Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Angel Kidney Care of Inglewood, Inc.
(CCN: 55-2656),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-2799

Decision No. CR4669

Date: August 1, 2016

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to terminate the participation in Medicare of Petitioner, Angel Kidney Care of Inglewood, Inc. The evidence in this case overwhelmingly supports a finding that Petitioner failed to comply with two Medicare conditions of participation.

I. Background

Petitioner, an end stage renal disease (ESRD) dialysis facility, requested a hearing in order to challenge CMS's determination to terminate its Medicare participation. I held a hearing on May 24, 2016. At that hearing I received into evidence exhibits from CMS that are identified as CMS Ex. 1 – CMS Ex. 24 and from Petitioner that are identified as P. Ex. 1 – P. Ex. 5. I afforded the parties the opportunity to cross examine witnesses whose written direct testimony is part of the record as exhibits.

II. Issues, Findings of Fact and Conclusions of Law

A. Issue

The issue is whether Petitioner failed to comply with one or more conditions of participation governing ESRD facilities, thereby giving CMS authority to terminate its participation in Medicare.

B. Findings of Fact and Conclusions of Law

Medicare participation of ESRD facilities is governed by regulations at 42 C.F.R. Part 494. As a general rule a failure by an ESRD facility to comply with even one of the conditions governing its Medicare participation will result in termination of its Medicare participation. 42 C.F.R. § 488.604(a).

Here, CMS asserts that Petitioner failed to comply substantially with two conditions that governed its participation and with standards that are subsumed in those conditions. Specifically, CMS argues that Petitioner failed to comply substantially with the condition set forth at 42 C.F.R. § 494.80 (patient assessment) and with subsumed standards at 42 C.F.R. § 494.80(a)(1) and (a)(2); and with the condition set forth at 42 C.F.R. § 494.90 (patient plan of care) and with the standard at 42 C.F.R. § 494.90(a).

The evidence supporting CMS's allegations of noncompliance is overwhelming and in the main not refuted by Petitioner. Petitioner's arguments in opposition to CMS's allegations are without merit.

End stage renal disease is marked by complete failure of one's kidneys to cleanse the blood of potentially lethal toxins. CMS Ex. 21 at 4. This condition causes the afflicted individual to suffer from grave problems including fatigue, anemia, bone disease, joint problems, itchy skin and sleep disorders. *Id.* at 11-14. Left untreated the illness ends in death. CMS Ex. 23 at 2.

Kidney dialysis is one of the means of treating the disease. CMS Ex. 23 at 2. It is a process by which a patient's blood is extracted, mechanically cleansed of wastes and toxins, and then reinserted into the patient. CMS Ex. 21 at 4-5. In order to do this access must be established to the patient's circulatory system. That can be accomplished by several means. All of them require surgical intervention and all of them have accompanying risks to the patient. CMS Ex. 22 at 1-4. Risks include the development of blood clots and scarring. *Id.* Patients who receive dialysis are at heightened risk for developing cardiovascular disease, heart attacks and stroke. CMS Ex. 23 at 2. Patients often have weakened immune systems as a result of their disease, and they are at an

enhanced risk for developing infections. *Dialysis Safety*, Centers for Disease Control and Prevention, www.cdc.gov/dialysis, last accessed on August 1, 2016. The potential problems associated with kidney dialysis make it imperative that caregivers carefully monitor and assess their patients.

The regulations governing ESRD facilities incorporate the requirements for close monitoring and careful assessment of patients receiving kidney dialysis. A participating ESRD facility must establish an interdisciplinary team that provides each patient with an individualized and comprehensive assessment of his or her needs. 42 C.F.R. § 494.80. That assessment must be used in developing the patient's plan of care. The assessment must contain an evaluation of each patient's current health status and medical condition. 42 C.F.R. § 494.80(a)(1). It must also contain an evaluation of the appropriateness of the patient's dialysis prescription, his or her blood pressure, and fluid management needs. 42 C.F.R. § 494.80(a)(2). The plan of care that the ESRD facility's interdisciplinary team develops, based on the patient's comprehensive assessment, must specify the services necessary to identify that patient's needs. It must include measurable and expected outcomes and estimated timetables to achieve those outcomes. 42 C.F.R. §§ 494.90; 494.90(a)(1).

CMS's allegations of noncompliance consist of the following:

- Petitioner failed to comply with the requirements of 42 C.F.R. § 494.80(a)(1) in that it failed to complete health status and medical condition assessments for patients identified as Patients 5, 11, 18, 19, 20, and 21. As respects Patient 5, CMS contends that Petitioner failed to document the placement of a catheter in the patient's chest and failed to document the removal and reinsertion of that catheter. CMS Ex. 6; CMS Ex. 18 at 4-5. Moreover, Petitioner failed to assess the resident's pre-dialysis catheter condition. CMS Ex. 6 at 3-13. CMS asserts that Petitioner failed to document the date of catheter insertion in Patient 11. CMS Ex. 7 at 2-3; CMS Ex. 18 at 5. It charges that Petitioner failed to assess the health status of Patients 18, 19, and 20. Specifically, Petitioner's staff failed to document the presence of sounds associated with blood flow ("thrill" and "bruit") at the sites of these residents' surgical interventions for dialysis. CMS Ex. 11 at 5, 7, 13, 14; CMS Ex. 12 at 5, 7, 9, 31, 33, 40, 42, 44; CMS Ex. 13 at 8, 10, 12, 14. Moreover, according to CMS, in the case of Patient 20, Petitioner's staff failed to assess her for patency of her catheter, for lung sounds, and for location of edema. CMS Ex. 13 at 10, 12, 14. Finally, in the case of Patient 21, CMS contends that Petitioner failed to record whether the patient had received catheter care, had manifested thrill or bruit, and whether the catheter was patent. CMS Ex. 8 at 4.

- Petitioner failed to comply with the requirements of 42 C.F.R. § 494.80(a)(2) because it failed to evaluate the appropriateness of dialysis prescription for Patients 18 and 19. CMS asserts specifically that Petitioner's staff failed to evaluate adequately and manage these patients' dialysis prescriptions. In the case of Patient 18, the medical

records show that the patient received a substantially larger dose of the medication Heparin, an anticoagulant, than had been prescribed by the patient's physician. However, Petitioner's staff provided no explanation for the increased dosage of this medication. CMS Ex. 11 at 17-19. CMS asserts also that there was an episode of bleeding involving this patient that Petitioner's staff failed to assess. CMS Ex. 11 at 3. As respects Patient 19, CMS contends that on one occasion Petitioner's staff failed to administer Heparin to the patient despite a physician's order that it be administered and failed to explain why the staff did not do so. CMS Ex. 12 at 13, 22. CMS argues also that on multiple occasions the patient manifested a blood flow rate that deviated from that which the patient's physician had ordered and again, the staff failed to explain or assess the discrepancy. CMS Ex. 12 at 13, 14, 16, 18, 20, 22.

- Petitioner failed also to comply with the requirements of 42 C.F.R. § 494.80(a)(2) in that it failed to monitor the appropriateness of dialysis treatment for three patients, Patients 18, 20, and 22. CMS contends, specifically, that Petitioner's staff failed to monitor and assess the patients' blood pressures and fluid management needs. CMS Ex. 1 at 25-30. CMS contends that on several occasions all three of these exhibited very high blood pressures. For example, Patient 18 had a blood pressure on one occasion of 191/97. CMS Ex. 11 at 24. Yet, there was no documentation that a registered nurse was informed of this development, that the patient was assessed, or that anti-hypertensive medication was administered to the patient, as the patient's physician ordered. *Id.* at 23, 24-25. CMS asserts additionally that in Patient 20's case, Petitioner's staff failed on several occasions to assess the patient despite very high blood pressure readings (205/102, 186/88, 186/89, and 186/66), to notify a registered nurse of the findings of hypertension, or to administer anti-hypertensive medication to the patient. CMS Ex. 13 at 19, 20-25. As respects Patient 22, CMS contends that Patient 22 registered a blood pressure reading of 191/103, yet there is no documentation that a registered nurse was notified so that she could assess Patient 22's condition and, if necessary, notify the patient's physician. CMS Ex. 9 at 3, 4. CMS asserts that Petitioner not only failed to comply with regulatory requirements in its care of Patients 18, 20, and 22, but also that it failed to comply with its own internal policy governing hypertension. That policy requires that a patient's blood pressure be monitored after dialysis and that findings of hypertension, including any systolic reading greater than 185 or diastolic reading greater than 100, must be reported to a registered nurse. CMS Ex. 16 at 11.

- Petitioner failed to comply with the requirements of 42 C.F.R. §§ 494.90 and 494.90(a)(1) in that it failed to develop plans of care to address medical issues confronted by Patients 5 and 19. In the case of Patient 5, CMS asserts that Petitioner's staff failed to document whatever interventions it may have decided upon to address problems with the patient's catheter. CMS Ex. 6 at 2, 17, 22; CMS Ex. 10 at 11. With respect to Patient 19, CMS contends that the resident wore a pacemaker after having experienced an episode of cardiac arrest, but that Petitioner's staff did not develop a care plan to address any problems that might be associated with the patient's use of a pacemaker. CMS Ex. 12 at

39, 57-59. Moreover, according to CMS, the staff did not develop a care plan to deal with blood clots that Patient 19 developed in association with a graft utilized in dialysis. CMS Ex. 12 at 28-30.

The exhibits of record amply support CMS's allegations. Furthermore, I find nothing in Petitioner's arguments or in its exhibits that undercut or contradict these allegations. Put simply, the record conclusively establishes that Petitioner failed to perform the assessments and care planning that is mandated by the regulations.

Petitioner argues that even if it failed in various respects to assess its patients or failed to plan their care consistent with regulatory requirements, there was no documented harm experienced by any of them and consequently, its deficiencies are not substantial. I find this argument to be without merit.

The regulations governing ESRD facilities do not specifically define what is meant by substantial compliance with conditions of participation. However, it is evident that these regulations do not require proof of actual harm in order for a facility to be out of compliance. Regulations governing providers and suppliers in general state that a provider or a supplier (such as an ESRD facility) will be found to be out of compliance with Medicare conditions of participation if it has deficiencies 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). Finding noncompliance that "adversely affects the health and *safety* of patients" (emphasis added) does not require a finding of actual harm. A potential for harm certainly affects safety. Thus, a *potential* for harm is all that is necessary to establish noncompliance.[1] CMS must terminate an ESRD facility where it fails to meet a condition of participation, and there is no exception to that requirement even though the facility's failure "did not result in actual harm to a patient or patients." *Dialysis Center at Moreno Valley, Inc.*, DAB No. 2193 at 23 (2008).

With ESRD facilities there is great potential for harm where a facility fails to comply with regulatory requirements. As I discuss above, kidney dialysis is a treatment that is fraught with peril for patients who receive it. There are issues concerning potential blood clots and infections. Patients receiving dialysis are at risk for strokes, heart attacks, and

[1] Moreover, the regulations governing ESRD facility compliance should be read consistently with regulations governing other providers and suppliers. Regulations governing compliance by skilled nursing facilities define failure to comply substantially with participation requirements as constituting a situation where a potential for more than minimal harm exists. 42 C.F.R. § 488.301.

potentially lethal infections. As a consequence, those who provide dialysis must be especially scrupulous in assuring that the care that they give and the patients' responses to that care are monitored and assessed.

In this case the record is manifest with omissions and errors by Petitioner's staff that had the potential for causing great harm to patients and that adversely affect their patients' safety. For example, failure to monitor patients' catheter care, including when catheters were placed and removed, meant that Petitioner's staff could not establish a baseline of the patients' conditions and could not, as a consequence, acquire individualized information in order to provide specific treatment to address patients' unique needs. CMS Ex. 16 at 4. Cases of serious hypertension pose a potential for possibly lethal consequences to patients. Petitioner's own internal policy identified that risk. And, yet, Petitioner's staff failed to monitor patients – including those who manifested extreme hypertension – consistent with Petitioner's internal policy. Petitioner's demonstrated noncompliance in this case, both with its own policies and with two conditions of participation, suggests that the threat it poses to the safety of patients in its care is greater than the sum of the specific incidents of noncompliance for which CMS cited it. Indeed, what emerges from the totality of the evidence is a picture of a facility that was, to say the least, slipshod in assuring that its patients received the monitoring and care planning that they needed in order to protect them against possibly dangerous adverse complications. Petitioner's many failures establish systemic noncompliance with participation requirements.

Petitioner argues also that the surveys conducted of its facility were unfair in the sense that surveyors pressured Petitioner's staff and acted unprofessionally. How the surveys were conducted is irrelevant. What matters here is the evidence of compliance and noncompliance that the parties adduce, not the conduct of the surveyors. *Beechwood Sanitarium*, DAB No. 1906 at 44 (2004). Furthermore, Petitioner has adduced no evidence to show that an ostensibly more professionally done survey would have produced results that were more favorable to Petitioner. I make my findings in this case based on the evidence of Petitioner's noncompliance and, as I have said, that evidence is overwhelming.

/s/
Steven T. Kessel
Administrative Law Judge