I conclude that, even viewing the facts in the light most favorable to Petitioner, the regulations mandate the effective date of participation as April 28, 2009, the date Petitioner's successful survey was completed.

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[2] The "date of last inspection" recorded on the survey report form is entered in relation to evaluating whether Petitioner met the requirements in 42 C.F.R. § 486.110 that its equipment be inspected every 24 months by a qualified radiation health specialist. CMS Ex. 12, at 9-10. This inspection relates to only one of the conditions that had to be met for the initial certification survey to find that Petitioner was in compliance.

b. The state agency's finding that Petitioner was entitled to priority exception status for its survey does not entitle Petitioner to a different effective date.

As mentioned above, it is undisputed that CMS granted Petitioner priority exception status and authorized the state agency to place Petitioner in their queue for an initial survey. CMS Ex. 5. In its hearing request Petitioner argues that denying Petitioner an earlier effective date undermines its priority exception status. P. Br. at 4.

The issue of what priority to accord to Petitioner's survey arose from a memorandum from CMS to state survey agencies in November 2007 regarding how to prioritize work in light of budget limitations. CMS Ex. 14. Overall, the first priority was to go to statutorily mandated surveys of existing providers, lower priority to investigations and recertifications of existing providers, and the lowest priority to most initial surveys of new suppliers. CMS Br. at 5; CMS Ex. 14, at 2-3, 6-9. The memorandum provides a process for suppliers to seek exceptions or receive higher priority due to various situations. CMS Br. at 5-6; CMS Ex. 14, at 3-4, 8. Newly-applying suppliers may be approved on an exception basis by the CMS Regional Office "due to serious health care access considerations or similar special circumstances . . . ." CMS Ex. 14, at 8. Petitioner sought such an exception by letters dated January 20, 2009 and January 26, 2009, supplemented by an email dated March 30, 2009. Premier Ex. 2; CMS Exs. 3 and 4. By letter dated April 16, 2009, CMS granted Petitioner's request based on the access to care issues and authorized the state survey agency to place Petitioner "in their queue for an initial survey," while noting that completion of the survey would still "be contingent on the accomplishment of the required recertification workload." CMS Ex. 5, at 2.

The effect of granting Petitioner priority exception status was thus to permit it to be surveyed before other suppliers seeking initial enrollment who did not possess such special circumstances. Prioritizing the survey offered some benefit to Petitioner by causing the survey to be completed at a date earlier than it might otherwise have been, so that an earlier effective date would result from the application of section 489.13(b). Petitioner points to nothing, however, that indicates that this status entitled it to an earlier effective date than that mandated by section 489.13(b). To the extent that Petitioner's real complaint is that the survey was not conducted even sooner, I note that section 498.3(d) specifically provides that "[a] decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier" is an administrative action that is not an initial determination and not subject to appeal.

I conclude that, even viewing the facts in the light most favorable to Petitioner, its priority exception status does not permit an effective date of participation earlier than April 28, 2009.

3. I do not have authority to find 42 C.F.R. § 489.13(b) invalid or unconstitutional.

Petitioner asserts that 42 C.F.R. § 489.13(b) as applied violates the Equal Access Provision of the Medicaid Act, 42 U.S.C. § 1396a. Petitioner asserts that its effective date of Medicare enrollment governs the effective date for Medicaid participation, so that setting Petitioner's effective date of enrollment to the date its survey was completed provides an additional financial burden on Petitioner and results in a serious lack of access to services to Medicaid patients in violation of the statute. Premier Ex. 1; P. Br. at 7-8 (citing CMS Ex. 5). Petitioner argues that "[r]egulations must be construed and applied in a manner that [does] not conflict with governing federal statutory laws," so that here a Medicare regulation should not be interpreted to thwart the statutory requirement to provide Medicaid patients with access to care. P. Br. at 8.

Section 489.13(b) is unambiguous in its provision of the relevant effective date. Therefore, it is not subject to interpretation but applies here by its plain terms. As Petitioner recognizes, it is not within my bailiwick to strike down an applicable federal regulation based on a claim that conflicts with a federal statute.

In any case, it does not appear to me that Petitioner has shown that section 489.13(b) as written or applied is in conflict with the Medicaid law. The cited statute provides that care and services shall be available to Medicaid beneficiaries "at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a. While CMS agreed that Medicare beneficiaries would suffer adverse access consequences if Petitioner did not become Medicare certified, Petitioner has not made a showing about the extent of access to portable X-ray services by Medicaid beneficiaries or by the general population in the Hennepin County area to which CMS referred. *See* CMS Ex. 5, at 2. Although Petitioner stressed that its financial losses included $6,698.95 in unpaid Medicaid services, in addition to $40,760.03 in unpaid Medicare services, Petitioner has not shown that the statute is intended to guarantee the financial status of suppliers, or that these losses would result in Petitioner not providing portable X-ray services in the future. *See* P. Br. at 7; Premier Ex. 1, at 3.

Turning to Petitioner's constitutional arguments, it is "well established that administrative forums, such as [the] Board and the Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional." *Sentinel Med. Labs., Inc.*, DAB No. 1762, at 9 (2001), *aff'd, Teitelbaum v. Health Care Fin. Admin.*, 32 F. App'x 865 (9th Cir. 2002). As previously discussed, the regulation is unambiguous in language and clear in application. I therefore am without authority to ignore the applicable regulation.

Petitioner contends that requiring it to begin operations and provide services before a survey can find compliance effects an unjust taking of its property in the form of uncompensated care. P. Br. at 9-10. The Board has previously noted that "[c]ourts that

have considered the issue have almost without exception concluded that a physician or other health care practitioner or entity does not have a protected interest in continuing eligibility for Medicare participation or reimbursement." *Robert F. Tzeng, M.D.*, DAB No. 2169, at 13-14 n.16 (2009) (citations omitted). Petitioner claims that this regulation interfered with "distinct investment-backed expectations," but does not explain how such expectations could reasonably have been formed in light of the notice provided by the regulation of how the effective date would be calculated (and the warnings in the SOM about the lag between opening services and obtaining a survey).

Petitioner also contends that section 489.13(b) denies it equal protection without any rational basis in that categories of suppliers that have recognized accrediting bodies can obtain retroactive effective dates. P. Br. at 12. Providers and suppliers that are already accredited by a national organization that CMS approved, such that its accreditation is deemed to constitute compliance with all federal requirements, are given effective dates when they initially request participation in Medicare (for those that must meet additional requirements, the effective date is when they meet those additional requirements). 42 C.F.R. § 489.13(d)(1). Section 489.13(d)(2) allows retroactive effective dates of up to one year to encompass dates when services were provided but not paid for those providers and suppliers. Petitioner argues that this distinction is irrational, because state survey agencies could evaluate past compliance with federal standards when they surveyed nonaccredited suppliers like Petitioner. Again, I could not strike down section 489.13(b) based on this constitutional argument, but I also find it difficult to see why it would be irrational for CMS to give weight to accreditation by organizations it has already approved but not choose to require state survey agencies to attempt to determine whether other applicants were in compliance at some date earlier than the initial survey.

Through each of Petitioner's arguments runs essentially the same theme -- that its enrollment date should be set at an earlier date based on equitable principles. However sympathetic I may find that theme, I have no authority to resort to equitable principles to establish an effective date earlier than that contemplated by section 489.13(b). *See US Ultrasound*, DAB No. 2302 (2010); *Oklahoma Heart Hosp.*, DAB No. 2183 (2008); *Forest Glen Skilled Nursing Ctr.*, DAB No. 1887 (2003).

IV. Conclusion

For the reasons set forth above, I grant CMS's motion for summary disposition and affirm CMS's determination to approve Petitioner's Medicare participation effective April 28, 2009, the date the state agency survey was completed finding Petitioner to be in compliance with all applicable federal requirements.

/s/
Leslie A. Sussan
Board Member