Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Renal CarePartners of Delray Beach, LLC, (CCN: 10-2854),	)	Date: May 8, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-09-140
	)	Decision No. CR1950
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

This matter is before me on the Motions for Summary Judgment filed by the Centers for Medicare & Medicaid Services (CMS) and by Petitioner Renal CarePartners of Delray Beach, LLC (Renal CarePartners). CMS and Renal CarePartners have filed briefs and exhibits in support of their positions. All proffered exhibits have been admitted. Having reviewed these pleadings and exhibits, I find that no material facts remain in dispute and conclude that CMS's position is correct as a matter of well-recognized and long-established law. I therefore grant CMS's Motion and thus summarily affirm CMS's determination to approve Renal CarePartners' provider agreement as an end-stage renal disease treatment center (ESRD) under the Medicare program effective November 21, 2007, but not earlier. Renal CarePartners' Motion is in all respects denied.

I. Procedural Background

Renal CarePartners is an ESRD located in Delray Beach, Florida. On or about April 18, 2007, Renal CarePartners began the process of applying for certification to participate in the Medicare program by submitting a CMS Form 855A (Form 855A) to the Medicare Part A fiscal intermediary for Florida, First Coast Service Options (First Coast). By letter dated May 11, 2007, Renal CarePartners informed the Agency for Health Care Administration (AHCA or state survey agency) that the facility was fully operational and providing treatment for dialysis patients. CMS Exhibit (Ex.) 1. Renal CarePartners requested AHCA to visit the facility to

perform the initial certification survey. CMS Ex. 1. On July 6, 2007, AHCA conducted the initial certification survey of Renal CarePartners. P. Ex. A. The survey revealed no deficiencies, and the survey report stated that Renal CarePartners "was found in compliance with the requirements for ESRD Facilities at 42 C.F.R. Part 405.2100, Subpart U." P. Ex. A. According to Renal CarePartners, at the exit interview, the state surveyor advised the facility's staff that the facility had no deficiencies and they could begin to admit Medicare patients.

On August 9, 2007, First Coast requested further documentation from Renal CarePartners to complete its Form 855A review process. P. Ex. B. On August 10, 2007, Renal CarePartners faxed the requested information to First Coast. P. Ex. C. On September 26, 2007, Renal CarePartners re-faxed the documents it had submitted to First Coast on August 10, 2007. P. Ex. D. By letter dated November 21, 2007, First Coast advised Renal CarePartners that its Form 855A had been validated, a recommendation had been made to AHCA, and that AHCA would determine the next steps in the enrollment process. P. Ex. E.

Renal CarePartners received correspondence from AHCA dated November 29, 2007. In this letter, the state survey agency informed Renal CarePartners that its Form 855A had been received and was complete, and informed it of the next steps in the process to be certified to participate in the Medicare program. P. Ex. F. Renal CarePartners received another letter from AHCA dated February 8, 2008, in which AHCA formally advised Renal CarePartners that it was found to be in compliance with the applicable federal regulations during its initial certification survey of July 6, 2007.[1] P. Ex. G. By letter dated March 26, 2008, CMS informed Renal CarePartners that it met all federal requirements for participation in the Medicare program effective November 21, 2007. The letter further explained that the effective date was established in part based on the date First Coast approved Renal CarePartners' Form 855A, which was November 21, 2007. P. Ex. H.

On September 22, 2008, Renal CarePartners requested that CMS reconsider its effective certification date and change the effective date to July 6, 2007. P. Ex. I.

CMS declined to alter the date, and affirmed the November 21, 2007 date in a letter to Renal CarePartners on October 16, 2008. CMS stated in the letter that the earliest date CMS could accept that Renal CarePartners met all federal requirements was the date that First Coast recommended approval for its enrollment in the Medicare program – November 21, 2007. P. Ex. J.
On December 10, 2008, Renal CarePartners timely filed a request for hearing contesting CMS's determination to certify Renal CarePartners eligible to

[1] AHCA's letter states that the survey of Renal CarePartners was conducted on "July 7, 2007." The date appears to be a typographic error.

participate in the Medicare program effective November 21, 2007. As it has below, Renal CarePartners asserts here the effective date should be July 6, 2007.

II. Issue

The issue before me is simply whether Renal CarePartners is entitled to approval or certification as a Medicare provider effective as of any date prior to November 21, 2007.

This issue has been addressed in a variety of factual settings by several other Administrative Law Judges (ALJs), by appellate panels of the Departmental Appeals Board (Board), and by me most recently in *Cedar Park Regional Medical Center*, DAB CR1919 (2009); *Dublin Methodist Hospital*, DAB CR1894 (2009); *University Behavioral Health of El Paso, LLC*, DAB CR1880 (2009); *Physicians Medical Center of Santa Fé, LLC*, DAB CR1790 (2008); and *Oklahoma Heart Hospital*, DAB CR1719 (2008), *aff'd*, DAB No. 2183 (2008). Some of those cases differ slightly from the present one in certain factual details, but all invoke rules well-settled in this forum, and all rest on principles that require the conclusion that Renal CarePartners is not entitled to approval or certification as a Medicare provider on any date prior to November 21, 2007.

III. Controlling Statutes and Regulations

In order to participate in the Medicare program, a prospective provider such as an ESRD must apply for and be granted an approved provider agreement with CMS.[2] The general framework of the application process is set out at section 1866 of the Social Security Act (Act), 42 U.S.C. § 1395cc. Before CMS will approve a provider agreement and certify that a prospective provider is eligible, the provider must meet all of the requirements of participation relevant to that provider. 42 C.F.R. §§ 488.3(a)(2), 489.10(a).

One requirement ESRDs wishing to participate in Medicare must meet addresses the identity, qualifications, and character of the prospective provider's *operating entity*. The eligibility of the *operating entity* must be assessed according to the criteria established at 42 C.F.R. §§ 489.10 and 489.12 for transparency of ownership, reliability, financial soundness, and compliance with important civil rights standards. CMS may decline to approve a provider agreement if the

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[2] ESRD facilities are classified as "suppliers," but it has been held that they are subject to the application, survey, certification, and enforcement requirements applicable to "providers." *Maher A. A. Azer (Florence Dialysis Center, Inc.)*, DAB CR994 (2003), citing *Renal Services Group of El Centro,* DAB CR482 (1997); and *SRA D/B/A St. Mary Parish Dialysis Center*, DAB CR341 (1994).

facility's *operating entity* does not meet the criteria listed at 42 C.F.R. §§ 489.10 and 489.12.

Another such requirement is that the ESRD's *facility* must be surveyed on-site by an agency authorized by CMS to do so, in order that its compliance with the requirements of the Medicare program can be assessed and certified. 42 C.F.R. §§ 489.2(b)(1) and 489.10(a). Either the state agency or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is authorized to conduct certification surveys. 42 C.F.R. § 488.5. When the surveying agency has completed its on-site survey, it reports the results and its recommendations to CMS. 42 C.F.R. § 488.11(a). On the basis of the agency's report and recommendations, CMS will determine whether the ESRD's *facility* is eligible to participate in the Medicare program. 42 C.F.R. § 488.12(a)(1).

Generally, the earliest date on which an ESRD may be certified by CMS to participate in Medicare is established by 42 C.F.R. § 489.13. If an ESRD's *operating entity* has satisfied all other requirements and the survey of that provider's *facility* is the final step in the review sequence, then 42 C.F.R. § 489.13(b) controls:

> b) *All federal requirements are met on the date of the survey*. The 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.

In practice, the survey is usually the last step in the process. But, significantly, 42 C.F.R. § 489.13(c) provides for situations in which the *facility* survey may be completed before the *operating entity* has been approved:

> (c) *All Federal requirements are not met on the date of survey*. If on the date the survey is completed the provider or supplier fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:
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> * * * *
>
> (2) For an agreement with, or an approval of, any other provider . . . the effective date is . . . :
>
> (i) The date on which the provider or supplier meets all requirements.

Until a facility's *operating entity*'s eligibility has been assessed and verified, and until the *facility* has been surveyed and certified, its agreement cannot be approved. Until its agreement has been approved based on those assessments, its status is that of a *prospective provider*. 42 C.F.R. § 498.2. With limited exceptions, none of which are relevant in the matter presently before me, a *prospective provider*, such as an ESRD, may not receive reimbursement for services provided to Medicare beneficiaries prior to the effective date of its provider agreement. Act, section 1814(a) (42 U.S.C. § 1395f(a)).

IV. Findings of Fact and Conclusions of Law

I find and conclude as follows:

1. Petitioner Renal CarePartners did not meet all applicable federal requirements for participation in the Medicare program when the AHCA survey of the facility was completed on July 6, 2007.

2. Petitioner Renal CarePartners did not meet all applicable federal requirements for participation in the Medicare program at any time between July 6, 2007 and November 21, 2007.

3. Petitioner Renal CarePartners first met all applicable federal requirements for participation in the Medicare program on November 21, 2007, when First Coast approved its Form 855A.

4. Petitioner Renal CarePartners is entitled to approval or certification as a Medicare provider effective November 21, 2007, but not earlier.

5. There are no disputed issues of material fact and summary disposition is appropriate in this matter. I have viewed the facts and the inferences reasonably to be drawn from the facts in the light most favorable to the nonmoving party. *See Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3rd. Cir. 1986); *Brightview Care Center*, DAB No. 2132 (2007); *Madison Health Care, Inc*., DAB No. 1927, at 5-7 (2004).

V. Discussion

Although Renal CarePartners attempts to distinguish them, the decisions of this forum and of the Board that govern its resolution are not in doubt, either as to their meaning or as to their application in this appeal. They are clear and unambiguous, and their holdings may be summarized simply: a facility's application to be a Medicare provider may not be approved, and CMS may not certify it as a Medicare provider, until the facility has been determined to meet all applicable

federal requirements for participation in the Medicare program, both as to its *facility* and as to its *operating entity*.

There is no dispute as to the material facts surrounding the sequence of steps leading to CMS's letter of March 26, 2008. Renal CarePartners applied to participate in the Medicare program on April 18, 2007, by submitting its Form 855A to First Coast. AHCA completed its survey of Renal CarePartners' facility on July 6, 2007, and, based on the survey report, the facility was found to be in compliance with the Medicare requirements for ESRD facilities. The record shows that First Coast completed its review of Renal CarePartners' operating entity on November 21, 2007, and found the operating entity in compliance with Medicare requirements. On that date, First Coast wrote to Renal CarePartners, informing it that its Form 855A had been validated, and that a favorable recommendation to AHCA had been made. By letter dated February 8, 2008, AHCA formally advised Renal CarePartners that it was found to be in compliance with the applicable federal regulations during its initial certification survey of July 6, 2007. Renal CarePartners was subsequently informed by CMS in a letter dated March 26, 2008, that it met all federal requirements for participation in the Medicare program effective November 21, 2007, which is the date First Coast approved the facility's Form 855A.

It may very well be that the sequence described above is a reversal of the more commonly-seen sequence in which the facility survey is not undertaken until the fiscal intermediary has approved the operating entity. Most of the earlier recorded litigation in this forum seems to have been based on an "*entity*-approval first, *facility*-survey next" model. But that sequence is not the unvarying model, and four significant exceptions to that model apply to these facts and control the disposition of this dispute.

The first significant exception to the usual sequence appears in *SRA, Inc., D/B/A St. Mary Parish Dialysis Center*, DAB CR341 (1994), a case in which an ESRD sought certification of its Medicare provider agreement. The ESRD successfully "passed" a state agency survey of its facility, but certain aspects of the ESRD's management, and of its supervisory and professional arrangements, were not then in compliance with Medicare requirements. Eventually those operating arrangements were corrected and approved by CMS's predecessor agency, the Health Care Financing Administration (HCFA). The ESRD claimed that it was entitled to certification as of the date of the successful survey, but HCFA insisted that the ESRD had not met all requirements until its operating arrangements were

finally approved. In upholding HCFA's position, the ALJ announced the rule that controls this case:

> The regulations provide plainly that, where a provider or supplier fails to meet certification requirements at the date of the inspection, it will be found to satisfy those requirements either on the date when it actually meets the requirements or on the date that it submits a plan of correction acceptable to HCFA, whichever comes first. 42 C.F.R. § 489.13(a) and (b). Thus, a provider or supplier cannot be certified effective the date of survey where: (1) deficiencies are found to exist as of the survey date, and (2) the deficiencies are not corrected (or an acceptable plan of correction is not submitted by the provider or supplier) until a subsequent date.

SRA, DAB CR341, at 20.

In the three more recent cases to which I have referred briefly above, hospitals had "passed" a state survey or alternatively, received accreditation by the JCAHO, but had simply not yet met "all requirements" for certification because their operating entities had not been approved by the fiscal intermediary. Relying on the rule enunciated in *SRA*, I concluded in these cases that the hospitals could not be certified effective the dates of survey or accreditation as they asked because the approvals of their operating entities remained unresolved on that date. *Cedar Park Regional Medical Center*, DAB CR1919; *Dublin Methodist Hospital*, DAB CR1894; *Physicians Medical Center of Santa Fé, LLC*, DAB CR1790.

There are no exceptions to these rules based on delays in the administrative process of reviewing a facility's satisfaction of the participation requirements, and there are no exceptions based on a facility's claimed reliance on allegedly-erroneous representations it complains were made to it by representatives of CMS, a state agency, or a fiscal intermediary. "The governing regulations are essentially unforgiving." *Tenet HealthSystem Philadelphia, Inc.*, DAB CR663, at 7 (2000).

Thus, Renal CarePartners' claim that it reasonably relied on the surveyor's incorrect statement allegedly made at the exit interview concerning the effective date of its participation in Medicare, and provided ESRD services to Medicare patients to its detriment, is immaterial. Renal CarePartners' assertion is based on the doctrine of equitable estoppel. And equitable estoppel, particularly in cases involving the effective dates of Medicare provider agreements, is specifically beyond my authority to consider. *Oklahoma Heart Hospital*, DAB CR1719, at 10-11 (2008), *aff'd*, DAB No. 2183, at 16-17 (2008); *Maher A. A. Azer (Florence Dialysis Center, Inc.*), DAB CR994 (2003); *Danville HealthCare Surgery Center*, DAB CR892 (2002); *Everett Rehabilitation and Medical Center*, DAB CR455 (1997), *aff'd*, DAB No. 1628 (1997).

Further, Renal CarePartners' asserts that First Coast failed to make a recommendation on its Form 855A within the 30-day time frame as stated in the State Operations Manual (SOM) and that it suffered a delay of over seven months before receiving notice of approval of its Form 855A. As I have stated above, any delay that may occur in the processing of a Form 855A does not entitle the provider to Medicare privileges. Moreover, without exploring in detail the provisions of the SOM upon which Renal CarePartners relies, it will suffice to state that the SOM's provisions are without the force or effect of law, and may not be relied on to extend, enlarge, or otherwise alter the plain meaning of applicable regulations. *Beverly Health & Rehabilitation Services, Inc. v. Thompson*, 223 F. Supp. 2d 73, at 99-106 (D.D.C. 2002); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Aase Haugen Homes, Inc.*, DAB No. 2013, at 15 (2006). I need not resolve Renal CarePartners' factual assertions because they raise questions of fact that have no bearing on the issues I may properly consider. They represent no bar to summary disposition.

VI. Conclusion

For the reasons discussed above, Renal CarePartners' Motion for Summary Judgment is DENIED. CMS's Motion for Summary Judgment should be, and it is, GRANTED. I affirm CMS's determination to certify Renal CarePartners to participate in the Medicare program as a Medicare provider effective November 21, 2007, but not earlier.

/s/
Richard J. Smith
Administrative Law Judge