Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Jackson Dialysis Center, (CNN: 11-2740),	Date: March 3, 2008
Petitioner,	Docket No. C-05-533 Decision No. CR1744
v.	
Centers for Medicare & Medicaid Services.	

DECISION

Petitioner, Jackson Dialysis Center, violated 42 C.F.R. § 405.2140 on June 22, 2005. Termination of Medicare coverage for services provided by Petitioner was required.

I. Background

Petitioner was an outpatient dialysis facility located in Jackson, Georgia, that was certified to participate in Medicare under the End-Stage Renal Disease (ESRD) Program as an ESRD facility providing renal dialysis and related services and supplies. Petitioner was subject to an unannounced, complaint survey by surveyors from the Georgia Department of Human Resources, Office of Regulatory Services (the state agency) on June 20, 21, and 22, 2005. The report of the survey in the form of a "Statement of Deficiencies" (SOD) (Form CMS-2567) dated June 27, 2005, was forwarded to the Centers for Medicare & Medicaid Services (CMS). CMS Exhibit (Ex.) 1. CMS notified Petitioner by letter dated July 1, 2005, with the SOD attached, that the survey found Petitioner in violation of five conditions of participation; that deficient practices at the facility were pervasive and presented immediate jeopardy for patients; that no plan of correction was requested and no revisits would be authorized; and that Petitioner's Medicare coverage was terminated and no further Medicare payments would be made for patients "whose plans of care begin on or after August 8, 2005." CMS Ex. 2.

Petitioner requested a hearing by letter dated August 30, 2005. The case was assigned to me for hearing and decision on September 2, 2005, and a Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on that date. On September 6, 2005, Petitioner moved for an expedited hearing. I convened telephonic prehearing conferences on September 9 and 12, 2005, the substance of which are memorialized in my Order dated September 13, 2005. During the conferences, CMS indicated no objection to the motion for expedited hearing; the motion was granted; an expedited schedule for case development was agreed to, amending the schedule established by the Prehearing Order; and the parties agreed to convene the hearing on October 31, 2005, in Atlanta, Georgia. On October 20, 2005, Petitioner moved to stay proceedings pending completion of a Georgia State administrative proceeding against Petitioner's license.[1] I denied the motion for stay by Order dated October 21, 2005.

A hearing was convened in this case on October 31 and November 1 through 3, 2005, in Atlanta, Georgia. A 988-page transcript of proceedings (Tr.) was prepared. CMS offered exhibits (CMS Exs.) 1 through 32. CMS Exs. 1 through 28, 30, and 31 were admitted as evidence. CMS Exs. 29 and 32 were not admitted. Petitioner offered and I admitted exhibits (P. Exs.) 1 through 7, 9 through 41, 45, 50 through 52, and 54 through 56. Petitioner's Exs. 8, 42 through 44, 46, and 53 were not admitted.

Petitioner filed a post-hearing brief on January 5, 2006 (P. Brief). CMS filed a post-hearing brief on January 6, 2006 (CMS Brief). The parties filed post-hearing reply briefs on February 3, 2006 and on February 6, 2006 (P. Reply and CMS Reply, respectively). On February 6, 2006, CMS also filed a motion for leave to offer additional exhibits or to reopen the hearing. On February 15, 2006, Petitioner filed an opposition to the CMS motion. The motion is denied for the reasons discussed in the analysis section of this decision.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

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[1] Petitioner must have a state license in order to operate according to the motion. Motion for Stay ¶¶ 3 & 7.

1. On June 22, 2005, Petitioner's employee terminated a patient's dialysis without wearing a protective gown. Tr. 434; CMS Ex. 1, at 18.

2. On June 22, 2005, Petitioner's employee terminated a patient's dialysis without wearing a protective eye and mouth shield. Tr. 434; CMS Ex. 1, at 18.

3. On June 22, 2005, three of Petitioner's employees, while cleaning dialysis machines, failed to empty the bucket on the machines that collected the fluid discharge from the dialysis process. Tr. 350, 434; CMS Ex. 1, at 18.

4. Termination of dialysis exposes staff to the blood of the patient undergoing dialysis.

5. Failure of staff to wear a protective gown and eye and mouth shield while terminating dialysis exposes staff to a patient's blood and blood borne disease. Tr. 509-10; Tr. 604-08, 618, 621-22.

6. Failure of staff to properly dispose of the contents of dialysis machine discharge buckets and then properly clean the buckets poses a risk for cross-contamination and the transmission of HIV, hepatitis, and other infectious diseases to staff and patients. Tr. 509-10; Tr. 604-08, 618, 621-22.

7. Petitioner failed to provide a sanitary and safe environment for patients and staff on June 22, 2005.

8. CMS notified Petitioner by letter dated July 1, 2005, that Petitioner's Medicare coverage was terminated and no further Medicare payments would be made for patients "whose plans of care begin on or after August 8, 2005." CMS Ex. 2.

9. Petitioner requested a hearing by letter dated August 30, 2005.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

2. Petitioner violated the condition for coverage established by 42 C.F.R. § 405.2140 related to physical environment.

3. Termination of Medicare coverage for services provided by an ESRD facility is required when the facility is found to have violated a condition for coverage.

4. No period for correction of a violation of a condition for coverage is permitted prior to termination of Medicare coverage.

5. Petitioner's violation of the condition for coverage established by 42 C.F.R. § 405.2140 required termination of Medicare coverage for services provided by Petitioner as an ESRD facility.

C. Issue

The issue in this case is:

> Whether there is a basis for the termination of Petitioner's eligibility to receive reimbursement from Medicare as a supplier of ESRD services to Medicare eligible patients.

D. Relevant Law

The Social Security Act (the Act) provides for Medicare coverage, i.e., benefits, for patients who suffer ESRD. Act, section 1881(a) (42 U.S.C. § 1395rr(a)). Section 1881(b)(1)(A) authorizes the payment of benefits on behalf of qualified beneficiaries for renal dialysis services and related supplies, including self-dialysis and support services provided by an ESRD facility. Medicare benefit payments on behalf of qualified ESRD beneficiaries may be paid directly to renal dialysis facilities[2] that meet such requirements as the Secretary establishes by regulation. The Act further provides in section 1881(g)(1):

> In any case where the Secretary –
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> (A) finds that a renal dialysis facility is not in substantial compliance with requirements for such facilities prescribed under subsection (b)(1)(A),
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> (B) finds that the facility's deficiencies do not immediately jeopardize the health and safety of patients, and
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> (C) has given the facility a reasonable opportunity to correct its deficiencies,

[2] An "ESRD facility" is a facility approved to furnish at least one specific ESRD service. A "renal dialysis facility" is an ESRD facility that is freestanding, i.e., not part of a hospital, that is approved to furnish dialysis services directly to a dialysis patient. 42 C.F.R. § 405.2102; SOM § 2280C.

> the Secretary may, in lieu of terminating approval of the facility, determine that payment under this title shall be made to the facility only for services furnished to individuals who were patients of the facility before the effective date of the notice.

A decision of the Secretary to restrict payments becomes effective only after notice to the public and the facility as the Secretary prescribes by regulation, and continues until the facility achieves substantial compliance with statutory and regulatory requirements or until the Secretary terminates approval of the facility to receive Medicare payments. Act, section 1881(g)(2). An ESRD facility dissatisfied with the Secretary's determination to restrict payments and/or terminate approval of the facility to receive Medicare payments has a right to a hearing as provided by section 205(b) of the Act and judicial review as provided by section 205(g) of the Act. Act, section 1881(g)(3).

The regulations the Secretary promulgated regarding coverage of ESRD services are found at 42 C.F.R. Part 405, Subpart U (§§ 2100-2184). Sections 405.2130 through 405.2140 of 42 C.F.R. set forth the general requirements for and description of the facilities required for delivery of ESRD services that may be compensable under Medicare. Sections 405.2160 through 405.2164 set forth the specific requirements for facilities that provide ESRD dialysis services. 42 C.F.R. § 405.2100(b). Section 405.2180(a) provides that failure of an ESRD supplier to meet one or more conditions of coverage required by the regulation will result in termination of Medicare coverage for ESRD services by that supplier.[3] If the condition violated is failure of the ESRD provider to participate in "network activities" or pursue "network goals" as required under 42 C.F.R. § 405.2134, then coverage may be reinstated when CMS determines that the supplier is making "reasonable and appropriate" efforts to satisfy the condition. 42 C.F.R. § 405.2180(b). If any other condition is violated, reinstatement cannot occur until CMS finds that the reason for termination has been removed and there is "reasonable assurance that it will not recur." 42 C.F.R. § 405.2180(c). The regulations authorize CMS to impose an alternative sanction, i.e., a sanction other than termination, when the ESRD supplier fails to participate in network activities or pursue network goals as required by the condition established by 42 C.F.R. § 405.2134 and the failure to comply with that condition does not jeopardize patient health and safety. 42 C.F.R. § 405.2181(a). Alternative sanctions are not authorized for violations of other regulatory

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[3] An ESRD facility does not have a "provider" agreement with the Secretary and is, by definition, a "supplier" of services. *See* 42 C.F.R. §§ 400.202, 405.2180. However, the Act specifies that a renal dialysis facility is treated as a "provider" of services for purposes of section 1878 of the Act, which relates to the Provider Reimbursement Review Board. Act, § 1881(b)(2)(D).

conditions. CMS is required to give the facility and the public notice of the imposition of a sanction and the effective date of the sanction at least 30 days after the date of the notice. 42 C.F.R. § 405.2182(a).

Termination of Medicare coverage for the ESRD services is an "initial determination appealable" under 42 C.F.R. Part 498, i.e., a hearing by an ALJ with review by the Departmental Appeals Board (the DAB or the Board).[4] 42 C.F.R. § 405.2182(b). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *The Residence at Salem Woods*, DAB No. 2052 (2006). The Board has addressed the allocation of the burden of persuasion and the burden of production or going forward with the evidence in past cases, in the absence of specific statutory or regulatory provisions. Application of the Board's analysis and approach is not disputed in this case and is appropriate. When a penalty is proposed and appealed, CMS must make a prima facie case that the facility has failed to comply substantially with federal participation requirements. "Prima facie" means generally that the evidence is "(s)ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB) (D. N.J. May 13, 1999), the Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611, at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to terminate is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold

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[4] Imposition of an alternative sanction is not subject to appeal under 42 C.F.R. Part 498. 42 C.F.R. § 405.2184 (2005).

the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy.

In *Evergreene Nursing Care Center*, DAB No. 2069 (2007), the Board explained as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the [skilled nursing facility] must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period. (Citations omitted)
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> CMS makes a prima facie showing of noncompliance if the evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. *Hillman Rehabilitation Center*, DAB No. 1663, at 8 (1998), *aff'd*, *Hillman Rehabilitation Ctr. v. HHS*, No. 98-3789 (GEB) (D. N.J. May 13, 1999); *see also Guardian Health Care Center*, DAB No. 1943 (2004). A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. *Tri-County Extended Care Center*, DAB No. 1936 (2004). "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Id.* at 4 (quoting *Western Care Management Corp.*, DAB No. 1921 (2004)).

DAB No. 2069, at 7-8.

E. Analysis

There is no question that Petitioner in this case was a supplier of ESRD services and it was approved to receive payment through Medicare for dialysis services and supplies provided to Medicare-eligible ESRD patients. There is also no dispute that Petitioner was subject to an unannounced complaint survey by state agency surveyors on June 20, 21, and 22, 2005, the results of which are reported in the SOD dated June 27, 2005. CMS Ex. 1. There is no dispute that CMS notified Petitioner by letter dated July 1, 2005, that the survey found Petitioner in violation of five conditions for coverage: 42 C.F.R.

§ 405.2136,[5] Governing Body and Management; 42 C.F.R. § 405.2139, Medical Records; 42 C.F.R. § 405.2140, Physical Environment; 42 C.F.R. § 405.2161, Director of a Renal Dialysis Facility; and 42 C.F.R. § 405.2162, Staff of a Renal Dialysis Facility. It is also not subject to dispute that the CMS notice advised Petitioner that the deficient practices at the facility were considered by CMS to be pervasive and that they presented immediate jeopardy for patients; that CMS was not requesting or allowing a plan of correction and no revisits would be authorized to determine whether Petitioner corrected the alleged deficiencies; and that Petitioner's Medicare coverage was terminated and no further Medicare payments would be made for patients "whose plans of care begin on or after August 8, 2005." CMS Ex. 2; Joint Stipulation.

1. Alternative sanctions are not available and Petitioner is not entitled to a period for correction prior to termination.

Section 1881(a) of the Act requires that the Secretary promulgate regulations establishing requirements that renal dialysis facilities must meet in order to be eligible to receive payment for services rendered to Medicare-eligible ESRD patients. Section 1881(g)(1) authorizes the Secretary to restrict payments for a supplier of ESRD services that does not meet the conditions established in the regulations as an alternative to the sanction of terminating such a supplier's participation. In promulgating the regulations in this area, the Secretary chose to authorize an alternative sanction only when the ESRD supplier fails to participate in network activities or pursue network goals. The Secretary has not authorized the use of an alternative sanction in the event of a violation of any other condition.[6]

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[5] The notice listed "42 C.F.R. § 405.3136 Governing Body and Management." CMS Ex. 2, at 1. However, because there is no "42 C.F.R. § 405.3136," I conclude that this is a clerical or typographical error. The referenced title of the section, "Governing Body and Management," is actually the title of the condition established by 42 C.F.R. § 405.2136. Accordingly, I conclude that the notice actually was intended to and, but for a clerical or typographical error would have been listed as 42 C.F.R. § 405.2136. Petitioner has alleged no prejudice related to adequacy of the notice in this regard; I conclude there is no prejudice; and I find that the notice was adequate.

[6] The notice of "final rule" for 42 C.F.R. § 405.2180 recognizes that during the rule-making process Congress granted the Secretary authority to impose alternative sanctions for other condition-level violations, that the option was under consideration, but not included in the final rule. 53 Fed. Reg. 36,274, 36,276 (Sep. 19, 1988).

In the case before me, the five conditions allegedly violated do not include failure to participate in network activities or failure to pursue network goals. Thus, no alternative sanctions are possible in this case and, if I conclude that Petitioner has violated a condition for coverage, then termination is the only available sanction. Furthermore, 42 C.F.R. § 405.2180(a) provides:

> Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U **will result in termination** of Medicare coverage of the services furnished by that supplier.

(Emphasis added.) As already noted, the exception provided by § 405.2181 permits an alternative sanction where the condition violated is failure to participate in network activities or failure to pursue network goals and does not apply in this case. The plain language of § 405.2180(a) mandates termination in the event I find even a single condition-level violation. The regulation goes on to provide:

> If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

42 C.F.R. § 405.2180(c). The language of § 405.2180 is clear. The regulatory scheme specifically established for a renal dialysis facility requires that, if a condition for coverage established in 42 C.F.R. Part 405 (except for failure to participate in network activities or pursue network goals) is violated, Medicare coverage for the ESRD facility's services **will be terminated** and coverage will not be reinstated until the violation is removed and reasonable assurance that it will not recur is accepted by CMS. I find nothing in the regulatory history that would cause me to reach a different conclusion. *See* 53 Fed. Reg. 36,274, 36,276 (Sep. 19, 1988).

Petitioner argues in this case that CMS erred by failing to grant a period in which Petitioner might remedy or correct the alleged violations or deficiencies before CMS decided to terminate Medicare coverage. Petitioner asks, if I find a condition-level violation but no immediate jeopardy, that I direct CMS to give Petitioner an opportunity to submit a plan of correction and conduct a revisit survey to determine whether Petitioner has achieved compliance with all conditions. P. Brief at 7. Petitioner's argument that it should be granted a period in which to take corrective action prior to

termination is based upon its reading of the State Operations Manual (SOM),[7] a policy document issued by CMS to guide state surveyors in conducting surveys and processing related documents. P. Brief at 4-7. Petitioner specifically cites SOM §§ 3010A and 3012 to support its argument. P. Brief at 5-6. Several parts of the SOM provide policy guidance regarding ESRD providers. SOM sections 2270 through 2287B are specifically applicable to the ESRD program. Appendix H of the SOM sets forth surveyor instructions and interpretive guidelines specific to ESRD facilities. SOM sections 3220 *et. seq*. cover expansion of ESRD facilities, among other topics. SOM section 5170 provides guidance for conducting complaint investigations against ESRD providers. SOM section 2284, titled "Termination Procedures," directs the reader to SOM Chapter 3. Chapter 3 of the SOM indicates that its procedures are to be used if adverse action is likely to be initiated against a provider or supplier. SOM § 3000A. SOM section 3005B, titled "Termination of Coverage of Supplier Services Subject To Certification," recognizes that section 1881(b) of the Act, which establishes the ESRD program, grants the Secretary authority to establish conditions of coverage for suppliers of services and that implicit within that authority is the authority to determine that such conditions are not met. Section 3005B also recognizes that while a "termination" of coverage for a supplier's services is not the same as termination of a provider agreement, the net effect is the same with regard to the supplier's eligibility to receive payment by Medicare for its services. Thus, procedures for certifying supplier noncompliance parallel those for certifying provider noncompliance. Section 3010A, referred to by Petitioner, provides a definition of "immediate jeopardy."

SOM section 3012 sets forth termination procedures when there is noncompliance with one or more conditions of participation or conditions for coverage and the deficiencies cited limit the capacity of the provider or supplier to furnish an adequate level or quality of care. It is this section of the SOM that Petitioner cites for the proposition that it must be given an opportunity to submit a plan of correction and achieve compliance before CMS can terminate. P. Brief at 5. CMS counters that it has the discretion as to whether or not to offer the facility an opportunity to correct if a condition-level deficiency is cited. I find neither position to be well-founded.

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[7] Available at http://www.cms.hhs.gov/Manuals/IOM/list.asp, Publication No. 100-07. Updates to the SOM sections applicable at the time of the survey in this case were Rev. 1, 05-21-04 and earlier.

I note that SOM section 3012 is not specific to ESRD facilities and, in fact, does not specifically mention to which providers or suppliers it applies. The section, by its terms, applies to both providers who have conditions of participation and suppliers who have conditions for coverage. The general termination procedures established by the section are applicable to multiple types of providers and suppliers under Medicare. The section also specifically states:

> Compliance with Conditions; i.e., condition level deficiencies, can never be certified based upon a PoC (plan of correction) or acceptable progress since the law specifically requires that all CoPs (conditions of participation) or CoCs (conditions of compliance) must be met.

SOM § 3012.[8] A note at the end of the section indicates that time-frames are maximum and that the CMS Regional Office may terminate more quickly as long as the regulatory requirement for notice of the public and provider are satisfied. If the general provisions of SOM section 3012 actually apply to ESRD providers, then my reading of the section is consistent with the CMS interpretation that it has the discretion to terminate more quickly than provided in that section, even if there is no allegation of immediate jeopardy, and that all the section requires CMS to do is observe the regulatory notice requirements.

I am disposed to take an even more restrictive view of the Act and regulations, specifically 42 C.F.R. § 405.2180(a), than CMS advocates. In section 405.2180(a), the choice of the phrase "will result in termination" in the event of even one condition-level violation is critical. If the Secretary intended to delegate to CMS authority to do something other than terminate in the face of a condition-level violation, than this would have been the most likely place for such a delegation to be made or referenced. Although the general language of SOM section 3012 and 3044, which has to do generally with terminating suppliers, can be read to suggest that CMS has such discretion, CMS identifies no statutory or regulatory authority granting it discretion not to terminate coverage for ESRD services in the face of a condition-level violation.[9] It is fundamental

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[8] I recognize that Petitioner does not argue that it is sufficient that it make "acceptable progress." Rather, Petitioner argues that it should be allowed to submit a plan of correction and achieve compliance within a reasonable period.

[9] CMS cites 42 C.F.R. §§ 488.24(b) and 488.28 in support of its position that it has discretion to permit or deny an opportunity to correct condition-level deficiencies. The CMS reading of these regulations is fundamentally flawed. First, these regulatory provisions are for general application and do not include a delegation for CMS to offer an

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that CMS cannot by a policy directive amend or supercede one of the Secretary's regulations. My reading of the regulation is consistent with the language of the second clause of 42 C.F.R. § 405.2180(c), which specifies that "coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur." The second clause would not have been necessary if a procedure was contemplated whereby CMS could allow a provider a period for correction and to achieve substantial compliance without loss of coverage. Rather, my reading is that the regulation clearly contemplates that when there is a condition-level violation, coverage ceases and cannot be reinstated until the conditions specified by the regulation are satisfied and the Secretary has reasonable assurance that the reason for the prior termination will not recur.

My conclusion is that neither Petitioner nor CMS are correct in their positions about whether an ESRD provider can be permitted to submit a plan of correction and have an opportunity to achieve compliance when there is a finding of a condition-level deficiency. The Secretary's regulation mandates termination of coverage for an ESRD facility's services when even one condition-level deficiency exists and such coverage may not be reinstated until the cause of the deficiency is removed and reasonable assurance exists

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[9](...continued)
ESRD provider an opportunity to correct a condition-level deficiency and thereby avoid the termination mandated by 42 C.F.R. § 405.2180. Second, even if these general regulatory provisions were viewed to control over the specific ESRD regulations, they do not give CMS discretion to offer a period for correction of a "condition-level deficiency." The language of 42 C.F.R. § 488.28 specifically limits its application to cases where there are no condition-level deficiencies identified on survey. Subsection (a) specifically states that it applies when a provider or supplier is found to deficient with respect to "one or more of the standards. . . ." 42 C.F.R. § 488.28(a). The language of 42 C.F.R. § 488.28(b) specifies that the provisions of the regulation only apply when deficiencies identified on survey "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" – the definition of "condition-level" deficiency established by 42 C.F.R. § 488.24(b). Subsection (c) further specifies that it is limited to a situation where a survey finds that a supplier is not in compliance with "one or more of the standards." 42 C.F.R. § 488.28(c).

that such deficiency will not recur.[10] Thus, if I find one condition-level violation existed, Medicare coverage for Petitioner's ESRD services is terminated based on that condition-level violation.

2. Petitioner violated the condition for coverage established by 42 C.F.R. § 405.2140, and termination of coverage is required.

CMS alleges that Petitioner violated the following conditions for coverage: 42 C.F.R. § 405.2136, Governing Body and Management (Tag V110)[11]; 42 C.F.R. § 405.2139, Medical Records (Tag V230); 42 C.F.R. § 405.2140, Physical Environment (Tag V255); 42 C.F.R. § 405.2161, Director of a Renal Dialysis Facility (Tag V420); and 42 C.F.R. § 405.2162, Staff of a Renal Dialysis Facility (Tag V430). CMS also alleges 12 standard-level deficiencies, which are included within the condition-level violations. CMS Ex. 1. Condition-level deficiencies are those that "are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). As already noted, violation of a condition of coverage is grounds for termination while violation of a standard is not.

a. Factual Background.

It is necessary to establish the factual background for this case to understand the result. The state agency received a complaint through the Southeastern Kidney Council, Inc. CMS Ex. 1, at 1; CMS Ex. 8; Tr. 140. The complaint referral dated June 9, 2005, indicates that a complainant contacted the Kidney Council and represented that her mother was a patient at Petitioner's facility and did not want to make the complaint herself. The complainant was the daughter of Patient 5. Tr. 140-42. Specific allegations of the complaint were that there was often no nurse in the facility while patients received

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[10] The regulatory requirement for termination with reinstatement only if the violation that caused termination is corrected with reasonable assurance it will not recur, puts a heavy burden upon Petitioner to ensure no condition-level violation and no break in Medicare payments. The procedure is clearly stated and with no hint that the Secretary intended to create another procedure that would permit a facility to correct a deficiency, except those specific deficiencies already mentioned, while maintaining Medicare coverage.

[11] The "Tag" identifier relates to SOM, Appendix H, Part V – "The Interpretive Guidelines," which sets forth the CMS guidance to surveyors. Each standard and condition established by the regulations is identified in the SOM by a unique number from 100 through 497 preceded by "V."

dialysis, with the nurse arriving two hours after dialysis started; facility staff did not remove all fluid from patients; Petitioner did not submit appropriate paperwork to the complainant's mother's insurance company so that her Medicare premium could be paid; for a long time the facility had no oxygen available for patient emergencies although they had oxygen at the time of the complaint; and staff told her mother that when they had no oxygen they locked the doors to keep the state survey agency out of the building. CMS Ex. 8. There is no evidence that anyone contacted the complainant or her mother to clarify the allegations or to obtain further information to permit a more focused or thorough investigation.

Based on the complaint, a state agency surveyor, Rebecca Warthen, went to the facility on June 20, 2005, to conduct an unannounced complaint investigation. Surveyor Warthen went alone on June 20, 2005. The survey was continued on June 21 and 22, 2005, as a full recertification survey because it was concluded that the complaint was substantiated. Ms. Warthen was joined in conducting the survey on June 21 and 22, by surveyor Cheryl Scott.

Ms. Warthen testified that on June 20, 2005, at 7:25 a.m., she walked into the lobby or patient waiting area of Petitioner's facility. The patient waiting area was empty, but Ms. Warthen believed that she heard dialysis machines running in another room.[12] Ms. Warthen went to the window between the lobby and reception office, and advised the man sitting there that she was there to do a survey and wanted to see the charge nurse. Ms. Warthen identified the man as Fred Deveroe, the facility water technician. Mr. Deveroe left the reception office and did not return. Ms. Warthen attempted to open the door between the lobby and the treatment area and found it locked. She rang a bell on the intercom near the door but there was no answer. Surveyor Warthen testified that Patient 1 entered the facility waiting room from outside and also rang the bell and knocked on the door and there was no answer. Patient 1 told Ms. Warthen that the door is always locked. Ms. Warthen testified that Patient 1 told her that when she was there for dialysis the registered nurse (RN) generally did not arrive until around 8:30 a.m. to 8:45 a.m., and that a Patient Care Technician (PCT) administered her heparin rather than the RN. Tr. 97-103. Patient 1 also told her that between November 2004 and August 2005 she only had

[12] Ms. Warthen testified in response to my questions that she could hear the dialysis machines running, with a sound like a refrigerator running, throughout the morning of June 20, 2005. Tr. 157-58. She also testified that when she entered the treatment floor she could tell the patients she saw were being dialyzed. Tr. 159. On cross-examination she agreed that the sound of the machines would be the same whether the patients were on dialysis or dialysis was complete and they were being reinfused with their blood. Tr. 173-74.

one pre-assessment by the RN, and that in the week prior to the survey she had been in the hospital for pneumonia for which she needed four doses of antibiotic, but that she only received one dose through Petitioner. Tr. 107-09.

According to Ms. Warthen, at approximately 7:50 a.m. (approximately 25 minutes after her arrival), Dallas Davis, an employee, came to the door of the reception area and advised her that the RN was present and would be right with her but that they were in the middle of an emergency that the RN was handling. Ms. Warthen testified that she could hear machines running and she heard no alarm sounding that might have indicated an emergency with the dialysis equipment. Tr. 110. She testified that at 8:10 a.m. (approximately 45 minutes after her arrival), RN Kathryn Harrison, Petitioner's Director of Nursing, allowed her to enter the treatment area. Ms. Warthen testified that Nurse Harrison apologized for keeping her waiting and explained that she had been working on an emergency with the water system. Tr. 111. After meeting Nurse Harrison, Surveyor Warthen went to the treatment floor where she interviewed eight patients, asking specifically whether the nurse had been there when they were put on dialysis that morning and who gave them their heparin.[13] Surveyor Warthen testified that six patients told her that the nurse was not present when they were put on dialysis that morning and that the nurse normally arrives around 8:30 a.m. Tr. 113, 200-01. She testified that seven of the patients told her that a PCT normally administers heparin. Tr. 112-13.

Ms. Warthen testified that in her opinion she was told inconsistent stories by Petitioner's staff about what was going on the morning of June 20, 2005, and why she was not immediately admitted to the treatment floor. She testified that, based upon the different stories she was told, her interviews with patients, and the fact she heard no alarms that morning, she concluded that there was no water problem that prevented staff from admitting her immediately. Tr. 147. Ms. Warthen agreed on cross-examination that emergencies with the water system in a dialysis clinic can occur; but she found no documentation in any patient record that any patient's dialysis was interrupted on June 20 due to an emergency. However, she agreed that some patients did tell her that they received their blood back that morning, indicating that dialysis was interrupted. Tr. 148-50.

[13] Ms. Warthen interviewed Patient 1 in the lobby and seven patients on the treatment floor, Patients 2, 3, 4, 5, 10, 11, and 12.

Surveyor Cheryl Scott joined Surveyor Warthen for the second and third days of the survey. She testified that Patients 2 and 3 told her during interviews that Nurse Harrison usually did not arrive until after 8:00 a.m. Tr. 346-47.

b. The weight of the evidence is that RN Kathryn Harrison was present when the surveyor arrived on June 20, 2005.

The surveyors concluded based upon the complaint, Surveyor Warthen's observations on the morning of June 20, 2005, and the statements of some patients, that Nurse Harrison was not at the facility when Surveyor Warthen arrived on June 20. Whether or not Nurse Harrison was at the facility when Surveyor Warthen arrived is hotly contested and consumed much of the attention of counsel on both sides. Nevertheless, the surveyors' conclusion that Nurse Harrison was not present only provided the basis for the alleged standard-level violation of 42 C.F.R. §§ 405.2136(c)(3)(i) (Tag V134)[14] and one of the five alleged condition-level violations, specifically § 405.2162 (Tag V430).[15]

Part of the original complaint filed with the state was that there was no nurse on duty when dialysis began and heparin was administered. There is no doubt that Surveyor Warthen was aware of the complaint. Tr. 95. She admitted in response to my questioning that there was no way for her to monitor all the exterior doors to the facility. She could offer no explanation for why more surveyors were not sent to the facility the first day to monitor the coming and going of staff in an effort to validate the complaint that a nurse was often not present when dialysis began. Tr. 323-25.

The CMS position that Nurse Harrison was not present when Surveyor Warthen arrived at the facility on June 20, is not based upon the surveyor's personal observation that Nurse Harrison was not present, but rather upon an inference that Nurse Harrison was not present because the nurse did not more promptly meet and greet Surveyor Warthen. The other evidence CMS relies upon for the proposition that Nurse Harrison was not present are hearsay statements of various patients who told the surveyors that Nurse Harrison was not present on June 20 and other days when dialysis began. Although hearsay is admissible in this administrative proceeding, the weight to be afforded hearsay is always in issue, particularly where, as here, the opposing party objects to the probative value of the hearsay. The hearsay from the patients is particularly troublesome, because it is not

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[14] This standard-level violation is one of five cited under the condition-level violation of 42 C.F.R. § 405.2136 (Tab V110).

[15] The surveyors also cited the included standard-level violation of 42 C.F.R. § 405.2162(b)(1).

recorded in written statements prepared or adopted by the patients, but is rather in the form of summaries by the surveyors who spoke with the patients. Petitioner rightly objects to my giving weight to the hearsay statements of the patients because Petitioner had no opportunity to test the credibility of the patients or their statements by face-to-face cross-examination and I had no opportunity to see the witnesses when judging their credibility. Tr. 69-74.

CMS complains that it was not permitted to have certain patients testify by telephone, because Petitioner objected to taking their testimony in that manner[16] and I concluded it necessary to avoid any due process issue arising from depriving Petitioner of face-to-face confrontation of fact witnesses against it.[17] Tr. 59-81. Post-hearing CMS seeks to reopen the record so that I may receive six depositions, three of which were patients CMS wanted to examine during the hearing by telephone. CMS Motion for Leave to Offer Additional Exhibits/Request to Reopen Hearing, dated February 6, 2006. Petitioner objects to my receipt as evidence and consideration of the depositions post-hearing. Petitioner's Brief in Opposition to CMS Motion for Leave to Offer Additional Exhibits/Request to Reopen Hearing, dated February 15, 2006. The CMS motion to reopen the record is denied. Given my disposition of this case, I find it unnecessary to reopen the record for the receipt of additional evidence.[18]

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[16] Petitioner filed its objection on October 27, 2005, four days prior to the hearing, asserting the importance of in-person testimony to permit assessment of the witnesses' credibility. Thus, CMS was not surprised by the objection at hearing.

[17] I did not rule that the witnesses could not testify, only that their testimony would not be received by telephone. Tr. 80-81. Subpoenas were issued at CMS's request on October 21, 2005, for witnesses Strickland, Knight, and Simpson, but the evidence does not show that CMS effected service or sought enforcement. CMS did not request prehearing that the hearing be convened in Jackson, Georgia, nearer to Petitioner's facility and the location of the witnesses CMS sought to have testify. CMS also did not request, until hearing, the opportunity to depose the witnesses.

[18] The evidence CMS offered post-hearing includes depositions of three patients, the same three CMS failed to produce at hearing, and three repairmen who worked on Petitioner's air conditioning system. CMS wants me to consider the depositions of the repairmen, believing they negate Petitioner's claim that Nurse Harrison was working on a water problem the morning of June 20, 2005. All the depositions were taken in conjunction with the state proceedings against Petitioner, which commenced after the hearing in this case. CMS should have recognized before the hearing that the three dialysis patients it wanted to call as witnesses might have difficulty traveling. CMS

(continued...)

I note, however, that even had I received testimony from the patients CMS proposed for me to hear,[19] it is not clear that such testimony would outweigh the evidence Petitioner offered to show Nurse Harrison was in fact present the morning of June 20 when dialysis began. Nurse Harrison testified that she arrived at the facility on June 20 at 5:08 a.m.; that there has never been a time when patients arrived before her; that Fred Deveroe opens the facility at 5 a.m.; that she usually arrives between 5:10 and 5:15 a.m.; and that she keeps her own time records (P. Ex. 1). Tr. 628-33. She also testified that she always loads the heparin on the dialysis machines and that she is the only person who can do so because she has the only key to the drug cabinet; she does not, however, put all the patients on the dialysis machine or start the dialysis process. Tr. 633-35. Petitioner also produced three patients who testified that RN Harrison was always present when they were put on dialysis and that she was there when they were put on dialysis on June 20, 2005. Tr. 808-11; 824-25; and 835. Given all the evidence and considering the testimony CMS proffered from the three patients CMS failed to produce, I find Nurse Harrison and the testimony of the patients who did appear at hearing to be credible and more weighty than either the proffered testimony or the hearsay to the contrary. Accordingly, I conclude the evidence sufficient to establish that Nurse Harrison was present the morning of June 20, 2005, as Petitioner alleges.

c. The condition-level violation of 42 C.F.R. § 405.2140 (Tag V255) – Physical Environment.

The fact that Nurse Harrison was present when the surveyor arrived on June 20, 2005, and that she may have always been present while patients were on dialysis, does not mean that Petitioner prevails in this case. To the contrary, the evidence shows that Petitioner was in violation of the condition for coverage established by 42 C.F.R. § 405.2140 (Tag V255) and termination of Petitioner's participation in Medicare as an ESRD supplier and Medicare coverage for ESRD services it provided was required.

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[18](...continued)
should have requested depositions or that the hearing be convened nearer to Petitioner's facility, but failed to do so. Further, CMS should have known from the allegations of the SOD (*e.g.*, CMS Ex. 1, at 1, 11, 30-32), and its interview of Surveyor Warthen, that Petitioner took the position that RN Harrison could not more promptly greet Surveyor Warthen the morning of June 20 because she was working on the water system. If CMS believed it important to rebut Petitioner's arguments, CMS should have called the repairmen to testify at the hearing in this case, but CMS failed to do so. Post-hearing motions to reopen are no substitute for prehearing preparation.

[19] CMS's proffer of the testimony of its witnesses is at Tr. 64-65.

The regulation requires that an ESRD facility maintain a physical environment that is functional, sanitary, safe, and comfortable for patients, staff, and the public. The condition includes standards: (a) the building must be constructed, equipped, and maintained to ensure safety of patients, staff and the public; (b) the space must be functional, sanitary, and comfortable for patients and includes, inter alia, the requirement for policies and procedures for preventing and controlling hepatitis and infections and for safe and comfortable dialysis with patient privacy, appropriate emergency medical supplies, and safe storage of dialysis supplies; (c) the facility must use appropriate technique to avoid cross-contamination; and (d) the facility must have written policies and procedures for handling emergencies that might threaten the health or safety of patients. 42 C.F.R. § 405.2140.

The surveyors allege in this case that the condition for coverage was violated because Petitioner's staff failed to use techniques to prevent cross-contamination and Petitioner failed to provide emergency supplies. CMS Ex. 1, at 18. The CMS expert, Glenda Payne, opined that both rose to condition level violations. Tr. 509. I find that the condition for coverage was violated by the former and that it is unnecessary to discuss the latter.

It is not disputed that on June 22, 2005, Surveyor Scott saw an employee terminating a patient's dialysis without wearing a protective gown; she observed an employee terminating a patient's dialysis without wearing a protective eye and mouth shield; and she saw three employees cleaning the dialysis machines but failing to empty the bucket on each machine that collected the fluid discharge from the dialysis process. Tr. 350, 434; CMS Ex. 1, at 18. The CMS expert testified that the fact that the buckets were not clean was a serious deficiency because it posed the risk for cross-contamination and transmission of hepatitis. Tr. 509-10. Petitioner's expert, Katrina Russell, agreed that the cited conduct amounted to a deficiency. Tr. 604. However, she noted that such a deficiency is common and, in her experience, not the basis for a facility losing its Medicare certification. Tr. 604. She further commented that staff can get complacent and not pay attention to infection control practices and it is a challenge for a facility to monitor and remind staff to use protective equipment. Tr. 604. Ms. Russell declined to comment about whether or not the errors or omissions observed by Surveyor Scott amounted to a condition-level violation, but she opined that the deficiency cited was correctable through staff education and a system for monitoring staff. Tr. 607-08. On cross-examination, she agreed that the buckets that were not emptied and cleaned posed the risk for the spread of hepatitis, HIV, and other infectious diseases. Tr. 618. On redirect, she stated that the failure to empty the buckets was a deficient practice and she noted that the risk extended to staff, including cleaning staff. Tr. 621-22.

Petitioner does not deny the observations of Surveyor Scott. Rather, Nurse Harrison suggested that the failure of the employee to wear protective equipment should be excused because it was hot that day and the air conditioning was not working. She asserted that technicians normally wear lab coats and eye and mouth shields. Tr. 759; P. Brief at 21. Nurse Harrison explained that she could not address the observation of Surveyor Scott regarding the buckets. However, she explained that the buckets are open and that normally they would be emptied after the technician primes the artificial kidney and the dialysis lines and blood lines. She testified that the bucket should be emptied between patients, and, in this case, no patient went on a machine with a bucket that had not been emptied, because there were only two patients for dialysis on the second shift. She also testified that the buckets Surveyor Scott observed would have been emptied sometime later in the day after the surveyor left. She did not dispute Surveyor Scott's observation that staff had already placed fresh or clean supplies on the machines, apparently before the machines were completely cleaned. Tr. 760-61. Petitioner presented no evidence as to when the buckets were emptied and cleaned on June 22, 2005.

Petitioner argues in post-hearing briefing that the deficiencies observed and cited by Surveyor Scott were easily correctable and "not grounds for de-certification nor an immediate jeopardy finding." P. Brief at 22. Petitioner further argues the deficiencies were really the result of the oppressively hot conditions at Petitioner's facility on June 22, 2005. P. Reply at 7.

The condition for coverage requires that Petitioner maintain a physical environment that is functional, sanitary, safe, and comfortable[20] for patients, staff, and the public. Petitioner does not dispute that staff did not use protective gear while terminating a patient's dialysis. There is no dispute that terminating dialysis exposed the staff member to blood. There is also no question that Surveyor Scott observed staff placing clean dialysis supplies on dialysis machines while potentially contaminated buckets of liquid remained on those machines. Petitioner's own expert testified that there was a risk for cross-contamination of equipment, a risk for spreading infectious diseases, and a risk of harm to staff exposed. These lapses occurred despite the fact that the surveyor was present and observing, giving credence to Petitioner's expert's opinion that staff had become complacent with infection control (Tr. 604) and that Petitioner was understaffed with licensed personnel to supervise the facility (Tr. 618). I conclude that Petitioner's facility was neither safe nor sanitary and, thus, Petitioner did not satisfy the condition for

[20] I note that the surveyors did not cite Petitioner for operating without air conditioning, causing patients and staff to suffer the oppressively hot conditions to which Petitioner alludes.

coverage established by the regulation. Whether Petitioner or its expert believe that the deficiencies are readily correctable is not the issue. The evidence shows that Petitioner's facility was not sanitary or safe for patients or staff and there was a violation of the condition for coverage.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated a condition for coverage and termination of Medicare coverage for services provided by Petitioner was required.

/s/
Keith W. Sickendick
Administrative Law Judge