Department of Health and Human Services

# DEPARTMENTAL APPEALS BOARD

## Appellate Division

In the Case of:

Renal CarePartners of Delray Beach, LLC,

Petitioner,

- v. -

Centers for Medicare & Medicaid Services. DATE: September 28, 2009

Civil Remedies CR1950 App. Div. Docket No. A-09-100

Decision No. 2271

### FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Renal CarePartners of Delray Beach, LLC (Renal CarePartners) appealed the decision of Administrative Law Judge (ALJ) Richard J. Smith in <u>Renal CarePartners of</u> <u>Delray Beach, LLC</u>, DAB CR1950 (2009) (ALJ Decision). The ALJ granted summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), holding that the effective date of approval for Renal CarePartners' participation in the Medicare program as a supplier of endstage renal disease (ESRD) services is November 21, 2007, but no earlier.

)

For the reasons explained below, we conclude that the effective date of approval is July 6, 2007, the date the state survey agency completed its survey and found no deficiencies with respect to Renal CarePartners' compliance with the conditions for coverage of its services. CMS has not identified any other applicable federal requirement that Renal CarePartners was responsible for meeting that it did not, in fact, meet on that date. Instead, CMS argues that the effective date of approval for ESRD services may not be before the date on which a CMS contractor recommends approval of the supplier's enrollment application after verifying the accuracy of the information in the application. CMS provides no citation to any regulatory provision or policy issuance that identifies CMS or contractor approval as a requirement an ESRD supplier must meet before it may <u>furnish</u> services for which it will be reimbursed under Medicare once it is enrolled and obtains billing privileges. Moreover, CMS's position that a determination to approve an enrollment application is itself an "enrollment requirement" is inconsistent with the wording and history of the enrollment regulations.

Accordingly, we reverse the ALJ Decision and enter summary judgment in favor of Renal CarePartners.

#### Factual and Legal Background

In 2006, CMS published regulations at 42 C.F.R. Part 424, subpart P, governing the process for enrollment of all providers and suppliers in the Medicare program. Subpart P describes completion of the enrollment process as a prerequisite for a provider or supplier "to bill" and "to receive payment" for Medicare covered services, "to be granted Medicare privileges," and "to establish eligibility to submit claims." 42 C.F.R. §§ 424.500; 425.505; and 424.502 (definitions of "Approve/Approval" and "Enroll/Enrollment"). To be enrolled, a provider or supplier must meet the "enrollment requirements" specified in section 424.510(d), which incorporates by reference the additional compliance and reporting requirements in section 424.520. CMS is responsible for validating the accuracy of the information submitted as part of the enrollment process, but CMS uses Medicare contractors to verify the information and to recommend approval or denial to CMS.

In this case, it is undisputed that Renal CarePartners submitted its enrollment application on April 18, 2007, was fully operational on May 11, 2007, and was surveyed on July 6, 2007. CMS Motion for Summary Judgment (MSJ) dated Jan. 14, 2009, at 1-3. The Medicare contractor, First Coast Options (First Coast), did not, however, notify Renal CarePartners until November 21, 2007 that First Coast had validated the enrollment application and was recommending

### that CMS approve it.<sup>1</sup> Id. at 3; P. Ex. E.

With respect to the effective date of Medicare <u>reimbursement</u>, the enrollment regulations incorporate by reference the regulation at 42 C.F.R. § 489.13, as well as other regulatory provisions. 42 C.F.R. § 424.510(b). The preamble to the 2006 final rule explained that, while CMS would not "grant billing privileges" until completion of the enrollment process and approval of the enrollment application, the "effective date for reimbursement of Medicare covered services would continue to be determined based on current Medicare regulations and policy based on the type of provider or supplier submitting the claims." 71 Fed. Reg. 20,754, 20,758 (Apr. 21, 2006).

Part 489 of Title 42 applies generally to "providers," which must enter into provider agreements to participate in Medicare. 42 C.F.R. §§ 489.2 (scope of part), 489.3 (definition of "provider agreement"). Section 489.13, however, also applies to supplier approval of entities such as ESRD centers that, as a basis for participation in Medicare, are subject to survey and certification by CMS or a state survey agency. 42 C.F.R. § 489.13(a). Section 489.13(b) provides that, if all federal requirements are met on the date of the survey, the effective date of supplier approval is the date the survey is completed.

CMS concedes in this case that the state survey agency, the Florida Agency for Health Care Administration (AHCA), found Renal CarePartners to be in compliance with the requirements for ESRD facilities at 42 C.F.R. Part 405, subpart U, on July 6, 2007, the date of the survey. CMS MSJ at 2-3. In other words, AHCA found that Renal CarePartners had no deficiencies in meeting either the applicable conditions for coverage of ESRD services or the lower level requirements in subpart U. CMS's only basis for denying Renal CarePartners' request that CMS reconsider its initial determination and set July 6, 2007 as the effective date of its approval as an ESRD supplier was that Renal CarePartners' enrollment application was not verified and approved until November 21, 2007. According to CMS, verification and approval of the enrollment application is

<sup>1</sup> CMS's appeal brief variously describes this date as the date First Coast recommended approval, the date of CMS's approval, and the date CMS accepted First Coast's recommendation.

one of the federal requirements referred to in the effective date provision. CMS's reconsideration determination did not identify any other requirement as an applicable federal requirement that Renal CarePartners failed to meet on the date of the survey. RC Ex. J.

Before the ALJ, the parties submitted cross motions for summary judgment. The ALJ Decision granted summary judgment to CMS, upholding its determination that the effective date of approval is November 21, 2007. In doing so, the ALJ relied on a 1994 ALJ decision and his own subsequent decisions to draw a distinction between the conditions of participation or coverage that a "facility" must meet and that are examined in the survey process and requirements for the "operational entity" (such as civil rights and disclosure of ownership requirements) based on which CMS may refuse to enter into a provider agreement or to grant supplier approval. The ALJ accepted CMS's position that approval of an enrollment application is an applicable federal requirement that was not met on the date of the survey, but did not find that any other "requirement for an operational entity" was not met on the date of the survey.

#### Standard of Review

Whether summary judgment is appropriate is a legal issue that we address *de novo*. Lebanon Nursing and <u>Rehabilitation Center</u>, DAB No. 1918 (2004). Summary judgment is appropriate if there are no genuine disputes of fact material to the result. <u>Everett Rehabilitation and</u> <u>Medical Center</u>, DAB No. 1628, at 3 (1997). The standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous.

Here, both parties moved for summary judgment, and there is no dispute of material fact. Thus, we may appropriately address not only whether the ALJ erred in granting summary judgment to CMS, but also whether summary judgment should be granted in favor of Renal CarePartners.

### Analysis

On appeal, Renal CarePartners raises a number of issues, including whether the phrase "all Federal requirements" in section 489.13(b) encompasses only those requirements that are part of the conditions and lower level requirements for

coverage and that are examined during the survey process or also includes additional enrollment requirements. We need not address all of these issues here. As noted above, the only alleged failure that CMS identifies as a basis for determining that Renal CarePartners did not on July 6, 2007 meet all applicable federal requirements, within the meaning of section 489.13(b), is that First Coast had not yet verified the information Renal CarePartners submitted and determined to approve Renal CarePartners' enrollment In other words, the issue here is not whether application. the effective date may be earlier than the date Renal CarePartners complied with a prerequisite it was required to meet in order to enroll, but whether the effective date must be delayed until the date the Medicare contractor notified CMS that the requirements were met. CMS takes the position that verification and approval of the enrollment application is an applicable federal requirement relevant for establishing when an approval of an ESRD supplier will be effective (and whether the supplier will be reimbursed for covered services it provides).

CMS does not support its position by citing to any regulatory requirement or policy issuance that directly addresses the issue here. For the reasons stated below, we conclude that CMS's reading of the effective date provision at section 489.13(b) is unreasonable and is inconsistent with CMS's regulations and policy issuances, read as a whole, and that verification and final approval of an enrollment application need not occur before the date that approval of an entity as an ESRD supplier is effective.

# 1. CMS's reading is inconsistent with the wording of section 489.13(b).

Section 489.13(b) states that "approval is effective on the date the survey . . . is completed, if on that date the provider or <u>supplier meets all applicable Federal</u> requirements as set forth in [chapter 400 of title 42 of the Code of Federal Regulations]." (Emphasis added.) CMS correctly points out that the enrollment requirements are in chapter 400. As Renal CarePartners argues, however, the alleged requirement that a Medicare contractor verify and determine to approve an enrollment application is not a requirement for the supplier to meet, but a requirement for contractor action.

CMS offers no basis for treating an action for which CMS or its contractor is responsible as a requirement that an ESRD supplier must meet. Nor does CMS explain how such a requirement could reasonably be considered a requirement that is "applicable" when determining <u>whether</u> to approve an entity as an ESRD supplier.

### 2. The enrollment regulations do not treat approval by CMS or a Medicare contractor as an "enrollment requirement" that every provider or supplier must meet in order to provide reimbursable items or services.

Contrary to what CMS suggests, the enrollment regulations do not treat verification and approval of an enrollment application as an "enrollment requirement" that all providers or suppliers must meet at a point in time before items or services they furnish will be considered reimbursable under Medicare. Certainly, the regulations require that the enrollment process must be completed before a provider/supplier may obtain billing privileges that allow it to submit claims and receive payment. The issue here, however, is the effective date of Renal CarePartners' approval as an ESRD supplier for purposes of determining whether it may be reimbursed for covered services it furnished on or after that date. Medicare regulations permit filing of some claims for covered services provided before the claim is submitted. 42 C.F.R. § 424.44. Thus, the fact that the enrollment process must be completed before a provider or supplier may obtain billing privileges, submit a claim, and receive payment does not necessarily preclude reimbursement for services provided before the enrollment process is complete.

For this reason, the enrollment regulations specify that the "effective date of reimbursement" will be determined by regulations that apply according to the type of provider or supplier. 42 C.F.R. § 424.510(b)(2007); <u>see also</u>, § 424.520 as revised by 73 Fed. Reg. 69,725, 69,939 (Nov. 19, 2008).

For some suppliers, the Medicare regulations make reimbursement dependent on whether billing privileges have been issued or approval given prior to the date the items or services are furnished. For example, 42 C.F.R. § 424.57 sets out "special rules" for suppliers of durable medical equipment, prosthetics, or orthotics (DMEPOS suppliers), specifying that they may not receive payment unless "the

item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges." For community mental health centers and Federally qualified health centers (which are not surveyed), the effective date is when "CMS accepts a signed agreement which assures" they met all federal requirements. 42 C.F.R. 489.13(a)(2).

Medicare regulations specify for some other providers or suppliers, however, that they may be "retroactively" reimbursed for services provided before the date of approval. For example, if a provider is accredited by an approved accrediting organization at the time the provider requests Medicare participation and is not subject to additional requirements, the effective date of the provider agreement may be the date of the initial request for participation if on that date the provider met all Federal 42 C.F.R. § 489.13(d). This effective date requirements. provision, which appears in the same section as the one at issue here, cannot reasonably be read to make participation as of the date of the initial request contingent on whether a Medicare contractor has determined on that date to approve that request. It simply is not feasible that the approval determination could occur on the same date as the date of the request.

Moreover, with respect to physicians and certain other non-DMEPOS suppliers, section 424.520 now specifies that the effective date for billing privileges is the later of the "filing date of the Medicare enrollment application that was subsequently approved by a [fee-for-service] contractor" or the date services were first provided at a (Emphasis added); see also 42 C.F.R. new location. § 410.33(i) (similar provision for independent diagnostic testing facilities). The preamble to the proposed revision explained that section 424.510 as originally enacted allowed newly enrolled physicians "to submit claims for services that were rendered prior to the date of filing or the date the applicant received billing privileges . . . ." 73 Fed. Reg. 38,502, 38,535 (July 7, 2008). In adopting the new provision limiting retroactive payment for physician services (with certain exceptions) to the filing date of an enrollment application that was subsequently approved, CMS rejected an alternative proposed approach that would have made the effective date for a physician "the date a Medicare contractor conveys billing privileges . . ." 73 Fed. Req. at 69,766.

While none of these provisions apply directly to suppliers such as ESRDs that are subject to survey and certification, they are inconsistent with CMS's position here, which treats approval of an enrollment application as a general enrollment requirement that <u>every</u> provider or supplier must meet <u>before</u> the provider or supplier may furnish items or services for which it will be reimbursed. Instead, these distinctions among types of providers and suppliers support our conclusion that the enrollment regulations do not make <u>reimbursement</u> for services dependent on the timing of a Medicare contractor's approval of enrollment and billing privileges.

# 3. CMS's position is inconsistent with the survey and certification regulations.

CMS's position is also inconsistent with the survey and certification regulations at 42 C.F.R. Parts 488 and 489. For providers and suppliers subject to the survey and certification process, the survey and certification are the means by which CMS receives assurance that conditions for participation or coverage (or requirements for long-term care facilities) are met (unless CMS deems that all of those requirements are met, based on accreditation by an approved accrediting body).

The survey and certification regulations have long treated a state survey agency's certification of compliance as merely a recommendation to CMS. See, e.g., 42 C.F.R. §§ 488.1 (definition of "certification"); 488.11. Thus, for example, they provide for CMS to decide, after receiving a certification of compliance by a state survey agency, whether to accept the recommendation and enter into a provider agreement. 42 C.F.R. § 489.11. CMS may refuse to enter into an agreement with a provider (or to grant approval of a supplier) if some requirements other than those examined in the survey are not met. 42 C.F.R. Under section 489.11, CMS does not send §§ 489.12; 488.60. a provider agreement to a provider for signature unless it determines that the provider meets the disclosure of ownership, civil rights, and other requirements. Despite the need for CMS to act to "accept" the state survey agency's certification of compliance, however, section 489.13(b) provides for the effective date of participation to be the date of the survey if all applicable federal requirements are met on that date. If CMS approval were

considered one of the applicable federal requirements, within the meaning of this provision, then the date of the survey could never be the effective date because the regulations contemplate that the survey will take place <u>before</u> the approval. Indeed, section 489.11 distinguishes the date CMS "accepts" a provider agreement from the "effective date of the agreement." 42 C.F.R. § 489.11(c).

In other words, for providers and suppliers subject to the survey and certification process, CMS's approval has always necessarily come <u>after</u> a survey, where one is required. Thus, reading the enrollment regulation as precluding granting an effective date on the date of the survey because CMS (or its contractor) had not yet determined to approve the provider or supplier on the date of the survey would be inconsistent with the regulations governing the survey and certification process.

CMS's reconsideration determination also relied on a State Operations Manual (SOM) provision that directs state survey agencies not to survey a provider or supplier until after the Medicare contractor has notified it of "initial clearance" of the enrollment application. RC Ex. J, at 1, citing SOM § 2005A. We note that CMS made no finding here that First Coast had not, in fact, given such "initial clearance" before AHCA performed its survey, and normally there is a presumption that the usual procedures are followed. Even if First Coast did not give the expected "initial clearance" before the survey, however, the SOM does not help CMS here. The SOM is simply silent on what happens if the survey is done before the initial clearance by the Medicare contractor. Moreover, the enrollment process will never be complete and final approval of billing privileges granted until the survey, if required, is completed. A survey, if required, is a prerequisite to completion of the enrollment process. 42 C.F.R. Thus, SOM section 2005A cannot reasonably be § 424.510. read as meaning that final approval (or a contractor's recommendation of final approval) of the enrollment application must occur before the effective date of reimbursement.

CMS also argues that Renal CarePartners is seeking to obtain reimbursement for a period prior to its "certification" as an ESRD supplier. CMS Br. at 11. Under the procedures in 42 C.F.R. Part 488, however, it is generally the state survey agency that certifies compliance

or noncompliance with the conditions for participation, conditions for coverage, or requirements for a long-term care facility. "Certification" is defined as "a recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation, requirements for [skilled nursing facilities and nursing facilities], and conditions of coverage." 42 C.F.R. § 488.1. The term "Conditions for coverage" is defined as "the requirements suppliers must meet to participate in the Medicare program." Id.; see also § 488.3(a). CMS ultimately accepted the certification by AHCA that Renal CarePartners was in compliance with the conditions for coverage on July 6, 2007, so it cannot fairly suggest that Renal CarePartners did not meet the conditions for coverage on that date.

### 4. CMS's reliance on some of the provisions setting out enrollment requirements is misplaced.

Section 424.510 sets out "enrollment requirements" a supplier or provider must meet to obtain billing privileges, incorporating by reference additional requirements in section 424.520. CMS cites sections 424.510(d)(4)-(5) for its proposition that "the verification of information and State survey are 'parts' of the Federal requirements that a prospective provider or supplier must satisfy to complete the enrollment process." CMS Br. at 8.

Section 424.510(d)(4) lists as an "enrollment requirement" the following:

Verification of information. The information submitted by the provider or supplier on the applicable enrollment application must be such that CMS can validate it for accuracy at the time of submission.

While this provision does require a provider or supplier to submit information that CMS can validate (or verify), CMS does not identify any information submitted by Renal CarePartners with its application that CMS or its contractor could not validate (or verify) for accuracy at the time of submission. Moreover, it is CMS or its agent that is required to take the steps necessary to verify the accuracy of the information, so "verification" cannot reasonably be treated as an act required of the supplier or provider.

Section 424.510(d)(5), moreover, arguably cuts against CMS's position in this case, rather than supporting it. That section provides:

Completion of any applicable State surveys, certifications, and provider agreements. The providers or suppliers who are mandated under the provision(s) in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to also enter into and sign a provider agreement as outlined in part 489 of this chapter, must also meet those requirements as part of the process to obtain Medicare billing privileges.

While this section makes clear that, for providers and suppliers subject to survey and certification, final approval of an enrollment application will not occur until after the survey and certification and signing of a provider agreement, where required, it does not make sense to treat this provision as establishing requirements a supplier or provider must meet on the date of the survey in order to have that be the effective date of the provider agreement or supplier approval. This reading is inconsistent with the regulations governing the survey and certification process and with the history of the enrollment regulations.

The survey and certification process contemplates that the certification will occur based on the survey and not necessarily on the same date. <u>See, e.g.</u>, 42 C.F.R. § 488.26. Under section 489.11, moreover, CMS does not send a provider agreement to a provider for signature unless there has been a survey and certification of compliance, where required, and CMS has determined that the provider meets the disclosure of ownership and other requirements. Moreover, as noted above, section 489.11 distinguishes the date CMS "accepts" a provider agreement from the "effective date of the agreement." 42 C.F.R. § 489.11(c).

CMS's brief also points to section 424.510(d)(8), as originally enacted, to support its position. That section originally included, as an enrollment requirement that providers and suppliers must meet, the following provision:

ę.

On-site review. CMS reserves the right, when deemed necessary, to perform on-site inspections of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

Based on this provision, CMS argues that the "regulation clearly establishes that 'enrollment requirements' and 'conditions of participation' are two different 'federal requirements' a provider must satisfy to complete the enrollment process." CMS Br. at 5. This statement is true, but irrelevant. The issue here is not what must be done to complete the enrollment process but what requirements an ESRD supplier must meet on the date of the survey to have that date as the effective date of reimbursement.

We also note that, in 2008, the on-site review provision was moved to a new section 424.517. 73 Fed. Reg. 69,726, 69,940 (Nov. 19, 2008). The preamble to the proposed rule explained that the reason for this revision was to "separate our ability to conduct onsite reviews from the provider and supplier enrollment requirements." 73 Fed. Reg. 38,502, 38,565. In other words, CMS itself has recognized that this provision does <u>not</u> establish an enrollment requirement.

The history of the enrollment provisions is also inconsistent with CMS's position here. For example, CMS originally proposed to include in the regulations not only a reference to other regulations such as section 489.13, but also a statement that the effective date for a provider or supplier that is deemed to meet the conditions for participation or coverage by reason of accreditation by an approved accrediting organization would be the <u>later</u> of the accreditation or the approval of the enrollment application. 68 Fed. Reg. 22,064 (Apr. 25, 2003). CMS deleted this proposed provision from the final rule in response to comments. Several commenters had stated that the language concerning effective billing dates was confusing or that they thought the proposal would change the current policy on submitting claims retroactively after the enrollment process was complete. In response, the preamble states:

While we understand these concerns, it was never our intent to change our policy on effective billing dates. We have clarified and referenced current policy citations in the final regulation text. We will continue to pay claims under all current reimbursement policies.

71 Fed. Reg. 20,754, 20,763 (April 21, 2006).

In response to a comment, the preamble also clarified the distinction between enrolling in the Medicare program and establishing billing privileges, as follows:

Providers and suppliers are required to enroll in Medicare prior to submitting a claim. The enrollment process allows Medicare to determine if the provider or supplier meets all applicable Federal and State requirements. Once a provider or supplier is enrolled in a Medicare program, it can obtain Medicare billing privileges.

71 Fed. Reg. at 20,766. Here, again, the phrase "applicable Federal . . . requirements" cannot reasonably be read to include a requirement for a determination to approve the enrollment application -- that determination is made only at the end of the process.

Nothing in the preamble indicates that, for a provider or supplier subject to survey and certification, CMS would treat a determination to approve an enrollment application as an "applicable federal requirement" that the supplier or provider would have to meet on the date of the survey in order to have that date be the effective date of reimbursement. Nor does the preamble suggest that the claims that may be submitted by such a provider or supplier and paid, once billing privileges are obtained, must necessarily be for services provided after the date on which an enrollment application was approved by CMS or its contractor.

# 5. CMS's reliance on the legislative history of the disclosure of ownership requirements is misplaced.

CMS further relies on the legislative history of the disclosure of ownership requirements enacted in 1977 in support of its position. CMS Br. at 7. Specifically, CMS relies on the following statement:

The committee views the disclosure requirements imposed by the bill to be of critical importance in the process of detecting and deterring fraudulent and abusive practices within the Medicare, Medicaid, and the maternal and child health programs.

H.R. Rep. No. 393, 95<sup>th</sup> Cong. 1<sup>st</sup> Sess. 3055 (1977). CMS argues that this shows that it "was Congress' intent" to treat "final approval of the [enrollment application as] a necessary prerequisite to the establishment of a provider's effective date." CMS Br. at 7.

While we agree that the disclosure of ownership requirements are important protections for the integrity of the Medicare program, it does not follow that final approval of enrollment must precede the date approval is effective in order to protect program integrity. CMS has not here identified any respect in which Renal CarePartners failed to comply with disclosure requirements on the date of the survey. Nothing in the guoted statement from the legislative history supports a conclusion that it is critical to program integrity to preclude reimbursement for services provided on or after the date of the survey, solely on the basis that CMS or its contractor had not yet determined that the disclosure requirements were met. Indeed, the cited report goes on to say that the disclosure provisions were designed to be incorporated into the ongoing certification process, so the Committee expected that they would be administered in such a way as to preclude unnecessary burdens on those complying with them. As Renal CarePartners points out, the applicable conditions for coverage for ESRD services included that the supplier meets disclosure of ownership and other operational 42 C.F.R. § 405.2136 (2007). CMS has requirements. offered no explanation of why AHCA's certification that Renal CarePartners had no deficiencies in meeting the conditions for coverage is not sufficient to show that the disclosure of ownership requirements were met on the date of the survey.

CMS does assert that "[i]t is indisputable that in order for CMS to determine whether the requirements enumerated at 42 C.F.R. § 489.10 and 489.12 have been met, a supplier must submit CMS Form 855A - Medicare Enrollment Application." CMS Br. at 6. Even if this were true, however, it does not follow that the requirements should be treated as <u>not</u> met on a particular date merely because CMS or its contractor had not yet determined they were met.

### 6. CMS's reliance on prior ALJ decisions is misplaced.

CMS relies on the ALJ decision in <u>Physicians Medical Center</u> of Santa Fe, LLC, DAB CR1790 (2008). This reliance is misplaced, for several reasons.

First, ALJ decisions are not precedent binding on the The issue here is one of first impression for the Board. Second, the legal conclusions the ALJ reached in Board. DAB CR1790 are based on a misreading of the ALJ decision in SRA Inc., d/b/a St. Mary Parish Dialysis Center, DAB CR341 (1994) as establishing a distinction between requirements for a facility and requirements for an operational entity. That decision stands merely for the proposition that section 489.13 (prior to its amendment in 1997) precluded an effective date of approval on the date of the survey, even if an entity met the conditions for participation or coverage on that date, if the entity did not also meet the lower level standards and elements in those conditions. The enrollment regulations at issue here had not yet been promulgated and were not at issue in that case. Moreover, in DAB CR1790, the ALJ did not explain how any distinction between the conditions of participation or coverage for a facility and requirements for an operational entity supports a conclusion that verification and approval of an enrollment application is an "applicable Federal requirement" within the meaning of section 489.13.

As the ALJ Decision here recognized, moreover, there are factual differences between the cited case and DAB CR1790, as well as other ALJ decisions on which the ALJ Decision relied. For example, in <u>Maher A.A. Azer (Florence Dialysis</u> <u>Center, Inc.)</u>, DAB CR994 (2003), the supplier sought a date of approval prior to the date the survey was completed.

### Conclusion

For the reasons stated above, we conclude that the ALJ erred in granting summary judgment to CMS and in determining that the effective date of approval of Renal CarePartners as an ESRD supplier is November 21, 2007. We further conclude that there are no disputes of material fact and grant summary judgment to Renal CarePartners, establishing the effective date of approval as July 6, 2007.

> /s/ Leslie A. Sussan

/s/ Constance B. Tobias

/s/

Judith A. Ballard Presiding Board Member