Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Fresenius Medical Care Randallstown, LLC,

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-14-735

Decision Number CR3343

Date: August 25, 2014

DECISION

Petitioner, Fresenius Medical Care Randallstown, LLC, met the requirements to be approved and enrolled in Medicare as an End Stage Renal Disease (ESRD) facility, effective September 5, 2013.

I. Background

The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated October 25, 2013, that Petitioner was approved as a supplier of ESRD services effective September 9, 2013. CMS Exhibit (Ex.) 1 at 21-22. On November 11, 2013, CMS notified Petitioner that CMS changed the effective date to September 5, 2013. CMS Ex. 1 at 23-26. On January 14, 2013, Petitioner requested reconsideration of the effective date and that the date be changed to August 5, 2013, the date Petitioner first provided dialysis services to patients. Petitioner's Exhibit (P. Ex.) 1; CMS Ex. 1, at 27-28.

On March 17, 2014, CMS notified Petitioner that the September 5, 2013 effective date was upheld on reconsideration. CMS Ex. 1 at 1-2.

Petitioner requested a hearing before an administrative law judge (ALJ) on February 10, 2014.[1] The case was assigned to me for hearing and decision on March 10, 2014, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. CMS filed a combined motion for summary judgment and prehearing brief (CMS Br.) with CMS Ex. 1 on April 8, 2014. Petitioner filed its prehearing exchange including its brief (P. Br.) and P. Exs. 1 through 7 on June 2, 2014. CMS filed a reply (CMS Reply) on July 15, 2014. The parties did not object to my consideration of the offered exhibits and CMS Ex. 1 and P. Exs. 1 through 7 are admitted.

II. Discussion

A. Applicable Law

The Social Security Act (the Act) requires that the Secretary of Health and Human Services (the Secretary) issue regulations to establish a process for the enrollment of providers and suppliers, including the right to a hearing and judicial review of certain enrollment determinations.[2] Act § 1866(j)(1) (42 U.S.C. § 1395cc(j)(1)). Section 1881 of the Act (42 U.S.C. § 1395rr) authorizes Medicare coverage and payment for the treatment of individuals suffering ESRD, subject to the conditions specified in the Act and regulations promulgated by the Secretary. Act § 1881(a), (b)(1).

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[1] Petitioner's February 10, 2014 request for hearing pre-dates the March 17, 2014 reconsideration determination. However, the parties have not raised any jurisdictional issue and I find none.

[2] A "supplier" furnishes services under Medicare and the term supplier applies to physicians or other practitioners and facilities that are not included within the definition of the phrase "provider of services." Act § 1861(d) (42 U.S.C. § 1395x(d)). A "provider of services," commonly shortened to "provider," includes hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice programs, and a fund as described in sections 1814(g) and 1835(e) of the Act. Act § 1861(u) (42 U.S.C. § 1395x(u)). The distinction between providers and suppliers is important because they are treated differently under the Act for some purposes. Petitioner is a supplier.

The Secretary's regulations establishing the conditions for coverage for ESRD facilities are at 42 C.F.R. pt. 494.[3] The Secretary's regulations governing the Medicare enrollment of providers and suppliers, including ESRD facilities, are found in 42 C.F.R. pt. 424, subpt. P. Pursuant to 42 C.F.R. § 424.510(a), a provider or supplier must submit the applicable enrollment application and, if applicable, be surveyed and certified or accredited, before CMS can enroll the provider or supplier. ESRD facilities are surveyed prior to enrollment to determine whether or not they meet the conditions for coverage established by 42 C.F.R. pt. 494. 42 C.F.R. §§ 488.3; 494.1(b). The effective date of enrollment and the date of eligibility for reimbursement is determined under 42 C.F.R. § 489.13 for providers and suppliers that require a survey and certification or accreditation. 42 C.F.R. § 424.510(b). If an ESRD facility meets all the conditions for coverage established by 42 C.F.R. pt. 494 at the time of the required survey, the effective date of the facility's approval to participate and its enrollment as a supplier in Medicare is effective the date on which the survey is completed or the date on which all other enrollment and participation requirements are met, whichever is later. 42 C.F.R. § 489.13(b). If the ESRD facility does not meet all the conditions for coverage established by 42 C.F.R. pt. 494 on the date the required survey is completed, assuming all other enrollment and participation requirements for supplier approval are met, the effective date of approval to participate and enrollment is the earlier of:

> The date on which the ESRD facility meets all conditions for coverage; or
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> The date on which the ESRD facility meets all conditions for coverage, but has lower-level deficiencies and CMS or the state receives an acceptable plan of correction for the lower-level deficiencies; or the date on which CMS receives an approvable waiver request.

42 C.F.R. § 489.13(c)(2)(i) and (ii).

If the ESRD facility does not meet other enrollment and participation requirements when it meets the conditions for coverage, the effective date of supplier approval and enrollment will be the date on which all other enrollment and participation requirements are met. 42 C.F.R. § 489.13(c)(2).

B. Issues

The issues in this case are:

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[3] Citations are to the 2012 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

Whether summary judgment is appropriate; and

Whether the effective date of Petitioner's approval and enrollment in Medicare as a supplier of ESRD services should be August 5, 2013, rather than September 5, 2013.

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold followed by my findings of fact and analysis.

1. Summary judgment is appropriate.

CMS has requested summary judgment. Summary judgment is not automatic upon request but is limited to certain specific conditions. The Secretary's regulations that establish the procedure to be followed in adjudicating Petitioner's case are at 42 C.F.R. pt. 498. 42 C.F.R. §§ 424.545(a), 498.3(b)(5), (15). The regulations do not establish a summary judgment procedure or recognize such a procedure. However, the Departmental Appeals Board (the Board) has long accepted that summary judgment is an acceptable procedural device in cases adjudicated pursuant to 42 C.F.R. pt. 498. *See, e.g., Ill. Knights Templar Home*, DAB No. 2274, at 3-4 (2009); *Garden City Med. Clinic*, DAB No. 1763 (2001); *Everett Rehab. & Med. Ctr.*, DAB No. 1628, at 3 (1997). The Board also has recognized that the Federal Rules of Civil Procedure do not apply in administrative adjudications such as this, but the Board has accepted that Federal Rule of Civil Procedure 56 and related cases provide useful guidance for determining whether summary judgment is appropriate. Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Prehearing Order dated March 10, 2014. The parties were given notice by the Prehearing Order that summary judgment is an available procedural device and that the law as it has developed related to Fed. R. Civ. Pro. 56 will be applied.

Summary judgment is appropriate when there is no genuine dispute as to any issue of material fact for adjudication and/or the moving party is entitled to judgment as a matter of law. 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. The party requesting summary judgment bears the burden of showing that there are no genuine issues of material fact for trial and/or that it is entitled to judgment as a matter of law. Generally, the non-movant may not defeat an adequately supported summary judgment motion by relying upon the denials in its pleadings or briefs but must furnish evidence of a dispute concerning a material fact, i.e., a fact that would affect the outcome of the case if proven. *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (and cases cited therein).

See also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The standard for deciding a case on summary judgment and an ALJ's decision-making in deciding a summary judgment motion differs from that used in resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment the ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009). The Board also has recognized that on summary judgment it is appropriate for the ALJ to consider whether a rational trier of fact could find that the party's evidence would be sufficient to meet that party's evidentiary burden. *Dumas Nursing and Rehab., L.P.*, DAB No. 2347, at 5 (2010). The Secretary has not provided for the allocation of the burden of persuasion or the quantum of evidence in 42 C.F.R. pt. 498. However, the Board has provided some persuasive analysis regarding the allocation of the burden of persuasion in cases subject to 42 C.F.R. pt. 498. *Batavia Nursing and Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 Fed. App'x 181 (6th Cir. 2005).

The material facts in this case are not disputed and there is no genuine dispute as to any material fact that requires a trial. The issues in this case that require resolution are issues of law related to the interpretation and application of the regulations that govern enrollment and billing privileges in the Medicare program to the undisputed facts of this case. Accordingly, summary judgment is appropriate.

2. Pursuant to 42 C.F.R. § 489.13(c)(2)(ii)(A), Petitioner's effective date of Medicare enrollment is September 5, 2013, the date on which CMS or the state agency received an acceptable plan of correction for lower-level deficiencies that did not amount to noncompliance with the ESRD conditions for coverage.

Petitioner constructed and operates an ESRD facility located in Randallstown, Maryland in the Randallstown Nursing and Rehab Center. Petitioner provides dialysis services for the long-term care facility residents. There is no dispute that Petitioner began providing dialysis services at its facility on August 5, 2013. P. Br. at 1; P. Ex. 2.

On June 12, 2013, Novitas Solutions, Inc. (Novitas), a CMS Medicare Administrative Contractor, informed CMS that on June 5, 2013, it received an application from Petitioner to enroll in Medicare as a supplier of ESRD services. Novitas further informed CMS that it was recommending approval of the application. CMS Ex. 1 at 3.

On July 29, 2013, the Ambulatory Care Unit of the Maryland Department of Health and Mental Hygiene (state survey agency) completed a state licensure survey. The state survey agency found that Petitioner was compliant with Maryland regulations governing

freestanding ambulatory care facilities. The report completed by the state survey agency does not show that Petitioner's compliance with the federal conditions for coverage established by 42 C.F.R. pt. 494 was assessed. CMS Ex. 1 at 4.

On August 21, 2013, the state survey agency completed an initial Medicare certification survey that investigated whether or not Petitioner's facility met the conditions for coverage established by 42 C.F.R. pt. 494. The report of the survey shows that the surveyors found no condition-level deficiencies. However, the surveyors did find seven lower-level or standard-level deficiencies. CMS Ex. 1 at 5-17; P. Ex. 5. On August 28, 2013, the state survey agency provided Petitioner a copy of the report of the August 21 survey and directed that Petitioner submit a written plan of correction for the cited deficiencies within ten calendar days. P. Ex. 5 at 1-2. On September 5, 2013, Petitioner submitted its plan of correction. P. Ex. 5 at 3-16; CMS Ex. 1 at 5-17 (right column). There is no dispute that the plan of correction was received by the state survey agency on September 5, 2013. There is also no dispute that the plan of correction received by the state survey agency on September 5, 2013, was approved by the state survey agency on September 9, 2013. CMS Ex. 1 at 5-20, 29; P. Ex. 6.

CMS notified Petitioner on October 25, 2013, that Petitioner was approved to participate in Medicare as an ESRD supplier effective September 9, 2013. CMS Ex. 1 at 21-22. However, on November 5, 2013, CMS corrected the effective date of Petitioner's enrolment to September 5, 2013. CMS Ex. 1 at 23-24. Petitioner was notified of the effective date change by CMS on November 11, 2013. CMS Ex. 1 at 25-26.

On January 14, 2014, Petitioner requested that the effective date of its approval to participate in Medicare as an ESRD supplier be changed from September 5, 2013 to August 5, 2013. CMS Ex. 27-28; P. Ex. 1. CMS denied Petitioner's request (CMS Ex. 1 at 1-2) and Petitioner argues before me that I should make the requested change. P. Br. at 2.

Petitioner argues that its effective date should be based on the July 29, 2013 survey that found no deficiencies. Petitioner argues that CMS conducted the July 29 survey; found no deficiencies; and cleared Petitioner to treat patients. P. Ex. 2 at 2; P. Br. at 1-2. Petitioner's argument mischaracterizes the evidence. The July 29 survey was completed by the state survey agency for the purpose of determining whether Petitioner met state licensing requirements, not for determining whether Petitioner met the federal conditions for coverage established by 42 C.F.R. pt. 494. CMS Ex. 1 at 4. Petitioner has presented no evidence that conflicts with my reading of CMS Ex. 1 at 4 or that shows a genuine dispute regarding whether Petitioner's compliance with federal conditions for coverage was assessed by the survey completed on July 29, 2013. The Board has considered this issue in prior cases and concluded that a state licensure survey is no substitute for the survey required to determine compliance with federal participation requirements or conditions for coverage. *Cmty. Hosp. of Long Beach*, DAB No. 1938, at 8-9 (2004) (fact

that state agency surveyors determined hospital met state hospital standards for licensure does not show facility met federal hospital standards on the date of state licensure survey); *Arbor Hosp. of Greater Indianapolis*, DAB No. 1591, at 6 (1996) (regulations require that the survey process be used to examine a facility's compliance with applicable program requirements and Medicare participation is not effective until all federal health and safety conditions of participation are met).

The evidence before me shows, and I conclude, that there is no genuine dispute as to the material fact that Petitioner's compliance with federal conditions for coverage was not assessed by a survey prior to the survey completed on August 21, 2013. Petitioner has presented no evidence from which I might infer that Petitioner's compliance with the federal requirements was assessed prior to August 21, 2013.

I am bound to follow the regulations and the regulation is clear in this case. The survey completed on August 21, 2013, was the survey that assessed whether Petitioner met the federal conditions for coverage. The survey found no condition-level violations but found standard-level deficiencies. When the required survey determines that an ESRD supplier meets all conditions for coverage but has standard-level deficiencies, the effective date of approval as an ESRD supplier is the date on which CMS or the state survey agency received an acceptable plan of correction for the standard-level deficiencies.[4] 42 C.F.R. § 489.13(c)(2)(ii)(A). Petitioner's plan of correction was received by CMS or the state survey agency on September 5, 2013, and that is the earliest effective date of approval and enrollment as an ESRD supplier permitted under the regulations.

Petitioner raises several equitable arguments related to the need for Petitioner to begin delivering dialysis services on August 5, 2013; the cost associated with delivering dialysis services; and the adverse economic impact upon Petitioner if Medicare does not reimburse for services rendered between August 5 and September 5, 2013. However, I have no authority to deviate from the requirements of the regulation to accord Petitioner relief on equitable grounds in the form of an earlier effective date or an order for CMS to reimburse for services rendered. *US Ultrasound*, DAB No. 2302, at 8 (2010) ("[n]either the ALJ nor the Board is authorized to provide equitable relief by reimbursing or enrolling a supplier who does not meet statutory or regulatory requirements.") I also have no authority to declare statutes or regulations invalid or ultra vires. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009) ("[a]n ALJ is bound by

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[4] There is no issue that Petitioner met all other enrollment requirements and there was no request for waiver under 42 C.F.R. § 489.13(c)(2)(ii)(B).

applicable laws and regulations and may not invalidate either a law or regulation on any ground.”).

III. Conclusion

For the foregoing reasons, I conclude that the effective date of Petitioner’s approval as an ESRD supplier and Medicare enrollment was September 5, 2013.

/s/
Keith W. Sickendick
Administrative Law Judge