

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:

SRA, Inc., D/B/A St. Mary  
Parish Dialysis Center,

Petitioner,

- v. -

Health Care Financing  
Administration.

DATE: November 3, 1994

Docket No. C-94-302  
Decision No. CR341

DECISION

On November 16, 1993, the Health Care Financing Administration (HCFA) advised Petitioner that it had determined that Petitioner would be certified as an end-stage renal disease (ESRD) facility. HCFA advised Petitioner that, pursuant to the requirements of 42 C.F.R. § 489.13, the effective date of certification would be October 1, 1993. Petitioner appealed this determination. In its appeal, Petitioner contends that it should have been certified effective either July 1, 1993, July 29, 1993, or August 30, 1993.

The case was assigned to me for a hearing and a decision. The parties agreed that there was no need for an in-person hearing. They agreed that the case could be decided based on exhibits and briefs. The parties have submitted their proposed exhibits and briefs. They have not objected to the admission into evidence of any exhibits. I have received into evidence all of the parties' proposed exhibits.<sup>1</sup>

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<sup>1</sup> Petitioner submitted 10 exhibits, which it designated as P. Ex. 1 through P. Ex. 10. I have received all of these exhibits into evidence.

HCFA submitted three appendices to its brief, which it labeled as Appendices "A," "B," and "C." Appendix "B" is  
(continued...)

I have considered the parties' exhibits and arguments and the applicable law. I conclude that the effective date for certification of Petitioner as an ESRD facility is October 1, 1993. I sustain HCFA's determination.

I. Issues, findings of fact, and conclusions of law

The central issue in this case is the correct date for certifying Petitioner as eligible to receive reimbursement from Medicare for supplying ESRD services. In deciding that HCFA correctly certified Petitioner as eligible to receive reimbursement from Medicare effective October 1, 1993, I reach findings of fact and conclusions of law which are set forth as follows. After each finding or conclusion, I cite to the pages in this decision at which I discuss the law and evidence which supports that finding or conclusion.

1. Although an ESRD facility is defined to be a "supplier" of services to Medicare beneficiaries, it is subject to the certification requirements which govern "providers" of services. Pages 3 - 4.

2. An ESRD facility meets all requirements for certification when it satisfies HCFA that it meets all of

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<sup>1</sup> (...continued)

the affidavit of Judy Brown, with 10 numbered exhibits (HCFA Ex. 1 - 10) attached. HCFA also submitted HCFA Ex. 1 - 10 separately as proposed exhibits. Ms. Brown's affidavit was not identified by HCFA as a proposed exhibit, although it is apparent that HCFA intends that the affidavit, along with the attached exhibits, be received into evidence. I have identified Ms. Brown's affidavit as HCFA Ex. 11 and have received it into evidence with HCFA Ex. 1 - 10.

Appendix "A" is an excerpt from an internal HCFA document which sets forth HCFA's policies concerning certification of suppliers for Medicare reimbursement. Appendix "C" is a decision from the Office of Hearings and Appeals, Appeals Council. Appendices "A" and "C" are policy statements or legal interpretations. While it is not, strictly speaking, necessary for me to admit these attachments into evidence in order for me to consider them, I have done so in order to simplify their incorporation into the record of this case. I have identified Appendix "A" as HCFA Ex. 12. I have identified Appendix "C" as HCFA Ex. 13. I have received both of these exhibits into evidence.

the conditions, standards, and elements of certification which govern ESRD facilities. Pages 4 - 5.

3. Under regulations governing certification, an ESRD facility becomes eligible to receive Medicare reimbursement for its services as of the date that it is surveyed for compliance, if, on the date that it is surveyed, it meets all conditions for certification and any other requirements imposed by HCFA, including standards and elements of certification. Pages 4, 17 - 18.

4. Under regulations governing certification, an ESRD facility not meeting certification requirements on the date that it is surveyed becomes eligible for reimbursement on the date that it meets all requirements, or on the date it submits a plan of correction which is acceptable to HCFA, whichever date is earlier. Pages 4 - 5, 19 - 21.

5. Under regulations governing certification, the burden is on the entity requesting to be certified to prove that it meets certification requirements. Page 5.

6. Petitioner did not prove that it satisfied certification requirements before October 1, 1993. Pages 6 - 16, 21.

7. Petitioner is not entitled to be certified prior to October 1, 1993 based on allegedly untimely notices of deficiencies. Pages 18 - 19.

## II. Governing law

The Medicare program provides for reimbursement for services provided to ESRD patients. Social Security Act (Act), section 1881. The Act provides that the Secretary of the Department of Health and Human Services (Secretary) may make payments to facilities which provide renal dialysis services to Medicare beneficiaries, pursuant to agreements entered into between such facilities and the Secretary. Id. at section 1881(b). The Act authorizes the Secretary to establish regulations governing institutional dialysis services. Id.

Regulations published by the Secretary establish both the substantive conditions which providers and suppliers of services must meet in order to qualify to receive Medicare reimbursement for their services, and the procedures by which providers and suppliers satisfy HCFA that they meet applicable conditions and standards. Regulations contained in 42 C.F.R. Part 405, Subpart U,

establish the conditions and standards which ESRD facilities must satisfy to qualify as Medicare suppliers.

The procedures by which providers and suppliers satisfy HCFA that they meet applicable conditions and standards for reimbursement are contained in 42 C.F.R. Part 489, Subpart A. These regulations apply specifically to "providers" of health care services, including hospitals, skilled nursing facilities, home health agencies, clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation facilities, and hospices. 42 C.F.R. § 489.2(b). An ESRD facility is a "supplier" of services, rather than a provider. 42 C.F.R. § 488.1. HCFA has determined that the regulations governing the procedures for qualification of providers govern also the procedures for qualification of suppliers. HCFA Ex. 12. Petitioner agrees with this determination. Petitioner's Brief at pages 6-7, fn 1.

HCFA's application of the provider certification regulations to govern the manner in which suppliers become certified, including ESRD facilities, is consistent with the Secretary's purpose in establishing a regulatory framework for certification. It is consistent also with Congress' decision that ESRD facilities be treated as "providers" for purposes of resolving certain reimbursement disputes between such facilities and fiscal intermediaries or the Secretary. Act, section 1881(b)(2)(D); see Act, section 1878.

The procedural regulations provide for the determination of an effective date for a provider agreement. An agreement between a provider or a supplier and HCFA becomes effective on the date that HCFA completes an on site survey of the provider or supplier, if, on that date, the provider or supplier meets all conditions for certification and any other requirements imposed by HCFA. 42 C.F.R. § 489.13(a). As of the effective date of the agreement, the provider or supplier will become eligible to receive Medicare reimbursement for its services.

However, if the provider or supplier fails to meet any of the requirements established by HCFA for certification on the date that the survey is completed, then the agreement becomes effective, and the provider or supplier becomes eligible to receive Medicare reimbursement for its services, on the earlier of two dates. These are: (1) the date on which the provider or supplier meets all HCFA requirements, or (2) the date on which the provider or supplier submits a plan of correction to HCFA which HCFA accepts, or an approvable waiver request, or both. 42 C.F.R. § 489.13(b)(1) and (2).

The regulation does not define what is meant by "other requirements" as stated in 42 C.F.R. § 489.13(a). However, it is apparent from the context of the regulation that this word means all conditions, standards, and elements established as prerequisites for certification.<sup>2</sup> This interpretation accords with a prior interpretation of "other requirements" made on behalf of the Secretary. River North Treatment Center v. Health Care Financing Administration, OHA Appeals Council Docket No. 000-61-7052 (1993); HCFA Ex. 13. Thus, HCFA will accept an ESRD facility's agreement on the date when HCFA determines that all conditions, standards, and elements established under governing regulations have been met. See 42 C.F.R. Part 405, Subpart U.

It is apparent also from the language and context of the regulation that it is a provider or supplier's burden to satisfy HCFA that it meets all requirements for certification. An ESRD facility will qualify for Medicare reimbursement for its services if it satisfies HCFA as of the date of the certification survey that it meets all of HCFA's requirements for certification. 42 C.F.R. § 489.13(a). If it fails to do that, then it will qualify either on the date that it proves that it meets all of HCFA's requirements, or on the date that it provides HCFA with a plan of correction that HCFA accepts, whichever is earlier. 42 C.F.R. § 489.13(b)(1) and (2).

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<sup>2</sup> The regulations establish both "conditions" and "standards" of certification. For example, a condition for certification of an ESRD facility is that treatment provided at the facility be under the general supervision of a director who is a physician. 42 C.F.R. § 405.2161. A standard governing the qualifications of an ESRD facility director requires that the director be a physician who is board eligible or board certified in internal medicine or pediatrics and has had at least 12 months experience or training in patient care at ESRD facilities. 42 C.F.R. § 405.2102(e) ("Physician-director"). "Elements" of certification consist of additional certification requirements prescribed by HCFA.

### III. Relevant facts

Petitioner is an ESRD facility.<sup>3</sup> Its chief executive officer and medical director is Saeed Ahmed, M.D. HCFA Ex. 1, page 1; HCFA Ex. 8, page 2. Dr. Ahmed is an internist and a nephrologist. HCFA Ex. 7, page 1.

In early 1993, Petitioner applied to be certified to receive reimbursement from Medicare for ESRD services. HCFA Ex. 11, page 1. On July 1, 1993, Petitioner was surveyed by the State of Louisiana Department of Health and Hospitals (State agency) on behalf of HCFA, in order to determine whether Petitioner met applicable HCFA requirements for certification as an ESRD facility. HCFA Ex. 1. The surveyors found that Petitioner met the conditions for certification established by the regulations. HCFA Ex. 11, page 2. However, they found also that Petitioner failed to meet several standards and elements governing ESRD facilities. HCFA Ex. 1.<sup>4</sup>

Among the standards which were found not to have been met is the standard governing the qualifications of the physician-director of an ESRD facility. HCFA Ex. 1, pages 5 - 6; 42 C.F.R. § 405.2161(a); 42 C.F.R. § 405.2102(e) ("Physician-director"). The standard defines a physician-director to be a physician who is board-certified or board-eligible in internal medicine or pediatrics, having at least 12 months experience or training in the care of patients at an ESRD facility. 42 C.F.R. § 405.2102(e) ("Physician-director"). The standard provides further that, if a physician who meets the definition of a physician-director is not available to direct the ESRD facility, then a back-up physician may direct the facility subject to the Secretary's approval. Id.

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<sup>3</sup> In many of the exhibits, Petitioner is referred to as "St. Mary Parish Dialysis Center." For example, HCFA Ex. 2, page 1; HCFA Ex. 9, page 1.

<sup>4</sup> HCFA represents that Petitioner was found to be in "compliance with all conditions of coverage." HCFA Ex. 11, page 2; HCFA's Brief at 7. As I conclude above, a facility does not qualify for certification by meeting conditions for certification if it does not meet the applicable standards and elements as well.

The surveyors found that the facility failed to meet the standard for physician-director because there was no proof that Dr. Ahmed was currently board-eligible or that he had a current medical license. Also, Dr. Ahmed worked in a city approximately two hours distant from Petitioner and was not readily available. HCFA Ex. 1, pages 5 - 6. The surveyors found, additionally, that the designated back-up physician for Dr. Ahmed, Dr. Metz, did not qualify under the applicable standard as a replacement for Dr. Ahmed. Id. They found that Dr. Metz was a full-time emergency room physician who lacked the requisite training to direct an ESRD facility. Id.

Additional standards for certification were found not to have been met as of the July 1, 1993 survey. These included standards governing: objectives and policies under which Petitioner operates, personnel policies and procedures, supervision of patient care, designation of a qualified physician as facility director, and direction of social services at the facility. HCFA Ex. 1, pages 1 - 7; 42 C.F.R. §§ 405.2136(b), 405.2136(d), 405.2136(g), 405.2136(h), and 405.2163(c).

In addition to finding that standards of certification had not been met by Petitioner, the surveyors found that elements of certification had not been met. These included elements relating to: personnel policies governing qualifications of staff members, maintenance of a roster of physicians who are available to treat emergencies, maintenance of a fully equipped emergency tray containing drugs needed to treat emergencies, and training of personnel. HCFA Ex. 1, pages 1 - 6. The surveyors found specifically that Petitioner had designated a licensed practical nurse to perform duties that should have been assigned to a registered nurse. HCFA Ex. 1, page 2. They found also that the emergency tray contained outdated drugs. HCFA Ex. 1, pages 4 - 5.

On or about July 30, 1993, Petitioner presented a plan of correction that addressed the deficiencies which were identified at the July survey of Petitioner's facility. HCFA Ex. 1; P. Ex. 1 - 3.<sup>5</sup> One deficiency addressed by

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<sup>5</sup> Petitioner's proposed corrective actions are expressed as handwritten notations in the right column of each page of HCFA Ex. 1. P. Ex. 2 duplicates HCFA Ex. 1. P. Ex. 3 consists of a copy of Dr. Ahmed's license to practice medicine in Louisiana, his curriculum vitae, and the credentials of Ms. Lucy Reed, the social worker employed by Petitioner. To the extent that there is any  
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the plan was the surveyors' finding that Petitioner had not designated an adequately credentialed back-up physician. Petitioner stated that Dr. Uribe, a nephrologist, would be on call. HCFA Ex. 1, pages 5 - 6. Another deficiency addressed by the plan was the surveyors' finding that Petitioner had assigned duties to a licensed practical nurse which, under the applicable element, ought to have been assigned to a registered nurse. Petitioner pledged that, effective immediately, those duties would be performed by a registered nurse. HCFA Ex. 1, page 2.

On August 2, 1993, surveyors again visited Petitioner's facility. On this visit, the surveyors found that some previously identified deficiencies persisted. HCFA Ex. 2. They found also some additional deficiencies. Id. Petitioner was found to be out of compliance with the standard governing patient environment. HCFA Ex. 2, pages 3 - 4; 42 C.F.R. § 405.2140(b). Specifically, the surveyors found that Petitioner was not disposing of its medical waste properly. Id. Petitioner was again found to be out of compliance with the standard governing the qualifications of a replacement physician-director. HCFA Ex. 2, page 4; 42 C.F.R. § 405.2161(a). Specifically, the surveyors found that Dr. Metz continued to be designated as the back-up physician. Id.

The surveyors found that Petitioner failed to meet the standard governing the full-time registered nurse responsible for supervising dialysis. HCFA Ex. 2, pages 4 - 5; 42 C.F.R. § 405.2162(a). They found that Ms. Gros, the registered nurse assigned to supervise dialysis, lacked documented training in dialysis. Id. at 5; see id. at 2.<sup>6</sup> Also, the licensed practical nurse on duty lacked documentation of medical clearance, training, and skills. Id. at 5. The surveyors found, furthermore, that on July 2, 1993, the day after the July 1, 1993

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<sup>5</sup> (...continued)

dispute that the documents contained in P. Ex. 3 were submitted by Petitioner as part of its plan of correction, I resolve that dispute in favor of Petitioner.

<sup>6</sup> Evidently, Ms. Gros had been hired to respond to the surveyors' previous finding that dialysis was being supervised by a licensed practical nurse. The surveyors referred to Ms. Gros as Ms. "Grow." Other exhibits in evidence refer to her as Ms. "Gros" and Ms. "Gross." P. Ex. 4, page 2; P. Ex. 5, page 5. In this Decision, I refer to her as Ms. Gros.



inspection, the licensed practical nurse had dialyzed a patient without the presence of a registered nurse. Id. The surveyors found also that Petitioner continued to fail to meet the element governing posting of a roster of physicians who are available to treat emergencies. Id. at 3.

On August 16, 1993, the State agency, acting on HCFA's behalf, returned Petitioner's July 30, 1993 plan of correction to Petitioner. HCFA Ex. 3. It advised Petitioner that the plan of correction was unacceptable in two respects. First, it found that Petitioner had failed to provide adequate documentation of Dr. Uribe's credentials. Id. Second, it found that Petitioner had not provided adequate documentation as to the credentials of the social worker employed by Petitioner. Id.

On August 30, 1993, HCFA advised Petitioner that it had determined that Petitioner did not meet the criteria for certification as an ESRD facility. HCFA Ex. 6. HCFA informed Petitioner that it was basing its determination on the surveys performed of Petitioner's facility and on the recommendation of the State agency. Id.

On August 30, 1993, Petitioner faxed additional documents to HCFA. P. Ex. 5. These included the curriculum vitae of Dr. Uribe. They included also a letter signed by Dr. Ahmed which stated that:

Miss June Gross RN did participate in Acute Hemodialysis in Lakewood Hospital with the LP Jonie Rochell and Debbie Nichol RN for at least six months in 1980-1982.

Id. at 5.<sup>7</sup>

On September 2, 1993, the State agency sent a letter to Dr. Ahmed. HCFA Ex. 4. It advised Dr. Ahmed that it had learned that Ms. Trina Granger, the individual whom the State agency found that Dr. Ahmed had designated as the registered nurse in charge of Petitioner at the time of the July 1, 1993 survey, was in fact employed as a full-time registered nurse at another facility operated by Dr. Ahmed. HCFA Ex. 4, page 1. Dr. Ahmed was advised that,

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<sup>7</sup> The statement concerning Ms. Gros' qualifications is similar, but not identical, to a letter which Dr. Ahmed attached to a submission to HCFA dated September 17, 1993. HCFA Ex. 7, page 2. I discuss that submission below.

had the survey team known that the designated registered nurse was in fact employed elsewhere on a full-time basis, then the surveyors would have cited this as an additional finding that Petitioner was deficient under the standards governing ESRD facilities. Id.

On September 17, 1993, Dr. Ahmed wrote to HCFA requesting reconsideration of HCFA's August 30, 1993 determination that Petitioner did not meet certification requirements. HCFA Ex. 7; P. Ex. 8. In that letter, Dr. Ahmed asserted that HCFA had probably failed to take into consideration documents which he had faxed previously to HCFA. Although not stated expressly, this reference appears to be to the documents which Dr. Ahmed had faxed on August 30. Dr. Ahmed stated further that "I am enclosing another set of documents which will prove that the nurse who was there, when the state survey went the second time on August 2, 1993, did have enough experience in Dialysis to be considered as the in charge nurse." HCFA Ex. 7, page 1; P. Ex. 8. He attached to the letter a version of the letter which he had faxed to HCFA on August 30, 1993, concerning the experience of Ms. Gros. HCFA Ex. 7, page 2; see P. Ex. 5, page 5.<sup>8</sup>

Petitioner was again surveyed on behalf of HCFA on October 1, 1993. On this occasion, the surveyors found only that Petitioner was deficient in the element governing personnel policies and procedures. HCFA Ex. 8, page 4. Specifically, the surveyors found that the personnel file for the technician responsible for equipment and water quality lacked information concerning that employee's qualifications, certification, health status, and contract. Id. On October 25, 1993, the State agency received a signed plan of correction from Petitioner, dated October 9, 1993. Id.; HCFA Ex. 11, page 9. In a letter dated November 16, 1993, HCFA certified Petitioner to receive reimbursement from Medicare for the services it provided, effective October 1, 1993. HCFA Ex. 10.

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<sup>8</sup> There are obvious and unexplained differences between the two letters. The letter which was faxed on August 30 is undated. P. Ex. 5, page 5. The letter which Petitioner sent on September 17, 1993 bears a typewritten date in the upper left hand corner of September 16, 1993. The word "September" has been crossed out and the word "August" has been handwritten above it. HCFA Ex. 7, page 2. Ms. Gros' name is spelled differently in the two letters.

#### IV. Petitioner's contentions of fact and arguments

Petitioner contends that some of the findings the surveyors made based on their July 1, 1993 survey are erroneous. Specifically, Petitioner contends that Dr. Uribe, and not Dr. Metz, was at all times the back-up physician for Petitioner. Secondly, Petitioner contends that Ms. Gros had sufficient training and experience to serve as the registered nurse in charge of dialysis at Petitioner. Petitioner argues also that the plan of correction which it submitted on or about July 30, 1993, established that any deficiencies identified by the surveyors had been corrected by Petitioner. Therefore, according to Petitioner, it complied with HCFA certification requirements on July 1, 1993, and ought to be certified effective that date.

Petitioner argues that, under applicable regulations, it was required to meet only the conditions for certification established by the regulations. Petitioner asserts that, as State agency surveyors found that Petitioner met all conditions for certification on July 1, 1993, it ought to have been certified effective that date. Implicit in this argument is Petitioner's assertion that it was not required to meet standards and elements of certification in order to qualify for certification.

Petitioner argues also that, even if it was not in full compliance with certification requirements as of July 1, it was in "substantial compliance" with them. According to Petitioner, it was not obligated to comply fully with HCFA's certification requirements in order to be certified. Rather, it was obligated to comply only with those requirements governing patient health and safety. Petitioner contends that it met those requirements effective July 1, 1993.

Petitioner argues additionally that, even if it was not in compliance with HCFA's certification requirements on July 1, 1993, it was effectively prevented from satisfying HCFA's requirements by the surveyors' failure to leave a statement of deficiencies with Petitioner at the completion of the July 1, 1993 survey and by subsequent delays in receiving notification from HCFA as to whether Petitioner was in compliance with certification requirements.

Finally, Petitioner asserts that if it did not meet certification requirements on July 1, 1993, then it ought to have been certified by HCFA either on July 29, 1993 or on August 30, 1993. Petitioner's Brief at 5, 13.

Petitioner has offered no satisfactory explanation as to why either of these alternative dates should be the certification date.

V. HCFA's arguments

HCFA argues that the facts of this case do not establish that Petitioner complied with certification requirements on July 1, 1993. Rather, according to HCFA, Petitioner cured deficiencies at dates after July 1, 1993. Therefore, Petitioner has not shown that it was in compliance on July 1, 1993.

HCFA argues, additionally, that Petitioner would have HCFA certify it "retroactively" effective July 1, 1993, based on evidence submitted by Petitioner after that date relating to conditions pertaining on July 1, 1993. According to HCFA, the regulations which govern certification do not permit retroactive certification of a facility.

VI. Analysis of the parties' contentions and arguments

As I hold above, Petitioner has the burden of proving that it meets HCFA's certification requirements. I conclude that Petitioner has not offered credible evidence to prove that it complied with HCFA certification requirements before October 1, 1993.

A. Petitioner's failure to prove that it met certification requirements prior to October 1, 1993

The remedial actions Petitioner undertook, prior to October 1, 1993, to cure deficiencies identified by State agency surveyors ameliorated some of the deficiencies which the surveyors identified. However, the evidence in this case establishes that at no time prior to October 1, 1993 did Petitioner meet all certification requirements. 42 C.F.R. § 489.13(a) and (b). Petitioner's efforts, prior to October 1, 1993, to resolve deficiencies identified by the State agency surveyors were not complete, nor did they account for additional deficiencies which were identified by surveyors at follow-up surveys.

I summarize the surveys, findings of deficiencies, and Petitioner's corrective actions as follows:

○ The State agency surveyors concluded, based on the July 1, 1993 survey, that Petitioner was deficient in meeting both standards and elements governing certification. Those deficiencies included findings that

Petitioner's back-up physician was not qualified to serve in that capacity, and that Petitioner did not have a full-time registered nurse to supervise its dialysis operations. The surveyors included also numerous additional findings of deficiencies in other areas. HCFA Ex. 1.

○ The plan of correction which Petitioner submitted on or about July 30, 1993 attempted to address the deficiencies which were identified by the surveyors at the July 1, 1993 survey. Among the remedial steps which Petitioner pledged to undertake was the hiring of a full-time registered nurse and the designation of Dr. Uribe to serve as the back-up physician. HCFA Ex. 1; P. Ex. 1 - 3.

○ However, the plan of correction did not establish that Petitioner met all federal requirements for certification. Among the issues that were not resolved by the plan of correction was the issue of Dr. Uribe's qualifications to serve as the back-up physician. P. Ex. 4; HCFA Ex. 3.

○ When the State agency surveyors revisited Petitioner on August 2, 1993, they identified a problem with the qualifications of Ms. Gros, the individual whom Petitioner had hired as the facility's full-time registered nurse. HCFA Ex. 2, pages 4 ~ 5. See id. at 2. The surveyors found other deficiencies at this visit as well, including the way in which Petitioner handled medical waste and Petitioner's continuing failure to post a roster of physicians who were available to respond to emergencies.

○ Petitioner did not respond to HCFA's questions about the credentials and qualifications of Dr. Uribe and Ms. Gros until August 30, 1993, when Dr. Ahmed faxed these individuals' credentials and qualifications to HCFA. Dr. Ahmed addressed also an unresolved deficiency concerning the qualifications of the social worker, Ms. Reed, by stating that a board-certified social worker would supervise her. P. Ex. 5.

○ Evidently, HCFA found this evidence to be acceptable, inasmuch as there is no evidence to suggest that HCFA continued to question the qualifications of Dr. Uribe, Ms. Gros, or Ms. Reed. However, Petitioner's submission did not address the other deficiencies found at the August 2, 1993 survey, including the questions of how Petitioner disposed of medical waste and its failure

to post a roster of physicians available to deal with emergencies.'

○ When the State agency conducted a third survey of Petitioner's facility on October 1, 1993, the surveyors evidently were satisfied that all of the previously identified deficiencies had been resolved. However, on that occasion they identified an additional deficiency relating to the maintenance of the personnel file of a technician. HCFA Ex. 8, page 4.

○ Petitioner resolved this final deficiency in its October 9, 1993 plan of correction. HCFA Ex. 8, page 4.

Even if correct, Petitioner's assertion that the surveyors erred in their findings based on the July 1, 1993 survey addresses only two of the deficiencies which the surveyors identified at that survey. These alleged errors concern the surveyors' conclusions as to who was the back-up physician, and the surveyors' finding that a full-time registered nurse was not present to supervise dialysis at Petitioner's facility. There were several other deficiencies found during the July 1, 1993 survey. Petitioner has not asserted that the surveyors' findings of these additional deficiencies were incorrect. Petitioner did not offer HCFA any proof that these deficiencies had been cured until it submitted its July 30, 1993 plan of correction to HCFA.

Thus, Petitioner did not produce evidence prior to July 30, 1993 that it had addressed the deficiencies which the surveyors identified in their July 1, 1993 survey. The information which Petitioner supplied in its July 30, 1993 plan of correction did not establish that any of the deficiencies had been resolved prior to July 30, 1993.

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<sup>9</sup> A problem with the record in this case is that neither HCFA nor Petitioner has been precise in identifying and addressing the deficiencies found at Petitioner or the remediation of those deficiencies. Petitioner's failure to provide HCFA with complete and accurate documentation of its attempts to remedy the deficiencies which State agency surveyors identified contributed to the delays in completing the certification process. However, HCFA never provided Petitioner with precise explanations of which deficiencies had been corrected or had not been corrected. For example, nowhere in the record of this case is there a statement by HCFA indicating that it was satisfied that Dr. Uribe and Ms. Gros were credentialed sufficiently to meet HCFA's certification requirements.

Furthermore, I am not satisfied by the evidence in this case that Petitioner proved that any of the findings by the surveyors which it now asserts to have been erroneous were, in fact, erroneous. Contrary to Petitioner's present assertions, Petitioner had neither an acceptable back-up physician nor a full-time registered nurse to supervise dialysis as of July 1, 1993. Petitioner did not prove that these deficiencies were corrected earlier than the end of July 1993.

Based on the information which Petitioner imparted at the July 1, 1993 survey, the surveyors found that Petitioner's back-up physician was Dr. Metz. Dr. Metz did not meet the criteria for serving as a back-up physician. HCFA Ex. 1, pages 5 - 6. The plan of correction which Petitioner submitted on July 30, 1993 does not deny that, as of the July 1, 1993 survey, Dr. Metz had been designated as the back-up physician. Rather, in the plan of correction, Petitioner designates Dr. Uribe as the back-up physician. HCFA Ex. 1, page 5.

I do not infer from the survey reports and Petitioner's plan of correction that the surveyors misidentified Dr. Metz as the back-up physician. The more reasonable inference is that Petitioner selected Dr. Uribe as the back-up physician when it learned that HCFA would not accept Dr. Metz as the back-up physician. Thus, Petitioner's notification to HCFA that Dr. Uribe would serve as a back-up physician is evidence of a correction of a deficiency implemented after July 1, 1993, and not proof of an error by the surveyors.

Based on their July 1, 1993 survey, the State agency surveyors did not conclude erroneously that Petitioner lacked a full-time registered nurse to supervise dialysis. I conclude that their finding that Petitioner had designated a licensed practical nurse to supervise dialysis is supported by the evidence of record. Petitioner did not correct this deficiency until nearly a month later, when it retained the services of Ms. Gros.

Petitioner's July 30, 1993 plan of correction states that a registered nurse had been designated to assume the duties formerly assigned to a licensed practical nurse. HCFA Ex. 1, page 2. The plan of correction is an admission that Petitioner did not have on staff a registered nurse to supervise dialysis at the time of the July 1, 1993 inspection.

Petitioner did not present satisfactory documentation of Dr. Uribe's and Ms. Gros' qualifications until August 30,

1993.<sup>10</sup> These qualifications evidently were acceptable to HCFA. Had there been no other outstanding deficiencies identified, HCFA could have determined that Petitioner's August 30 submission to HCFA documented the qualifications of Dr. Uribe and Ms. Gros as of July 30, 1993, and could have certified Petitioner as of that date.<sup>11</sup> What precluded certification of Petitioner as of the end of July 1993 was the presence of additional deficiencies that Petitioner had not corrected.

As is evident from the record of this case, the State agency surveyors found additional deficiencies at Petitioner's facility when they conducted their second survey on August 2, 1993.<sup>12</sup> Petitioner has not denied the existence of these deficiencies. I conclude that these deficiencies were corrected by October 1, 1993, because they were not identified as continuing deficiencies by the surveyors who conducted the October 1, 1993 survey. But Petitioner furnished no proof prior to the October 1, 1993 survey that these deficiencies had been corrected at any date previous to October 1, 1993, and, therefore, I cannot find that they were corrected earlier than October 1, 1993.

B. Petitioner's argument that it was required only to meet conditions for certification

In its reply brief, Petitioner argues that an entity qualifies for certification once it meets all conditions for certification established by the regulations. Petitioner implies, without explanation, that an entity need not meet other certification requirements established by HCFA, including applicable standards and elements, so long as it satisfies the conditions for certification established in the regulations. Petitioner asserts further from this argument that it should have

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<sup>10</sup> On September 17, 1993, Petitioner resubmitted to HCFA documentation concerning Ms. Gros' qualifications. See P. Ex. 8.

<sup>11</sup> I discuss HCFA's arguments as to "retroactive" certifications at Part VI E of this Decision.

<sup>12</sup> The State agency surveyors found these deficiencies to exist before Petitioner provided HCFA with satisfactory evidence that it had cured the deficiencies found at the July 1, 1993 survey. Thus, there is no point in time between July 1, 1993 and October 1, 1993 at which HCFA had evidence that Petitioner had cured all outstanding deficiencies.



been certified effective July 1, 1993, the date when the State agency surveyors concluded that Petitioner was "in compliance with all conditions of coverage." Petitioner's Reply Brief at page 5; see HCFA Ex. 11 at 2.

I do not agree with Petitioner's interpretation of the law. As I discuss in Part II of this Decision, and as is evident from the regulations governing certification, an entity must meet all requirements for certification established by HCFA, in addition to conditions for certification, in order to be certified. 42 C.F.R. § 489.13(a). Applicable requirements plainly include standards set forth in the regulations and elements of certification established by HCFA.

Thus, the fact that State agency surveyors found that, as of July 1, 1993, Petitioner met all conditions for certification is not a basis for me to conclude that Petitioner ought to have been certified effective that date. The State agency surveyors found that Petitioner had failed to meet standards and elements governing certification. Because these certification requirements were not met as of July 1, 1993, Petitioner could not be certified effective July 1, 1993.

C. Petitioner's assertion that it was in "substantial compliance" with certification requirements on July 1, 1993, and ought to have been certified effective that date

Petitioner asserts that it should have been certified as of July 1, 1993, because it was in "substantial compliance" with certification requirements on that date.<sup>13</sup> Although Petitioner does not explain precisely what it means by the term "substantial compliance," it appears that Petitioner is arguing that it should have been certified as of the date when it met nearly all of the certification requirements, or at least as of the date when it met all requirements which pertain to patients' health and safety. Petitioner's Reply Brief at 7 - 8.

I do not accept the premise of Petitioner's argument, that a facility may be certified even where it does not comply with all certification requirements, so long as it complies substantially with those requirements. The regulations do not provide for certification of a

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<sup>13</sup> HCFA used the term "substantial compliance" in advising Petitioner that it did not comply with certification requirements. HCFA Ex. 6, 9.

facility where the facility meets most, but not all, certification requirements, or where a facility falls just short of meeting all certification requirements. The regulations provide expressly that a facility will be certified as of the date when it meets all requirements for certification established by HCFA. 42 C.F.R. § 489.13(a).<sup>14</sup>

Furthermore, I do not agree with Petitioner's implicit assertion that some of the certification requirements (including, apparently, those which Petitioner did not comply with) do not relate to the health and safety of patients. The standards and elements which are at issue here on their face all relate to the health and safety of patients. The deficiencies which the surveyors found to be present at Petitioner related to patient health and safety. For example, a continuing deficiency which Petitioner did not provide evidence of having remedied prior to October 1, 1993, was its failure to post a roster of physicians available to handle emergencies.

D. Petitioner's assertion that it was prevented from correcting deficiencies by allegedly untimely notices from the State agency or HCFA

The basis for certification is compliance with certification requirements. A provider or supplier is not entitled to be certified based on a State agency's or HCFA's failure to notify it timely of findings of deficiencies, if, in fact, deficiencies exist. There is nothing in the regulations which establishes a basis for certifying a provider or supplier where a State agency or HCFA fails to evaluate information within a prescribed period of time. Thus, even had the State agency or HCFA delayed sending their notices to Petitioner, as Petitioner alleges, this would not be a basis to certify Petitioner at a date earlier than the date when Petitioner met all requirements for certification.

However, I do not find that HCFA or the State agency delayed notifying Petitioner of their findings. Petitioner asserts that, on or about July 22, 1993, it received notice of the deficiencies which the State

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<sup>14</sup> It is unclear to me what HCFA meant by its use of the term "substantial compliance." See HCFA Ex. 6. Notwithstanding HCFA's use of the term, however, the criterion for certification is full compliance with certification requirements.

agency identified at its July 1 survey of Petitioner.<sup>15</sup> If this is true, I do not find a three-week span of time between the survey and the notification to be unreasonable, given the number and nature of the deficiencies which were identified by the surveyors.

Nor do I find the additional notices which were sent to Petitioner to have been delayed. The State agency sent notification of its findings of the August 2, 1993 survey to Petitioner on August 16, 1993. See HCFA Ex. 4, page 1. Also, on August 16, 1993, it advised Petitioner that Petitioner's July 30, 1993 plan of correction was inadequate. P. Ex. 4, page 1. Both of these actions by the State agency were accomplished approximately two weeks after the State agency received information to evaluate. I do not find it to be unreasonable for the State agency to have taken two weeks to evaluate the information it received.<sup>16</sup>

In some respects, Petitioner's argument that it was prevented from qualifying for certification by untimely notices from the State agency or HCFA is an "estoppel" argument that ignores the purpose of the certification regulations. The certification regulations are intended to protect the welfare of Medicare beneficiaries by assuring that only providers and suppliers who comply with applicable criteria governing the delivery of services are reimbursed for those services. It would serve no public purpose to permit a provider or supplier who does not comply with applicable criteria to qualify for reimbursement simply because a State agency or HCFA did not provide it with timely notice of deficiencies.

#### E. HCFA's "retroactivity" argument

HCFA asserts that a provider or supplier may not be certified retroactively as of the date of a survey if

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<sup>15</sup> Petitioner stated that it received notice of the deficiencies on July 16, 1993. Petitioner's Reply Brief at 7.

<sup>16</sup> The notices which the State agency and HCFA sent to Petitioner were not exactly models of clarity. I can understand Petitioner's apparent frustration in attempting to resolve the deficiencies which HCFA identified, and to complete the certification process. Nonetheless, there were deficiencies at Petitioner which precluded certification, and there is no proof in this case that Petitioner corrected them fully prior to October 1, 1993.

deficiencies are identified at the survey and if the provider or supplier does not cure those deficiencies until a later date. I agree with that analysis. 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.

The regulations do not permit HCFA to certify a provider or supplier "retroactively" based on a plan of correction, unless the plan of correction establishes that outstanding deficiencies had been cured at a date earlier than the date of the plan of correction. Thus, a plan of correction that states that a provider or supplier intends to implement protocols to remedy deficiencies cannot be a basis for certifying that provider or supplier at an earlier date.

In this case, Petitioner presented its first plan of correction on July 30, 1993. That plan was found to be insufficient. However, it would not have justified certification of Petitioner as of July 1, 1993, even if it had addressed adequately all of the previously-identified deficiencies. That is so because the deficiencies were not shown to have been corrected at any date prior to July 30, 1993. For example, the July 30, 1993 plan of correction did not establish that Petitioner had obtained the services of a qualified back-up physician at a date earlier than the date of the plan. Nor did it establish that it had cured other deficiencies identified by the surveyors at dates earlier than the date of the plan of correction.

However, the regulations do not preclude a provider or supplier from providing evidence to HCFA that it met certification requirements at a date earlier than the date of its submission of proof that it met requirements. The regulations establish that the date of certification can be the date that a provider or supplier actually meets certification requirements. *Id.* For example, in its July 30, 1993 plan of correction, Petitioner stated that it had designated Dr. Uribe as its back-up physician and that it had retained the services of a full-time registered nurse to supervise dialysis. The State agency

found these corrections to be inadequate because Petitioner did not supply the credentials of Dr. Uribe. Subsequently, the State agency found also inadequate the documentation of Ms. Gros' qualifications. The record shows that Petitioner presented HCFA with proof of these individuals' credentials and qualifications on August 30, 1993. This information was accepted by HCFA.

The information which Petitioner provided to HCFA on August 30, 1993, established that a qualified back-up physician and a qualified full-time registered nurse had been retained by Petitioner by July 30, 1993. Had there been no other outstanding deficiencies at Petitioner, then, under the regulations, HCFA could have certified Petitioner effective July 30, 1993.<sup>17</sup> HCFA was not obligated to certify Petitioner as of July 30, 1993, only because there existed other deficiencies which Petitioner did not prove that it had corrected prior to the October 1, 1993 survey.

#### VII. Conclusion

I conclude that Petitioner has not proven that it complied with all certification requirements for an ESRD facility prior to October 1, 1993. Therefore, I sustain HCFA's determination to certify Petitioner effective October 1, 1993.

/s/

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Steven T. Kessel  
Administrative Law Judge

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<sup>17</sup> Indeed, HCFA certified Petitioner effective October 1, 1993, based on information which Petitioner supplied to HCFA after October 1, 1993, and which HCFA did not receive until October 25, 1993.