Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Renal Services Group of El Centro,	)	Date: July 30, 1997
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-97-202
	)	Decision No. CR482
Health Care Financing Administration	)	
	)	
	)	

DECISION

I decide that the Health Care Financing Administration (HCFA) correctly certified Petitioner, Renal Services Group of El Centro, to participate in the Medicare program as a supplier of dialysis services, effective August 19, 1996. I base this decision on my conclusion that a renal dialysis facility, such as Petitioner, must obtain approval from HCFA to claim reimbursement for covered services that it provides to Medicare beneficiaries under the regulations contained in 42 C.F.R. Parts 488 and 489 that govern certification of providers and approval of suppliers to participate in Medicare. Under these regulations, the earliest date that HCFA could approve Petitioner to be a supplier was August 19, 1996.

This case is before me on a request for a hearing by Petitioner from HCFA's determination to approve Petitioner to supply covered services to Medicare beneficiaries, effective August 19, 1996. I held a prehearing conference on April 14, 1997, at which the parties agreed that the case could be heard and decided based on written submissions by the parties. Petitioner submitted a brief and nine proposed exhibits (P. Ex. 1 - 9). HCFA submitted a brief and seven proposed exhibits (HCFA Ex. 1 - 7). Neither party has objected to my receiving into evidence any of the proposed exhibits. I receive into evidence P. Ex. 1 - 9 and HCFA Ex. 1 - 7. I note that, to some extent, the parties have submitted the same documents as exhibits. However, neither party will be prejudiced by my receiving into evidence all of the exhibits, even if, to some extent, they duplicate each other.

The issue in this case is whether HCFA correctly determined to approve Petitioner to supply covered services to Medicare beneficiaries, effective August 19, 1996. I make findings of fact and conclusions of law (Findings) to support my decision upholding HCFA's determination. I set forth each of my Findings below, as a separately numbered heading. I discuss each Finding in detail.

1. Petitioner is entitled to a hearing concerning whether HCFA correctly determined to approve Petitioner to be a renal dialysis facility, effective August 19, 1996.

Petitioner asserts that it is entitled to relief in the amount of $16,275. The claim for $16,275 is for the services to Medicare beneficiaries that Petitioner alleges to have provided between July 31, 1996 and August 19, 1996. Petitioner predicates this claim on its assertion that HCFA ought to have approved it to supply Medicare services effective July 31, 1996, rather than August 19, 1996. Petitioner's Brief at 3.

HCFA urges that I dismiss Petitioner's request for a hearing on the ground that Petitioner seeks relief that I have no authority to grant. HCFA argues that Petitioner is seeking money damages from HCFA and that I have no authority to award damages to Petitioner.

HCFA asserts correctly that I have no authority to award money damages to Petitioner. However, HCFA has interpreted Petitioner's request for a hearing too narrowly. Petitioner has, although not artfully, raised an issue which I have authority to hear and decide and concerning which Petitioner is entitled to a hearing. For that reason, I deny HCFA's motion to dismiss Petitioner's hearing request.

I have authority to hear and decide the issue of whether HCFA determined correctly that Petitioner should be approved to be a renal dialysis facility effective August 19, 1996. 42 C.F.R. § 498.5(d)(2). Petitioner's hearing request raises this issue. Petitioner's request is predicated on its assertions that HCFA incorrectly approved Petitioner to be a supplier, effective August 19, 1996, and that HCFA ought to have approved Petitioner to be a supplier at an earlier date.

2. An applicant for approval from HCFA to be a supplier of Medicare services must apply for approval, be surveyed, and be approved, pursuant to the regulations contained in 42 C.F.R. Parts 488 and 489.

Petitioner is a renal dialysis facility. A renal dialysis facility is one of several types of end-stage renal disease (ESRD) facilities that are described in the Social Security Act (Act) as facilities which provide services which may be covered

under Medicare. Act, section 1881(b)(1). The Act authorizes the Secretary of the United States Department of Health and Human Services (Secretary) to publish regulations which contain substantive criteria that an ESRD facility must satisfy in order to be approved by HCFA to claim reimbursement for covered services that it provides to Medicare beneficiaries. Id. These regulations are published at 42 C.F.R. Part 405, Subpart U.

Certain types of entities which provide Medicare items or services are described under the Act and regulations as providers of services. Act, section 1866; 42 C.F.R. § 488.1. Other types of entities which supply Medicare items or services are defined by regulations to be suppliers of services. 42 C.F.R. § 488.1. An ESRD facility, including a renal dialysis facility, is defined to be a supplier of services. Id.

In order to become an approved supplier of Medicare services, an ESRD facility must be surveyed on-site, so that HCFA may determine whether the ESRD facility is complying with the requirements contained in 42 C.F.R. Part 405, Subpart U. Regulations contained at 42 C.F.R. Part 488 establish the process by which entities who apply to participate in Medicare as providers, or to be approved as suppliers, satisfy HCFA that they are in compliance with applicable law and regulations. The regulations describe a process whereby applicants for participation or approval apply to participate or be approved, and are surveyed on behalf of HCFA to establish that they meet participation or approval requirements. Id. The application and survey process applies to both providers of services and suppliers of services, such as ESRD facilities. See 42 C.F.R. § 488.1.

Regulations contained in 42 C.F.R. Part 489 establish the mechanism by which HCFA certifies a provider to participate in Medicare based on the results of an initial on-site survey. 42 C.F.R. § 489.13. Generally, the earliest date that a provider which applies to participate may be certified by HCFA to participate in Medicare is the date of completion of an on-site survey of that provider, assuming that the provider satisfies all Medicare participation requirements as of that date. 42 C.F.R. § 489.13(a).

The regulations which establish the mechanism for provider certification do not, by their terms, establish a mechanism for approval of a supplier. See 42 C.F.R. Part 489. The regulations in 42 C.F.R. Part 489 refer only to certification of providers. There are no regulations which refer to suppliers and describe an approval mechanism which applies to suppliers and not to providers. The regulations' failure to explicitly describe the mechanism by which HCFA approves a supplier raises the question of how HCFA approves a renal dialysis facility such as Petitioner.

I conclude that approval of a renal dialysis facility such as Petitioner is governed by the same review and approval process in 42 C.F.R. Part 489 that governs the certification of a provider. A renal dialysis facility may not be approved as a supplier until after it has been surveyed on site. It must satisfy all substantive requirements which govern a renal dialysis facility, as a prerequisite to being approved. The earliest date that a renal dialysis facility may be approved is the date of completion of an initial on-site survey of the facility, assuming that the facility is found to have satisfied all Medicare requirements as of that date. 42 C.F.R. § 489.13(a).

I base my conclusion on the following analysis:

- Congress intended that the Secretary establish the same process for dealing with providers and ESRD facilities, including renal dialysis facilities. Congress specifically directed the Secretary to treat ESRD facilities as "providers" for purposes of resolving certain reimbursement disputes between ESRD facilities and fiscal intermediaries or the Secretary. Act, section 1881(b)(2)(D); see Act, section 1878.

- Logically, it would make no sense to subject providers and suppliers to the same application and initial survey process (Part 488) and not to subject them to the same approval process (Part 489). Withholding certification of a provider until completion of an on-site survey of that provider satisfies a need to assure that the provider is complying with applicable participation requirements before it begins to treat Medicare beneficiaries on a regular basis and to seek reimbursement for the treatments that it provides to those beneficiaries. The identical need exists to assure that a supplier complies with Medicare requirements.

- The regulations at 42 C.F.R. Parts 488 and 489 are part of a coherent application, survey, and approval process. When the Part 489 regulations are read in their entirety, and in the context of the Part 488 regulations, it is apparent that the Part 489 regulations were intended to apply both to providers and suppliers. The Part 488 regulations explicitly apply to providers and suppliers. See, e.g., 42 C.F.R. § 488.1. And, although the language of the regulations in 42 C.F.R. Part 489 refers only to providers of services, the Part is entitled "Provider agreements and supplier approval."

- As further evidence that the Secretary intended that providers and suppliers be treated in the same way for purposes of certification or approval, the Secretary gave the same administrative hearing and appeal rights to suppliers who are dissatisfied with determinations by HCFA concerning their approval to obtain reimbursement from Medicare for

> covered services as she gave to providers who are dissatisfied with determinations by HCFA concerning their participation in Medicare. 42 C.F.R. § 498.5. This decision by the Secretary shows that she intended the entire process of application, survey, approval, and appeal to apply equally to providers and suppliers.

The Secretary's intent to apply the same process to providers and suppliers, from beginning to end, is made more evident by the fact that the Secretary is under no specific statutory obligation to give suppliers the same administrative hearing and appeal rights as are granted to providers. A provider has a statutory right to an administrative hearing from an adverse determination by HCFA concerning its participation in Medicare, whereas a supplier does not have that statutory right. Act, section 1866(h)(1); see Act, section 205(b).

HCFA cites to my decision in SRA, Inc., D/B/A St. Mary Parish Dialysis Center, DAB CR341 at 3 - 4 (1994), as authority that the Part 489 regulations govern an ESRD's approval to obtain reimbursement for Medicare services. However, SRA is distinguishable from this case in one respect. In SRA, HCFA and the petitioner agreed that the Part 489 regulations would apply to the facts of the case. Here, Petitioner has not agreed to be governed by the Part 489 regulations, although Petitioner has not asserted that the regulations are inapplicable. Therefore, although my decision in SRA is entirely consistent with the decision I reach here, I do not rely on it to reach my decision in this case.

3. HCFA approved Petitioner to be a supplier of Medicare services, effective August 19, 1996.

The undisputed facts of this case are that, on July 31, 1996, Petitioner requested the California Department of Health Services, the California State survey agency, to survey Petitioner for approval by HCFA as a Medicare supplier. P. Ex. 3. Petitioner was surveyed on August 19, 1996. HCFA Ex. 1. No deficiencies were identified at this survey. Id. On October 9, 1996, HCFA advised Petitioner that it had been approved as a supplier, effective August 20, 1996. HCFA Ex. 3.

Petitioner requested reconsideration of this determination. On December 16, 1996, HCFA advised Petitioner that, inasmuch as the on-site survey of Petitioner was conducted on August 19, 1996, HCFA could not approve Petitioner as a supplier at any date earlier than August 19, 1996. HCFA Ex. 4. Although HCFA did not state explicitly that it was changing the date of Petitioner's approval from August 20, 1996 to August 19, 1996, I infer from HCFA's December 16, 1996 letter to Petitioner that it changed the date of Petitioner's approval to August 19, 1996. Id.

4. HCFA approved Petitioner to be a supplier of Medicare services on the date when Petitioner first became eligible to be approved.

HCFA approved Petitioner to be a supplier of Medicare services, effective August 19, 1996, which is the date when Petitioner first became eligible to be approved. The first date when a provider may be certified by HCFA or a supplier may be approved by HCFA is the date of completion of an initial on-site survey of that provider or supplier, assuming that the provider or supplier satisfies all applicable Medicare requirements as of that date. 42 C.F.R. § 489.13(a). The date of completion of the initial on-site survey of Petitioner was August 19, 1996. HCFA Ex. 2. Petitioner satisfied all applicable Medicare requirements as of that date. Id. HCFA approved Petitioner as a supplier as of August 19, 1996.

Petitioner asserts that the initial on-site survey of Petitioner was delayed by HCFA's imposition of a requirement that as a prerequisite to being surveyed and approved, a renal dialysis facility must have treated at least ten patients and generated records for those patients. Petitioner asserts that, but for the imposition of this requirement by HCFA, Petitioner could have been surveyed at an earlier date than August 19, 1996. Petitioner argues that it would have been able to establish compliance with Medicare requirements as of July 31, 1996. Petitioner's Brief at 2 - 3.

Petitioner contends that a requirement that Petitioner generate at least ten patient records as a prerequisite to being surveyed is unreasonable. First, Petitioner asserts that imposition of this requirement constituted substantive rule making by HCFA in violation of the Administrative Procedure Act. Petitioner's Brief at 3 - 4. Second, Petitioner asserts that imposition of the requirement by HCFA was arbitrary and capricious. Petitioner's Brief at 4 - 5.

In addition to these two arguments, Petitioner asserts that HCFA reneged on a promise it made to Petitioner concerning the date of Petitioner's approval as a supplier. Petitioner asserts that HCFA's representatives promised it that Petitioner would be approved retroactive to the date when Petitioner was licensed by the State of California, and that the approval date of August 19, 1996, violates this alleged promise. Petitioner's Brief at 5 - 6.

Petitioner's first two arguments reduce to an assertion by Petitioner that the on-site survey of Petitioner was delayed for reasons that are unlawful. It is unnecessary for me to decide the merits of this assertion or of Petitioner's underlying arguments. Under the regulations governing approval, a supplier may not be approved at any date earlier than the completion date of an on-site survey. 42 C.F.R. § 489.13(a). The regulations do not permit either HCFA or an administrative law judge to look behind the completion date of an onsite survey

and order approval at an earlier date, even if the survey was delayed unreasonably or unlawfully by HCFA. Id. I would not have authority to order that Petitioner be approved prior to August 19, 1996, even if Petitioner could prove that the initial survey of it was delayed due to imposition of an unlawful or unreasonable requirement that it generate ten patient records as a prerequisite to being surveyed.

Nor do I have authority to direct HCFA to honor any asserted promise that its employees may have made concerning retroactive approval of Petitioner. The regulations do not give HCFA or its employees the authority to waive the requirements of 42 C.F.R. § 489.13. I do not have authority in equity to direct HCFA to carry out an asserted promise that HCFA may not lawfully implement under the applicable regulation. Petitioner's contentions about what HCFA's employees may have promised it, therefore, are irrelevant, even if they arguably are true.

All three of Petitioner's arguments are, in effect, arguments that HCFA ought to be estopped from applying the provisions of 42 C.F.R. § 489.13(a) to approve Petitioner effective August 19, 1996. Similar arguments were raised by the petitioner in GranCare Home Health Service & Hospice, DAB CR464, at 9 - 11 (1997). In GranCare, I held that I did not have authority to estop HCFA from applying the provisions of 42 C.F.R. § 489.13(a) to determine the effective date of participation of a provider. I reaffirm that holding here. My authority is limited to deciding whether HCFA approved Petitioner in accordance with the applicable regulation. There is nothing in 42 C.F.R. § 489.13(a), or in any other regulation, to suggest that I may estop HCFA from acting pursuant to 42 C.F.R. § 489.13(a), even where HCFA arguably has acted unfairly or unlawfully to delay an on-site survey.

HCFA argues that, if Petitioner was required to generate ten patient treatment records as a prerequisite to being surveyed initially, that requirement is reasonable and was not imposed in contravention of the Administrative Procedure Act. It is unnecessary that I address the merits of HCFA's arguments for the same reason that it is unnecessary that I address the merits of Petitioner's arguments. Even if I were to agree with HCFA's arguments, that would not affect my conclusion that I am without authority to direct HCFA to approve a supplier at a date earlier than the completion date of the initial survey of that supplier.

My decision in this case should not be read as a holding that a provider or a supplier is precluded from challenging the *determinations* that HCFA makes from an initial survey concerning whether or not a provider or a supplier was complying with Medicare requirements as of the date of the survey. The regulations provide that a provider or a supplier has a right to a hearing on the issue of whether it was in compliance with Medicare requirements as of the date

of the initial survey. 42 C.F.R. § 498.5. That right, potentially, could be meaningful in a case where HCFA determines that a provider or a supplier should not be certified or approved as of the completion date of an initial survey based on a determination that the provider or supplier was not complying with all Medicare requirements as of that date. In that case, the provider or supplier might be able to prove that it was complying with applicable requirements as of the completion date of the survey, and, thus, prove that it ought to have been certified or approved as of the completion date of the initial survey.

/s/

Steven T. Kessel
Administrative Law Judge