Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Renal Care Partners of Hialeah, (CCN: 10-2785),	)	Date: November 20, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-387
	)	Decision No. CR1695
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Located in Hialeah, Florida, Petitioner, Renal Care Partners of Hialeah (Petitioner or facility), was, until recently, an end stage renal disease (ESRD) facility that supplied dialysis services under the Medicare program. Following surveys completed on March 7 and 29, 2007, the Centers for Medicare & Medicaid Services (CMS) determined that the facility did not meet requirements for Medicare participation because of deficiencies that posed an immediate and serious threat to patient health and safety. CMS terminated Petitioner's Medicare participation and Petitioner has appealed.

For the reasons set forth below, I find that Petitioner was not in substantial compliance with the Medicare conditions for coverage and sustain CMS's determination to terminate its Medicare provider agreement.[1]

[1] Although the facility's deficiencies unquestionably posed immediate jeopardy to resident health and safety, I need not make that finding in order to sustain termination. 42 C.F.R. § 405.2180(a); *see* Discussion, below.

I. Background

Statutory and Regulatory Framework. Section 1881 of the Social Security Act (Act) extends Medicare coverage to ESRD patients. The Act establishes the general scheme by which participating individuals qualify and facilities deliver ESRD services; implementing regulations fill in the details and are found at 42 C.F.R. Subpart U, §§ 405.2100 - 405.2184.

Medicare classifies most healthcare delivery entities as either "providers" or "suppliers." 42 C.F.R. § 488.1. Although classified as "suppliers," ESRD facilities are subject to the same application, survey, certification, and enforcement requirements that apply to "providers." 42 C.F.R. § 488.3(a)(2); *Maher A. A. Azer (Florence Dialysis Center, Inc.)*, DAB CR994 (2003); *Renal Services Group of El Centro*, DAB CR482 (1997); *SRA, Inc., d/b/a/ St. Mary Parish Dialysis Center*, DAB CR341 (1994). Thus, in order to qualify as an approved supplier of Medicare services, an ESRD must be surveyed on-site as if it were a provider of Medicare services, so that its compliance with the requirements of Subpart U can be assessed and certified. Each facility must be surveyed at least once every 12 months, and more often, if necessary, to ensure that identified deficiencies are corrected. 42 C.F.R. § 488.20(a).

To participate in and receive payment from Medicare, an ESRD facility must satisfy all the provisions of section 1881 of the Act and it must be in substantial compliance with Subpart U's conditions for coverage. 42 C.F. R. § 405.2180; 42 C.F.R. § 488.3(a). A "condition for coverage" represents a broad category of services. Each condition is contained in a single regulation, which is divided into subparts called standards. *See* 42 C.F.R. § 488.26(b). With one exception,[2] the failure of an ESRD supplier to meet one or more of the conditions for coverage set forth in Subpart U will result in termination of Medicare coverage for the services furnished by the supplier. 42 C.F.R. § 405.2180(a).

If a facility is deficient with respect to one or more *standards*, it may participate in the Medicare program only if: a) it has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary; and b) the deficiencies "neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care." 42 C.F.R. § 488.28. If the facility meets these criteria, the state agency/CMS may grant it a "reasonable time" in which to achieve compliance. Ordinarily that amount of time is 60

[2] Where an ESRD facility does not participate in and pursue the goals of its ESRD network, as required by 42 C.F.R. § 405.2134, CMS may impose an alternative sanction. 42 C.F.R. § 405.2181.

days but depends on the nature of the deficiency and the survey agency's judgment as to the capabilities of the facility to provide adequate and safe care. 42 C.F.R. § 488.28(c). Nothing in this or any other regulation authorizes a period of correction where a facility is found out of compliance at the condition level.

CMS has established "ESRD networks in which the approved ESRD facilities collectively provide necessary care for ESRD patients." Act, § 1881(c); 42 C.F.R. § 405.2110. Among other responsibilities, the network conducts its own on-site reviews to identify facilities that fail to provide appropriate care. 42 C.F.R. § 405.2112(i).

Procedural Background. In its *2006 Dialysis Facility Report*, the University of Michigan Kidney Epidemiology and Cost Center reported that, from 2002 through 2005, this facility had a whopping **63% annual observed death rate** among its patients. Considering the characteristics of the patient population, a rate of 26% would have been expected (*i.e.*, the facility had 146% more deaths than expected). CMS Ex. 7, at 3. Because of this high mortality rate, as well as the facility's poor performance on other outcome measures (adequacy of treatment, anemia management, vascular access management, and hospitalizations), and the facility's repeated failure to improve (notwithstanding the network's efforts), Florida's ESRD network recommended that CMS impose sanctions. CMS Ex. 3, at 1; CMS Ex. 5, at 1; CMS Ex. 6; s*ee also* CMS Ex. 7; CMS Ex. 24, at 2-3 (Payne Decl.); *see* Act, § 1881(c)(2)(G).

Responding to the network's recommendation, surveyors from CMS and the Florida Agency for Healthcare Administration (State Agency) conducted a complete recertification survey from March 5-7, 2007. CMS Ex. 24, at 3 (Payne Decl.). The surveyors determined that the facility was not in substantial compliance with four conditions for coverage – 42 C.F.R. § 405.2136 (governing body and management), 42 C.F.R. § 405.2140 (physical environment), 42 C.F.R. § 405.2161 (director of renal dialysis facility), and 42 C.F.R. § 405.2162 (staff of a renal dialysis facility) – and that its deficiencies posed immediate jeopardy to patient health and safety. CMS Ex. 3. Petitioner does not contest these survey findings. Petitioner's Closing Brief (P. Cl. Br.) at 1.

By letter dated March 16, 2007, CMS reminded Petitioner that to participate in the Medicare program as a supplier of services, a renal dialysis facility "must meet all of the Medicare Conditions of Coverage for Renal Dialysis Facilities, and be free of hazards to patient health and safety." CMS Ex. 1, at 1. The letter said that, unless the immediate threat to patient health and safety was removed, CMS would terminate Petitioner's Medicare provider agreement effective April 3, 2007. CMS further directed Petitioner to submit a plan of correction within ten days in order to ensure a revisit survey before April

3, 2007. The letter urged that Petitioner "immediately and thoroughly address the deficient practices outlined in the attached [survey] document as well as the problems reported to you by the [ESRD] network after their January visit to your facility." CMS Ex. 1, at 3. The letter specifically warned:

> **You must send us a letter of credible allegation and an acceptable plan of correction (PoC) within ten days of receipt of this notice in order to ensure a revisit by or before April 3, 2007.** Upon written notification of how and when you actually corrected all serious deficiencies, CMS will evaluate the information provided and, if it seems possible another survey may result in a finding of compliance, we will try to arrange it before the termination date. The decision will be based on all the facts surrounding the termination, and a new survey may be authorized before the impending termination date even though not required by law or our procedures.

(Emphasis in original) CMS Ex. 1, at 1.

Petitioner submitted its plan of correction. Notwithstanding the above warning, it listed completion dates later than April 3 – the proposed termination date. One of the surveyors, Glenda Payne, RN, is also CMS's ESRD technical advisor and nurse consultant for two regions covering 13 states (including Florida). She called the facility to advise its management that CMS could not authorize a revisit without a credible allegation that the facility had achieved substantial compliance; to avoid termination, the facility had to correct in time for the State Agency to conduct a revisit survey prior to the termination date. CMS Ex. 24, at 3 (Payne Decl.) Petitioner therefore amended its plan, promising to complete most of its corrections by March 28, 2007. CMS Ex. 4. The State Agency then scheduled a revisit. CMS Ex. 24, at 3 (Payne Decl.); P. Ex. 26, at 2 (Allen Decl.).[3]

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[3] Robert Allen, who is vice-president of operations for Renal CarePartners, Inc., complains that, on one day's notice, Surveyor Payne required the facility to amend its completion dates, and make all identified corrections. In fact, the March 16 notice letter warned that the facility had to achieve compliance before the termination date. Moreover, as the letter states, nothing in the statute or regulations requires that CMS resurvey prior to termination, particularly where, as here, the facility's deficiencies "jeopardize health and safety," or "are of such character to seriously limit the provider's capacity to render adequate care." 42 C.F.R. § 488.28(b). I note also that many of the facility's problems were cited by the ESRD network during its January 2007 visit, and

On March 29, 2007, the surveyors re-visited the facility and concluded that its substantial noncompliance with four conditions for coverage (42 C.F.R. §§ 405.2136, 405.2140, 405.2161, and 405.2162) continued, and that its deficiencies still posed immediate jeopardy to patient health and safety. In an April 2, 2007 letter, CMS informed Petitioner that it was terminating Medicare coverage because of the facility's continuing deficient practices at an immediate jeopardy level of severity. CMS Ex. 2.

On April 19, 2007, Petitioner requested an expedited hearing before an administrative law judge (ALJ). On May 2, 2007, I held a pre-hearing conference, during which I proposed, in light of Petitioner's request for an expedited hearing, a shortened briefing schedule. The parties were directed to submit their written arguments, exhibits, and written declarations of witnesses. CMS submitted a brief (CMS Br.) with 30 exhibits (CMS Exs. 1-30). Petitioner submitted a brief (P. Br.) with 27 exhibits (P. Exs. 1-27). Following receipt of the parties' submissions, I held another pre-hearing conference on June 20, 2007, during which the parties agreed that this matter could be resolved on the basis of written submissions without the need for an in-person hearing. I directed the parties to submit closing briefs, with reply briefs to follow in two weeks. The parties accordingly submitted closing briefs, followed by reply briefs. With its closing brief (CMS Cl. Br.), CMS submitted an additional exhibit, CMS Ex. 31. With its reply brief, Petitioner submitted three attachments (Tabs A-C) from CMS manuals, and an additional five exhibits (P. Exs. 28-32). Following these submissions, CMS filed a surreply and Petitioner replied to the surreply, both of which I have accepted. In the absence of objections, I admit into evidence CMS Exs. 1-31 and Petitioner's Exs. 1-32.

II. Issues

The sole issue before me is whether, based on the survey findings, CMS was authorized to terminate Petitioner's Medicare participation.

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earlier. CMS Ex. 1, at 3; CMS Ex. 6; CMS Ex. 7.

III. Discussion

A. Without affording it an opportunity to correct, CMS may terminate a facility's program participation if the facility does not maintain substantial compliance with Medicare Conditions for Coverage.[4]

As a threshold matter, Petitioner all but concedes that it was not in substantial compliance at the time of the March 7 survey; it does not contest CMS's determination as to the level of its noncompliance at that time. However, Petitioner complains that it "was not allowed a reasonable time to return to substantial compliance." P. at 3. Petitioner's underlying assumption is incorrect; in fact, neither the statute nor regulations afford a substantially deficient facility the opportunity to correct its deficiencies before a penalty – including termination – is imposed.

The Act itself simply authorizes the Secretary to terminate if he determines that a facility "has consistently failed to cooperate with network plans and goals. . . ." Act, §1881(c)(3). And the subpart U regulations mandate termination where a condition for coverage is not met. 42 C.F.R. § 405.2180(a) ("failure . . . to meet one or more of the conditions for coverage . . . will result in termination . . . ."). Section 488.28 of 42 C.F.R., however, says that, under certain circumstances, deficient providers or suppliers, other than skilled nursing facilities (SNFs) and nursing facilities (NFs), will be afforded a reasonable opportunity to correct.[5] The facility must not have any condition-level deficiencies. If its deficiencies are standard-level, they may not, "individually or in combination," jeopardize the health and safety of patients nor be of such character as to

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[4] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions of this opinion.

[5] Elsewhere, the regulations provide that whenever CMS finds a SNF or NF substantially noncompliant, it may impose a remedy without affording an opportunity to correct, notwithstanding its (or a state agency's) routine practice of allowing facilities such an opportunity. *See* 59 Fed. Reg. 56,171 (Nov. 10, 1994) ("[N]either the Act nor the Constitution require that providers have the opportunity to correct deficiencies before sanctions are imposed."); *see also Rosewood Living Center*, DAB No. 2019, at 9 (2006); *Beechwood Sanitarium*, DAB No. 1824, at 15 (2002); 42 C.F.R. § 488.456(b) (may terminate whether or not there is immediate jeopardy); 42 C.F.R. § 488.410 (must terminate within 23 calendar days if ongoing immediate jeopardy not removed); 42 C.F.R. § 488.438(e) (no review of CMS's determination to impose a remedy against a substantially noncompliant facility).

seriously limit the facility's capacity to render adequate care. The amount of time afforded for correction depends on the nature of the deficiency and the state survey agency's judgment as to facility's capacity to provide adequate and safe care. Ordinarily, the facility is expected to achieve compliance within 60 days, but, in individual situations where the state survey agency considers 60 days unreasonable, it may recommend that the Secretary grant additional time for correction.[6]

Here, the facility is not entitled to the opportunity to correct described in 42 C.F.R. § 488.28. The March 7 survey findings – which Petitioner does not now challenge – were voluminous and alarming. Among them:

- Six of six staff members assigned responsibility for testing the water used for dialysis treatment failed to demonstrate competency, "exposing all of the patients to the risk of sustaining possible, probable, or actual harm from exposure to chloramine and chlorine, resulting in hemolysis, harm and death. All patients would be exposed at once with the possibility of mass casualties."

- The facility had no system in place to ensure prompt response to critical laboratory values; for example, serum potassium levels for those patients using an altered potassium bath were not closely monitored, and care was not delivered in accordance with physician orders.[7]

- Staff responsible for mixing bicarbonate, adding electrolytes, and cleaning the bicarbonate tank were not following facility policies and procedures to ensure safe cleansing and creation of bicarbonate solution for use during patient dialysis.

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[6] CMS's declination to afford a facility the opportunity to correct or, if it allows an opportunity to correct, the amount of time it allows are probably not reviewable in this forum. My jurisdiction is limited to "initial determinations," which include whether the services of a supplier continue to meet the conditions for coverage (42 C.F.R. § 498.3(b)(6); *see* 42 C.F.R § 405.2182(b)), but not determinations as to the opportunity to correct. 42 C.F.R. § 498.3(b).

[7] This specific deficiency was not corrected at the March 29 survey. *See* Discussion Part B *infra*.

- Administrative staff and the medical director had not developed an effective quality management program to monitor care, and to address and improve their low performance on measured patient outcomes such as mortality, which presented the risk of continued poor outcomes for all patients treated at the facility (*e.g.,* a mortality rate almost two and a half times higher than expected based on the patient population). Among a long list of specific examples, the facility had no organized system to review each patient death for a potential relationship to the treatment provided.

- No action was noted in response to a patient's reported potassium blood level of 8.7 (which is extraordinarily high).[8]

- The physical environment was not properly maintained.[9]

- The facility did not have a program to identify equipment requiring repair or service, presenting potential hazards to patients and personnel. Among other specific findings, an electronic meter used to measure the chlorine level in water was dusty; its bottles were stained, precluding accurate testing; it was not calibrated.

- The facility had no functional alarm for water quality and did not ensure that patients would be protected from potential harm during times that deionization tanks were used as the primary water treatment, with the potential to harm all patients on treatment when the tanks were in use.

CMS Ex. 3, at 1, 2, 4, 7-9, 9, 13-14, 15-16, and 17-18, respectively.

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[8] This specific deficiency is related to the absence of a system for responding to critical lab values. *See* Discussion Part B *infra*.

[9] During the March 29 survey, the surveyors concluded that this deficiency had not been corrected. Among other findings, the employee bathroom still lacked hot water. *See* Discussion Part C *infra*.

These represent only a fraction of the findings; the list goes on and on. CMS Ex. 3. It shows that the facility had condition-level deficiencies that immediately jeopardized patient health and safety. Nothing in the statute or regulations provides a facility with this level of noncompliance the opportunity to correct.[10]

I recognize that, notwithstanding the plain language of 42 C.F.R. § 488.28, CMS has decided to afford even egregiously deficient facilities the opportunity to correct, although, as here, with a shortened time line for correction. This is apparently wholly within the agency's discretion, and Petitioner can hardly complain that CMS has been more generous to it than called for in the statute or regulations.

Petitioner nevertheless suggests that it should have been given at least 60 days for correction, pointing to selected provisions of the State Operations Manual (SOM), and claiming that, prior to the March 29 survey, its deficiencies no longer posed immediate jeopardy to patient health and safety. I note first that to continue its participation, the facility still has to achieve substantial compliance, and removal of the immediate jeopardy finding (even if true) would not entitle the facility to an extended period in which to achieve that compliance.[11]

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[10] I find this level of noncompliance particularly alarming in light of the fact that, since at least 2005, the ESRD network had purportedly been working with the facility, providing technical assistance and tools for quality improvement. The results of the March 2007 surveys seem to confirm the network's conclusion that the facility's action plans "have not reflected the urgency of the situation." CMS Ex. 6, at 1.

[11] Petitioner argues that it received inadequate notice as to the basis for its termination. P. Reply Br. at 3, *et seq*. While the notice letter says that CMS will terminate "unless the immediate threat to patient health and safety is removed," it also says that to participate in the Medicare program a renal dialysis facility "must meet all of the Medicare Conditions for Coverage for Renal Dialysis Facilities, and be free of hazards to patient health and safety." CMS Ex. 1, at 1. The letter instructs the facility to "immediately and thoroughly address the deficient practices" set forth in the survey document. *Id*. at 3. It warns the facility that its plan of correction must explain how the facility has corrected "all serious deficiencies," and warns that CMS will not even schedule a survey unless "it seems possible another survey may result in *a finding of compliance*." (Emphasis added) *Id*. at 1. CMS also provided the facility with a detailed

Second, Petitioner bases its claim on a purported oral remark from the state surveyor. According to Petitioner, Surveyor Arlene Schweitzer told the facility administrator that the immediate jeopardy had been removed. P. Ex. 26, at 2 (Allen Decl.); P. Ex. 27, at 3 (Fernandez Decl.). But the state surveyor was not empowered to decide whether the immediate jeopardy had been removed. Only the *Secretary* (for whom CMS acts) has the final authority to make that determination. 42 C.F.R. § 488.18(c). Under no circumstances would the determination be made by a single state surveyor, and any purported representations she made would not bind CMS. *See Heckler v. Community Health Services of Crawford County*, 467 U.S. 51 (1984).[12]

Third, once a finding of substantial noncompliance has been made, the presumption is that the facility's level of noncompliance continues until the facility establishes that it has corrected, which ordinarily requires a resurvey. Certainly, considering the nature of the March 7 survey findings, the immediate jeopardy determination would not have been removed unless CMS made that determination following a revisit survey. *See, e.g., Asbury Center at Johnson City*, DAB No. 1815, at 19-20 (2002).[13] In fact, as shown by the March 29 survey results, the facility had not removed the immediate jeopardy. CMS Ex. 5.

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statement of deficiencies. CMS Ex. 3. I am therefore satisfied that Petitioner received adequate notice of its specific deficiencies, and well understood (or should have) that, in order to continue its Medicare participation, it had to bring itself into substantial compliance with program requirements. I note also that Petitioner had a duty to familiarize itself with the legal requirements for Medicare participation. *Heckler v. Community Health Services of Crawford County*, 467 U.S. 51, 64 (1984).

[12] In *Crawford County*, the Supreme Court expressed particular skepticism at the Medicare supplier's purported reliance on oral advice. *Crawford County* at 65.

[13] I need not address the issue because, under any standard of review, the facility did not meet the requirements for participation in the Medicare program, but for this reason, the *Hillman* analysis (*Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Ctr. v. HHS*, No. 98-3789 (GEB) (D. N.J. May 13, 1999)) may not apply here, where everyone agrees that the facility was not in substantial compliance at the time of the March 7 survey. The presumption is that the noncompliance continues until the facility establishes otherwise, so CMS would not necessarily bear any additional burden of going forward.

Fourth, even assuming that, based on the surveyor's remarks, Petitioner genuinely believed that its deficiencies no longer posed immediate jeopardy, nothing suggests that it was prejudiced by that belief. The facility was still substantially noncompliant. As it knew, or should have known, it could only continue its participation in the Medicare program if it corrected its deficiencies and achieved substantial compliance. The surveyor's purported mis-statements therefore should not have changed Petitioner's course of action.

Finally, if there were a misunderstanding as to whether the immediate jeopardy had been removed, the evidence suggests that Petitioner was not without fault in creating that impression. As discussed below, Petitioner made representations as to the steps it had taken to correct, which misled CMS into accepting its plan of correction in the first place.

With respect to Petitioner's complaints that, in imposing termination, CMS and the state agency did not follow certain provisions of the SOM, particularly as to the time tables for termination, I note that such manual provisions offer guidance to the state agency, but their provisions do not change the Medicare participation requirements set out in the regulations, by which I am bound. *Alden-Princeton Rehabilitation & Health Care Center*, DAB No. 1873, at 8 (2003); *Beverly Health and Rehabilitation Center – Williamsburg*, DAB No. 1748, at 8 (2000). Moreover, Petitioner's citations to the SOM are selective. In its instructions for processing immediate jeopardy terminations, the manual says that the "processing times given here are the *maximum allowed*. Do not postpone or stop the procedure unless *compliance* is achieved and documented through onsite verification." SOM § 3010B (P. Cl. Br. Attach. A) (Emphasis added). It seems, then, that CMS's actions were in accord with these provisions of the SOM.

B. The facility had no system in place for tracking laboratory test samples, and therefore was not able to respond promptly to critical lab results, which puts the facility out of substantial compliance with Medicare Conditions for Coverage (42 C.F.R. §§ 405.2136, 405.2161, and 405.2162).

Patients requiring renal dialysis are particularly vulnerable to alterations in their blood chemistry. Among other reasons, blood tests are necessary to assess the effectiveness of the dialysis. A monthly blood test measures blood urea nitrogen (BUN), an indicator of the overall level of waste products in the patient's system. CMS Ex. 26, at 10.

As the parties agree, blood potassium levels are important and must be monitored. Dialysis patients are more likely to have abnormal levels, which can lead to muscle cramps or weakness, nausea, diarrhea, dehydration, low blood pressure, confusion, paralysis, irregular heart beat, and even cardiac arrest. The only way to monitor blood potassium levels is to take a blood sample and send it to the lab for analysis. Based on

the lab results, adjustments may be made to the patient's dialysate. CMS Ex. 26, at 9.[14] If the levels are too low, potassium can be added; if too high, it should be removed. Of course, in order to make the necessary adjustments, staff must first draw the blood, send it to the lab, receive back the test results, review the test results, and advise the treating physician of changes. The physician may then change his orders in response to the patient's altered condition. CMS Ex. 30, at 3-4 (Schweitzer Decl.).

At the time of the March 7 survey, the surveyors noted that the necessary tracking and response were not occurring in any reliable, systematic way; staff were not responding to critical lab values and were not monitoring the patient's dialysis treatment plan. As a result, vulnerable patients were put at increased risk for adverse outcomes, including even death.

The survey report cites specific examples of patients with abnormal potassium levels whose lab values were not adequately monitored. Possibly the most egregious involved Patient #10. The laboratory results of a December 7, 2006 blood draw showed that Patient #10's potassium level was a dangerously high 8.7 (normal ranges 3.4 to 5.0), which the lab characterized as "absurd." Laboratory staff were apparently so concerned about the result that on December 9 (a Saturday) they called the facility to notify staff of the elevated level. Yet no documentation suggests that anyone notified the physician of these results nor that the test was repeated to verify or refute the results. *Id*. at 36-37.

In its plan of correction, the facility said that, although it had in place computer programs for monitoring patient care, not all of its nursing staff were using them. Therefore, "in order to maintain continuity and to maintain up to date records, the nurses *have returned* to a process utilizing Kardex's for daily treatment orders." *Id*. at 37 (Emphasis added). Under this system, the physician writes his orders and the nurse transcribes it on to a patient-specific card, called a Kardex. Changes in treatment orders, start and stop dates for medications, dosage changes, dialysate changes, and changes in the parameters of treatment are all recorded on the Kardex, according to the plan of correction. The facility also assured CMS that its administrator would check weekly to verify that the process was being followed, and would review weekly the information in the Kardex and compare it to the physician orders to verify accuracy. *Id*.

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[14] Dialysate is the fluid in the dialyzer that helps remove wastes and extra fluid from the patient's blood.

When the surveyors arrived for the March 29 survey, the Kardex system was not operational. Although each patient file apparently contained a Kardex, the cards were all completely blank except for the patient's name. CMS Ex. 19; s*ee also* P. Cl. Br. at 46 ("the cards were not blank. They had patient names. . . .").[15]

Even if the cards had been filled out, it does not follow that the facility had an effective system in place. The system had to be operational. That means that staff should have been able to determine: whether blood had been drawn as ordered; whether the blood sample had been sent to the lab with the appropriate order for testing; whether the lab had returned the test results; whether appropriate staff had reviewed the test results; whether they had notified the physician of any changes; and whether the physician has responded by issuing new orders.

Surveyor Schweitzer tested the effectiveness of the facility's "system" by reviewing the patient records for the facility's five patients who had been identified as requiring altered potassium dialysate.

Patient #1 had a March 17, 2007 physician order for weekly lab tests of potassium level. CMS Ex. 14, at 1. The record contained no evidence that the blood samples had been drawn. Surveyor Schweitzer saw no lab test results for the two weeks prior to the survey. CMS Ex. 30, at 4-5. The facility simply continued to give the patient a 4.0 level dialysate bath, without knowing the patient's potassium blood levels.

Patient #2 had a March 24, 2007 physician order for weekly potassium levels. CMS Ex. 15. A blood sample should have been drawn on March 27, based on the facility's practices, but at the time of the survey, the clinical record contained no evidence that a blood sample had been drawn, nor could staff produce any evidence that the blood had been drawn. Again, the facility simply continued to administer a higher level of dialysate bath, without regard to what the patient's levels might have been.

Patient #3 had a March 13, 2007 order for weekly potassium levels. CMS Ex. 16, at 1. On March 17, 2007, the physician ordered a 1.0 dialysate bath, based on the patient's serum potassium level of 6.3. But on March 27, the facility neglected to include a request for potassium level when they sent the patient's blood sample to the lab. The facility continued to administer the lower concentration dialysate bath, again without regard to what the patient's potassium levels might have been.

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[15] Petitioner attributes its failure to develop cards for all residents to "the unreasonable time period for correction." P. Br. at 19. I have already addressed this issue.

Patient #5 had physician orders for weekly serum potassium levels that were dated March 14 and March 21, 2007. CMS Ex. 17, at 1, 2. On March 23, the physician ordered a 1.0 dialysate bath. Blood was drawn on that day but staff did not request testing for potassium levels. *Id*. at 4. Blood was next drawn on March 26, and sent to the lab, but the facility neglected to request a potassium level. *Id*. at 3. Staff just continued to administer a lower concentration dialysate bath.

Since the time of the survey, Petitioner has apparently determined the status of these patients' blood tests, and argues that, in fact, for all but one of these patients, blood tests were performed as ordered. But this misses the point. That the Administrator did not know and could not promptly find out what was going on with four out of five of these vulnerable patients shows that the facility's system for tracking lab tests was not effective. It is not sufficient that the facility might eventually be able to track down the lab results; it must have a system in place to monitor the blood draws, testing, and lab reports so that it can respond *timely* to any changes in the patient's blood levels.

I reject Petitioner's remarkable argument that such timely response is not necessary. According to the facility's medical director, Dr. Rodolfo Gutierrez, missing a potassium lab test, or even multiple lab tests, creates no potential for harm, since he is only concerned about "trends" in potassium levels. In an emergency, according to Dr. Gutierrez, he would order the lab on a "stat" basis, and review it immediately. P. Ex. 20, at 4 (Gutierrez Decl.). But based on what was going on at the facility, Dr. Gutierrez would not necessarily have known if test results showed an emergency, as demonstrated by the March 7 survey finding that Patient #10's blood test showed a potassium level of 8.7. Nothing in the record suggests that the information was even conveyed to the physician. I agree with Surveyor Schweitzer that a patient's life could be compromised if the incorrect dialysate bath is used for any length of time, and the physician cannot order appropriate treatment if staff fail to provide him with timely lab results. CMS Ex. 30, at 7-8 (Schweitzer Decl.).

Nor do I agree with Petitioner's suggestion that monthly reviews by its medical team make up for its ineffective tracking system because the reviewers would, at the time of the review, notice any errors or irregularities. *See* P. Br. at 14. Waiting up to a full month to respond to a critical test result is not acceptable. Moreover, what would the facility do if it determined that ordered testing had not been performed? Presumably the physician would re-order the tests, but, without an effective tracking system in place, the facility still would have no way of ensuring that the samples were taken, the tests ordered, and the results received and reported.

With respect to the individual patients whose charts were reviewed by Surveyor Schweitzer, the ordered testing was not even performed for at least two of them – omissions that no one picked up on because of the facility's ineffective tracking system. Petitioner admits that the ordered blood labs were not drawn for Patient #1. P. Br. at 15; P. Ex. 23, at 7 (Savage Decl.). Lab reports show that blood was drawn on March 15 (two days prior to the date of the physician order) and on March 29, the date of the survey. P. Ex. 9. The facility thus failed to follow the physician order, and waited 12 days before testing Patient #1's potassium levels.

Nor were the ordered tests performed for Patient #5. Administrator Savage suggests that CMS looked at the wrong patient chart, and claims that, for Patient #5, all ordered labs were drawn timely. P. Ex. 23, at 8 (Savage Decl.). Misidentified or not, CMS has produced a physician order and test results that are unquestionably for the same facility patient. The documents show that the patient had a physician order for weekly potassium levels. CMS Ex. 17. The lab report shows no testing for potassium, and the record contains no evidence of any test for potassium levels from the date of the order (March 14) through the date of the survey, more than two weeks later.

The regulations require that an ESRD be under the control of an identifiable governing body responsible for the governance and operation of the facility. The governing body must ensure safe and effective patient care, which includes developing written patient care policies, and periodically reviewing implementation of those policies to ensure that they have been carried out. 42 C.F.R. § 405.2136. Patient treatment is under the general supervision of a physician-director who must devote sufficient time to the facility to carry out his responsibilities of planning, organizing, conducting, and directing the professional ESRD services. The physician-director must ensure adequate monitoring of the patient and the dialysis process. 42 C.F.R. § 405.2161(b)(3). In addition, properly trained staff must be present in adequate numbers to meet the patient needs. 42 C.F.R. § 405.2162.

The absence of an effective system for monitoring lab tests, which would have enabled the facility to respond promptly to critical lab results, means that the governing body was not doing its job, the physician-director was not performing his job, and the staff were not meeting the patient needs. It represents a serious breakdown in the delivery of care, jeopardizes patient health and safety, puts the facility out of substantial compliance with the three cited conditions for coverage, and, without regard to any of the other deficiencies cited, justifies termination here.

C. The facility was not in substantial compliance with 42 C.F.R. § 405.2140(b) because it failed to correct its infection control problems, which jeopardized patient health and safety, and seriously limited the facility's capacity to render adequate care. Based on these ongoing deficiencies, CMS was justified in terminating the facility's Medicare participation.

I need not resolve the infection control issue since the facility's failure to track patient lab tests, by itself, justifies termination.[16] Nevertheless, because certain dispositive facts are undisputed and because Petitioner's arguments – that the regulation is met so long as it has written procedures in place, and that hot water is not necessary for effective infection control – are plainly and dangerously wrong, I address the issue. I conclude that the facility's continuing failure to correct its infection control problems justifies termination.[17]

People on dialysis are especially vulnerable to infection, which is the second leading cause of death among dialysis patients. CMS Ex. 31. To protect them, the facility must be maintained and equipped to provide a sanitary environment. 42 C.F.R. § 405.2140(b). It must have written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies must include, but are not limited to, appropriate procedures for surveillance and reporting infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection.

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[16] For this reason, I decline to address the hotly contested issue of whether the facility was using a potentially dangerous device called a "dummy drip chamber" in setting up its machines.

[17] Petitioner characterizes CMS's raising the infection control issue in its closing brief as "trial by ambush" since CMS did not discuss the deficiency in its opening brief. However, the deficiency is set forth in the Statement of Deficiencies. Petitioner itself obviously recognized that the issue was on the table because it addressed it in its opening brief and even moved for partial summary judgment, arguing that it was in compliance with 42 C.F.R. § 405.2140(b)(1). Although CMS initially did not address the issue in its motion for summary judgment, we discussed it at the prehearing conference, CMS addressed it in its closing brief, and Petitioner had ample opportunity to reply and even sur-reply.

Petitioner's record on infection control is particularly grim. Among its many concerns, the ESRD network complained that the facility lacked effective and efficient infection control management, citing its high rate of hospitalizations due to infection (25%).[18] CMS Ex. 6, at 2. The network also charged that staff members failed to wash their hands and use complete personal protective equipment. *Id*.

At the time of the March 7 survey, the facility's significant problems with infection control continued. Petitioner had in place written policies and procedures for controlling and preventing infection, and CMS voices no objections to the contents of those documents. However, in CMS's view, these policies and procedures were not "in effect" because Petitioner failed to follow them. Among other cited deficiencies, the staff bathroom had no hot water. CMS Ex. 3, at 30. Behind the nurses' station, "clean" and "dirty" sinks sat side-by-side, with splatter from the dirty sink contaminating the contents of the clean sink (containers of clamps and bleach-soaked cloths used for cleaning machinery and patient chairs). A third sink, located at the far end of the room, contained the emergency eyewash station but could not be used because clean supplies were stacked on the entire counter and sink edge. *Id*. at 29.

In its plan of correction, Petitioner responded to the absence of hot water in the employee bathroom by assuring CMS that "lack of hot water in the facility was rectified immediately and the facility has hot water for hand washing and patient care." *Id*. at 29.[19] With respect to the problem of the clean and dirty sinks, the facility promised that the "front sink" would be designated the clean sink, and the "back sink" would be designated as the dirty sink, assuring CMS that "these sinks have been labeled as such and the staff

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[18] In its *2006 Dialysis Facility Report*, the University of Michigan Kidney Epidemiology and Cost Center recommended review of infection control practices at the facility because, during the period 2002-2004, 26% of the facility's patients were hospitalized for septicemia, compared with 10.9% nationally. CMS Ex. 7, at 4.

[19] Petitioner asserts that, in making this representation, it was not claiming that it had hot water in the employee bathroom. P. Reply Br. at 16. At the time of the March 3 survey, the facility apparently had *no* hot water *at all anywhere in the facility* – a problem that inexplicably seems to have escaped the notice of the surveyors since they did not cite it in the statement of deficiencies. CMS Ex. 3. In any event, I do not find it credible that Petitioner offered corrections to problems that were not cited, but then said nothing about the problem that was cited – the absence of hot water in the employee bathroom. I find it more likely that Petitioner's ambiguously-worded plan of correction was intended to mislead CMS into believing that the cited problem had been remedied when it had not.

have been informed of the change." *Id*. The facility then claimed that all dirty clamps and bleach solution "have been moved" to the dirty sink, and that all the supplies that prevented the use of the eyewash station had been relocated to a cart. *Id*.; *see also* CMS Ex. 4.

But when the surveyors arrived at the facility on March 29, the facility still had no hot water in its employee bathroom. According to Petitioner, the hot water heater "intended for that purpose" was in the trunk of the car of a corporate director.[20] P. Br. at 18.

Petitioner argues that 42 C.F.R. § 405.2140(b)(1) requires only written procedures, and, so long as the written documents were in place, the facility's failure to provide effective hand washing facilities for staff does not state a deficiency under the regulation. P. Br. at 10; P. Reply Br. at 6-7. I reject this. The plain language of the regulation requires that policies and procedures be "in effect." *See also* 42 C.F.R. § 405.2136(f) (governing body must ensure that intent of written policies is carried out).

Petitioner also argues that hot water was not required because: 1) alcohol-based hand rubs were available for staff use; 2) other sinks in the facility had hot water, which staff could have used; and 3) hot water is not necessary for hand washing anyway. I reject all three arguments.

To justify substituting alcohol-based hand rubs for hand washing, Petitioner quotes at length a section from the Federal Register amending nursing home regulations to allow alcohol-based hand rubs in egress corridors, notwithstanding the potential fire hazard posed. The preamble to those regulations cites literature from the Center for Disease Control (CDC) discussing the virtues of hand rubs for infection control. 70 Fed. Reg. 15229, 15230 (March 25, 2005). While alcohol-based rubs may be sufficient for some purposes, they are not appropriate for staff who have used the bathroom, because their hands are then susceptible to contamination with proteinaceous materials. The CDC advises that alcohol gels are not appropriate for use when hands are visibly dirty or contaminated with proteinaceous (blood or other bodily fluids such as fecal material or urine) materials. CDCl, *Guideline for Hand Hygiene in Health-Care Setting (2002), available* at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116al.htm.

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[20] CMS also asserts that the facility had not resolved the problem of cross-contamination between its clean and dirty sinks, which Petitioner vehemently disputes. I need not resolve this factual dispute in order to find, based on the absence of hot water in the employee bathroom, that the facility was not in substantial compliance with 42 C.F.R. § 405.21409(b).

The facility's own policy for hand washing emphasizes that hand washing "is the single most important procedure for preventing nosocomial (hospital-based) infection." Routine hand washing requires "vigorous rubbing together of all surfaces of lathered hands for at least 45 seconds, followed by thorough rinsing under a stream of water for a minimum of 30 seconds." Personnel are instructed to wash their hands "after touching inanimate sources that are likely to be contaminated with organism: these sources include . . . urinal, using restroom, etc." P. Ex. 19, at 2. In a January 15, 2007 staff meeting and January 16 inservice, the director of clinical services, Judi Fernandez, RN, added, "Visible residue or material on hands require hand washing with *warm* water, antibacterial [soap], for 30-45 seconds, vigorously and do in between fingers, fingers, and both sides of the hands up to the wrist, but further up if there has been contamination with blood or other fluids." *Id*. at 1 (Emphasis added); CMS Ex. 22.

With regard to Petitioner's argument that hot water was available in other facility sinks, staff using the employee bathroom would have had to go from the second floor to the first floor to reach those sinks, creating multiple opportunities for the spread of infection.

Finally, Petitioner argues that hot water is unnecessary, pointing to various portions of the CDC's instructions that say nothing about water temperature. But, as noted above, Nurse Fernandez's instructions included the admonition that hands be washed in *warm* soapy water. These instructions are consistent with CDC recommendations. *See* CDC, *Clean Hands Save Lives!*, *available at* http://www.cdc.gov/cleanhands. The CDC recommends warm, rather than hot water, in order to prevent dermatitis. But body oils on the hands hold soils and bacteria. Hot or warm soapy water is more effective than cold, soapy water in removing oily soils and the bacteria in them (which should come as no surprise to anyone who has ever attempted to wash a greasy pan with cold water). *See* U.S. Food and Drug Administration, *Hand Washing*, *available at* http://www.cfsan.fda.gov. Obviously, unless the facility provided hot water, staff would not have access to any warm water.

I note finally that, in light of this facility's history of infection control problems, it should have been doing all in its power to prevent the spread of infection. Offering its staff warm water in which to wash after using the bathroom required a relatively simple fix, but, for some reason, Petitioner did not make that correction. Although CMS did not cite this as a condition-level deficiency, I find that it nevertheless jeopardized patient health and safety and justifies termination.

IV. Conclusion

The facility was not in substantial compliance with program requirements at the time of the March 3, 2007 survey. CMS afforded it an opportunity to correct its deficiencies, but the evidence establishes that, at the time of the March 29, 2007 survey, it was not in compliance with multiple Medicare conditions of participation. Its deficiencies jeopardized patient health and safety. CMS is therefore authorized to terminate its Medicare participation.

/s/
Carolyn Cozad Hughes
Administrative Law Judge