Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Angel Kidney Care of Inglewood, Inc.
Docket No. A-17-1
Decision No. 2795
June 15, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Angel Kidney Care of Inglewood, Inc. (Petitioner, AKC), a dialysis facility located in California, appealed the decision of an Administrative Law Judge (ALJ) upholding the Centers for Medicare & Medicaid Services' (CMS's) termination of Medicare coverage of AKC's services, *Angel Kidney Care of Inglewood, Inc.*, DAB CR4669 (2016) (ALJ Decision). Based on a survey conducted by the State survey agency, the California Department of Public Health, CMS found that AKC did not meet several conditions for coverage and notified AKC that coverage of its services would be terminated on May 23, 2015.

For the reasons discussed below, we conclude that the ALJ's conclusion that AKC failed to meet conditions for coverage for dialysis services is supported by substantial evidence in the record and is free of legal error, and we uphold the termination.

Legal Background

Section 1881 of the Social Security Act[1] authorizes Medicare coverage and payment for the treatment of end-stage renal disease (ESRD) in renal dialysis facilities that meet requirements prescribed by the Secretary for institutional dialysis services and supplies. Part 494 of 42 C.F.R. sets forth the requirements that dialysis facilities must meet to be certified and receive Medicare payments. The regulations include both conditions and standards for certification. Each condition represents a general requirement, and the standards represent the components of the conditions.

[1] The current version of the Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssacttoc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

Section 494.80, "Condition: Patient Assessment," requires in relevant part that the facility's interdisciplinary team "provide each patient with an individualized and comprehensive assessment of his or her needs that meets" standards including the following:[2]

> (a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:
>
> (1) Evaluation of current health status and medical condition, including co-morbid conditions.
>
> (2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

Section 494.90, "Condition: Patient plan of care," states in relevant part as follows:

> The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.
>
> (a) *Standard: Development of patient plan of care.* The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:
>
> (1) *Dose of dialysis.* The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

Dialysis facilities are subject to the survey, certification, and enforcement requirements in 42 C.F.R. Part 488. Under 42 C.F.R. §§ 488.10 – 488.12, state agencies under agreement with CMS conduct surveys and make recommendations regarding whether these suppliers meet the applicable conditions and standards. Under section 488.24(b), a state agency will certify that a supplier –

[2] Section 494.80 states: "The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian."

> is not or is no longer in compliance with the . . . conditions for coverage where the deficiencies are of such character as to substantially limit the . . . supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients[.]

Section 488.604(a) provides, with an exception not relevant here, that–

> failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

A supplier dissatisfied with a CMS determination to terminate coverage of services furnished by the supplier for failure to meet a condition for coverage may request a hearing before an ALJ. 42 C.F.R. §§ 488.24(c), 498.3(b)(6).

Case Background[3]

ERSD is marked by complete failure of one's kidneys to cleanse the blood of potentially lethal toxins. ALJ Decision at 2. Kidney dialysis is one means of treating the disease. *Id*. It is a process by which a patient's blood is extracted, mechanically cleansed of wastes and toxins, and then reinserted into the patient. *Id*. In order to do this, access must be established to the patient's circulatory system. *Id*. That can be accomplished by the insertion of a catheter into a vein in the patient's neck, chest or leg near the groin or by the creation of an arteriovenous fistula or graft. *Id*.; CMS Ex. 22, at 1, 3. A common problem with all of these methods of access, particularly the use of a catheter, is low blood flow due to blood clotting in the access. CMS Ex. 22, at 4. An anticoagulant (blood thinner) may be prescribed to keep blood from clotting. *Id*.

AKC is a facility that provides kidney dialysis services to patients with ERSD. The State survey agency completed a recertification survey of AKC on February 13, 2014, a first revisit survey on June 16, 2014, and a second revisit survey on December 12, 2014. Each survey found AKC out of compliance with Medicare conditions for coverage. CMS Exs. 2, at 1; 3, at 2; and 4, at 1-2. CMS issued a determination dated April 8, 2015 notifying AKC that, based on the December 12, 2014 survey, "your coverage as a supplier of ESRD services will be terminated" on May 23, 2015. CMS Ex. 4, at 1. According to CMS, the survey "documented deficiencies that . . . reasonably support a conclusion that your facility continuously has failed to meet" the conditions for coverage at 42 C.F.R. § 494.80 (Patient Assessment) and 42 C.F.R. § 494.90 (Patient Plan of Care). *Id*. at 2.

[3] We have drawn the factual material in this section from the ALJ Decision and the record below and provide it for the benefit of the reader but do not intend to make any new factual findings.

AKC timely requested an ALJ hearing on the termination. The ALJ held a hearing at which he admitted CMS's Exhibits 1-24 and AKC's Exhibits 1-5, which included the written direct testimony of each party's witnesses, and gave the parties an opportunity to cross-examine each other's witnesses. ALJ Decision at 1. The ALJ concluded that CMS's exhibits "amply support CMS's allegations" of noncompliance and that "nothing in Petitioner's arguments or in its exhibits . . . undercut[s] or contradict[s] these allegations," further stating, "Put simply, the record conclusively establishes that Petitioner failed to perform the assessments and care planning that [are] mandated by the regulations." *Id*. at 5. The ALJ specifically relied on the following allegations of noncompliance made by CMS:

- AKC failed to complete health status and medical condition assessments for six patients, as required by section 494.80(a)(1).
  Patient 5 AKC failed to document the placement of a catheter in the patient's chest and failed to document the removal and reinsertion of that catheter. In addition, AKC failed to assess the patient's pre-dialysis catheter condition.
  Patient 11 AKC failed to document the date of catheter insertion in the patient.
  Patients 18, 19, and 20 AKC failed to document the presence of sounds associated with blood flow ("thrill" and "bruit") at the sites of these patients' surgical interventions for dialysis. In addition, AKC's staff failed to assess Patient 20 for patency of her catheter, for lung sounds, and for location of edema.[4]
  Patient 21 AKC failed to record whether the patient had received catheter care, had manifested thrill or bruit, and whether the catheter was patent.

- AKC failed to evaluate the appropriateness of dialysis prescription for two patients, as required by section 494.80(a)(2).
  Patient 18 The patient received a substantially larger dose of the medication Heparin, an anticoagulant, than had been prescribed by the patient's physician, and AKC's staff provided no explanation for the increased dosage of this medication. AKC's staff also failed to assess an episode of bleeding involving this patient.

  Patient 19 AKC'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. In addition, on multiple occasions, the patient manifested a blood flow rate that deviated from that which the patient's physician had ordered and the staff failed to explain or assess the discrepancy.

[4] "Patency" is defined as "the quality of being open or unobstructed." MedlinePlus Medical Dictionary at https://medlineplus.gov/mplusdictionary.html.

- AKC failed to monitor the appropriateness of dialysis treatment by monitoring and assessing blood pressures and fluid management needs for three patients, as required by section 494.80(a)(2) and AKC's internal policy governing hypertension (requiring that a patient's blood pressure be monitored after dialysis and that any reading greater than 185 systolic or 100 diastolic be reported to a registered nurse.)
  Patient 18 The patient on one occasion had a blood pressure of 191/97 but 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.
  Patient 20 AKC's staff failed on several occasions to assess the patient despite blood pressure readings of 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.
  Patient 22 The patient registered a blood pressure reading of 191/103 but there is no documentation that a registered nurse was notified so that she could assess the patient's condition and, if necessary, notify the patient's physician.

- AKC failed to develop plans of care to address medical issues confronted by two patients, as required by sections 494.90 and 494.90(a)(1).
  Patient 5 AKC's staff failed to document in a care plan whatever interventions it may have decided upon to address problems with the patient's catheter.
  Patient 19 AKC's staff did not develop a care plan to address any problems that might be associated with a pacemaker the patient wore after having experienced an episode of cardiac arrest. In addition, AKC's staff did not develop a plan to deal with blood clots the patient developed in association with a graft utilized in dialysis.

See ALJ Decision at 3-5.

The ALJ further concluded that the record "is manifest with omissions and errors by AKC's staff that had the potential for causing great harm to patients and that adversely affect their patients' safety." *Id.* at 6. Accordingly, the ALJ sustained the termination based on AKC's "fail[ure] to comply substantially" with the two conditions for coverage at issue. *Id*. at 2.

Standard of review

The Board's standard of review on a disputed conclusion of law is whether the ALJ's decision is erroneous. The Board's standard of review on a disputed finding of fact is whether the ALJ's finding is supported by substantial evidence in the record. *See Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* (*Guidelines*), accessible at http://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-toboard/guidelines/index.html?language=en.[5]

Analysis

On appeal, AKC argues that termination was not warranted for three main reasons. First, AKC argues that the ALJ erred in concluding that AKC's failure to document an assessment or evaluation establishes that the assessment or evaluation was not done. Second, AKC argues that CMS failed to show that any of the deficiencies at issue posed a risk to patients greater than the potential for causing minimal harm. Third, AKC argues that the survey process was improper and reflected the State survey agency's bias against it. We explain below why we conclude that these arguments have no merit. We then discuss two additional arguments raised by AKC, which we also conclude have no merit.[6]

1. AKC has not shown any error in the ALJ's conclusion that required assessments or evaluations were not performed.

In its request for review, AKC notes the survey findings that it failed to meet the requirements of section 494.80(a)(1) and (a)(2) because it did not document assessments of the medical condition of Patients 5, 11, 18, 19, 20 and 21; did not document that it informed a registered nurse of, or took other appropriate action regarding, high blood pressure readings for Patients 18, 20 and 22; and did not adequately evaluate and manage dialysis prescriptions for Patients 18 and 19. Request for Review (RR) at 11, 14. AKC argues that CMS erroneously concluded, merely because AKC did not document the

[5] We cite to these guidelines even though the Act and the regulations in 42 C.F.R. Part 494 refer to a dialysis facility as a supplier, not a provider, since termination of a dialysis facility's Medicare and/or Medicaid coverage is similar to the termination of a provider's participation in the Medicare/Medicaid program. We note too that a "renal dialysis facility" is considered a "provider" for purposes of the requirements for payment of covered services furnished to Medicare beneficiaries. *See* 42 C.F.R. § 405.1801(b).

[6] AKC's request for review also addresses several survey findings that CMS did not rely on as a basis for termination and which we therefore do not discuss here.

required assessments and evaluations or other actions, that it did not perform them. According to AKC, its "purported failure to document all assessments does not in and of itself indicate that the assessments were not done at the time of the treatment" and its "[f]ailure to document is not evidence that the evaluation was not completed." RR at 11, 14.

AKC raised these arguments in its pre-hearing brief but did not pursue them in its post-hearing brief, and the ALJ did not address them. However, the Board, addressing similar arguments, has stated that it "has generally been unwilling to accept that treatments that are not documented have nevertheless been performed[.]" *River City Care Ctr.*, DAB No. 2627, at 9 (2015), *aff'd*, *River City Care Ctr. v. U.S. Dep't of Health & Human Servs.*, No. 15-60315 (5th Cir. Apr. 28, 2016). The Board has also stated that a factfinder "is entitled to assume, absent contrary evidence, that a resident's medical records accurately reflect the care and services provided (or not provided)." *Western Care Management Corp. d/b/a Rehab Specialties Inn*, DAB No. 1921, at 48 (2004). Under these precedents, a facility's failure to document the care it provides does not conclusively establish that the care was not provided if there is other evidence in the record based on which the factfinder could conclude that the care was provided. Here, however, AKC does not point to any evidence in the record to show that it took the actions in question.

AKC does claim that it attempted to provide "certain documentation" to the surveyors but the surveyors "refused to review" it. RR at 14, 17, citing P. Exs. 3 (declaration of AKC's medical director stating that AKC offered documentation of a prescription order she wrote for a patient and "logs and records of disinfections and interdisciplinary team meetings"), and 4 (declaration of AKC's registered dietician stating that AKC offered documentation for lack of placement of a fistula in a specific location). However, none of the documentation identified by these individuals on its face relates to the actions for which CMS found no documentation.

Moreover, CMS submitted medical records for some of the patients at issue from which it is apparent that AKC's practice was to document most of the actions at issue. These records include hemodialysis treatment sheets for each date a patient receives dialysis with places for recording a "pre" and "post" treatment assessment of items including blood pressure and edema, as well as the type and location of the access, whether "thrill" and "bruit" are present, whether the catheter is "patent," whether catheter care was given, and the amount of Heparin prescribed and "[i]nstilled." *See, e.g.*, CMS Ex. 6, at 3-13 (treatment sheets for Patient 5). It is reasonable to infer from the fact that information that should have been recorded on these treatment sheets was missing as to the patients at issue that AKC never took the actions required to obtain it.

AKC also asserts that it was in the process of implementing a new electronic documentation system that "would have eliminated any potential deficiencies" but did not complete implementation. RR at 12; *see also* RR at 14. However, AKC did not point to any requirement in the regulations that a dialysis facility be given an opportunity to correct its noncompliance prior to termination of Medicare coverage of its services.[7] Accordingly, AKC's assertion that it would have corrected its noncompliance had it not been terminated is irrelevant. In any event, prior to the survey that was the basis for the termination, CMS conducted two surveys that also found that AKC had not met requirements in sections 494.80 and 494.90. Thus, AKC had ample opportunity to correct its noncompliance.

2. AKC has not shown any error in the ALJ's conclusion that AKC failed to meet the conditions of coverage because its deficiencies had a great potential for harm.

On appeal, AKC argues that the termination was not justified because the deficiencies identified by the survey "posed no greater risk than the potential for causing minimal harm." RR at 19, citing 42 C.F.R. § 488.301 (definition of term "Substantial compliance"); *see also* RR at 6 ("survey identified issues and concerns that were not shown to potentially cause harm or risk to patients.").[8]

AKC's reliance on the definition of "substantial compliance" in section 488.301 is misplaced since that definition applies only to long-term care facilities. *See* 42 C.F.R. § 488.300 (definition applies to term as used in subpart F of 42 C.F.R. Part 488, Survey and Certification of Long-Term Care Facilities); *see also* 42 C.F.R. §§ 488.330(b) and 489.53 (providing that CMS may not terminate a long-term care facility's participation in Medicare and/or Medicaid if the facility is in "substantial compliance" with participation requirements). The regulations applicable to all providers and suppliers other than long-term care facilities state that a facility fails to meet a condition for coverage where "deficiencies are of such character as to substantially limit the . . . supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(a)-(b). Applying this definition, we construe AKC's argument as being that deficiencies found by CMS did not adversely affect the health and safety of patients because they had only the potential for minimal harm to patients. As the ALJ noted, the Board has held that a deficiency may adversely affect the health and safety of patients

[7] The Board has specifically held that CMS is not required to afford the opportunity to correct noncompliance before terminating providers that, like dialysis facilities, are subject to the survey, certification, and enforcement procedures at 42 C.F.R. Part 488. *See, e.g.*, *Aspen Grove Home Health*, DAB No. 2275, at 23 (2009).

[8] AKC actually cites to 42 C.F.R. § 480.301; however, it is apparent that this is a typographical error as there is no such section.

within the meaning of section 488.24 even when it does not result in actual harm. ALJ Decision at 5, citing *Dialysis Ctr. at Moreno Valley, Inc.*, DAB No. 2193, at 23 (2008) (stating that section 488.24 does not create an "exception" for the situation where failure to meet a condition for coverage "did not result in actual harm to a patient or patients"). Since, as discussed below, the ALJ reasonably concluded that AKC's deficiencies had a "great potential for harm," we need not decide whether the health and safety of patients would be adversely affected if the deficiencies posed a risk of no more than a potential for minimal harm.

The ALJ Decision states in relevant part:

> Kidney dialysis . . . can be accomplished by several means. All of them require surgical intervention and all of them have accompanying risks to the patient. . . . Risks include the development of blood clots and scarring. . . . Patients who receive dialysis are at heightened risk for developing cardiovascular disease, heart attacks and stroke. . . . 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. . . .
>
> * * * *
>
> With ESRD facilities there is a 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 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.

ALJ Decision at 2-3 (citations to CMS exhibits omitted); 5-6.

AKC does not dispute any of these findings. Thus, there is substantial evidence in the record to support the ALJ's conclusion that AKC's failed to meet the conditions for coverage because its deficiencies had a "great potential for harm." We agree with the ALJ that the resulting situation had an adverse effect on patients.

3. AKC has not shown any error in the ALJ's conclusion that how the surveys were conducted is irrelevant.

AKC argues that the Statement of Deficiencies resulting from the December 12, 2014 survey was "faulty in several aspects and failed to provide information sufficient to result in" AKC's termination in part because "the survey was conducted in an atmosphere of chaos and intimidation;" "the survey process itself was disorganized . . .;" and "the surveyors were biased in their evaluation." RR at 4; *see also* RR at 16-18. The ALJ addressed similar arguments AKC made below as follows:

> 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.

ALJ Decision at 6.[9] The ALJ's analysis is consistent with a long line of Board cases. *See, e.g., Nightingale Home Healthcare, Inc.*, DAB No. 2784, at 11 (2017) ("evidence about the survey process is not relevant where the provider has not shown how any alleged defects in the conduct of the survey ... undercut or impeach the evidence of noncompliance offered by CMS") (internal quotes omitted).

The ALJ did not specifically address AKC's allegation that surveyor bias led to its termination for deficiencies for which similar facilities were not sanctioned. However, the Board has held that "an ALJ's de novo evaluation of the objective evidence would correct any alleged bias in a surveyor's evaluation of that evidence." *Jewish Home of Eastern Pennsylvania*, DAB No. 2254, at 15 (2009), *aff'd, Jewish Home of Eastern PA v. Ctrs. for Medicare & Medicaid Servs.*, 693 F.3d 359 (2012). The Board further stated:

> CMS's treatment of other facilities cannot undercut Jewish Home's responsibility to show that it was in compliance with the applicable legal requirements or remove CMS's authority to take actions which it is authorized by statute and regulation to take in response to Jewish Home's noncompliance. Thus, the Board

[9] AKC cites to a 2012 federal district court decision which it claims held five State survey agency employees "liable for unconstitutional retaliation against [the owners of a nursing home] for their exercise of their First Amendment rights." RR at 18, citing *Beechwood v. Leeds*, 856 F.Supp.2d 580 (2012). Contrary to what AKC indicates, however, the cited decision is not a decision on the merits. In any event, AKC did not explain why such a holding is relevant here.

> has held in numerous cases that allegations by a party against which an action has been taken that the treatment accorded to it is harsher than that accorded to others similarly situated "do not prohibit an agency of this Department from exercising its responsibility to enforce statutory requirements[.]"

Id. at 15 (citations omitted).

Accordingly, we conclude that the ALJ did not err in finding irrelevant AKC's complaints about the survey process.

4. AKC's other arguments have no merit.[10]

AKC raises two arguments regarding specific allegations by CMS based on which the ALJ concluded that AKC failed to meet conditions for coverage. We find no merit in either argument.

AKC argues that there is no requirement that, in order to evaluate whether appropriate care is being provided, a dialysis facility check the vascular access for problems with blood flow before each dialysis treatment or check the thrill in the access every day. RR at 13.[11] As noted, the ALJ relied in part on survey findings that AKC "failed to document the presence of sounds associated with blood flow ("thrill" and "bruit") at the sites of . . . surgical interventions for dialysis" for Patients 18, 19 and 20; failed to record whether Patient 21 "had manifested thrill or bruit"; and "failed to explain or assess the discrepancy" on several occasions when Patient 19 "manifested a blood flow rate that deviated from that which the patient's physician had ordered." ALJ Decision at 3-4. AKC acknowledges that a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) publication "advise[s] that health care providers check the access for . . . problems before each dialysis treatment," but asserts that "[t]his recommendation . . . was directed at dialysis patients" for purposes of evaluating whether they are receiving appropriate care. RR at 12-13. AKC asserts that "NIDDK is not the regulatory agency providing definitive procedure and guidelines in how health care providers care for their patients" and that CMS has never informed dialysis facilities that they must comply with the NIDDK recommendations. *Id*.

[10] Although AKC raised these arguments in its pre-hearing brief, it did not pursue them in its post-hearing brief, and the ALJ did not address them.

[11] AKC also argues that there is no requirement that a dialysis facility check for signs of infection before each dialysis treatment. *Id*. However, the ALJ did not rely on any allegation that AKC failed to do that.

AKC's argument is not persuasive. The regulations require in relevant part that the facility "provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis" and that it "evaluate the appropriateness of dialysis prescription . . . and fluid management needs." 42 C.F.R. §§ 494.90(a)(1), 494.80(a)(2). AKC does not dispute that in order to meet these standards it was necessary to check the patency of a patient's catheter and whether thrill and bruit were present and evaluate whether a patient's blood flow was as prescribed by the physician each time dialysis was provided. Indeed, the hemodialysis treatment sheet AKC used each time a patient had dialysis includes a section for recording the extent of clotting at the access site and whether thrill and bruit were present. *See, e.g.*, CMS Ex. 6, at 3. Thus, AKC's own practice undercuts its argument.

AKC also disputes the ALJ's finding that AKC failed to develop plans of care to address certain medical problems that Patients 5 and 19 had. RR at 15, citing AKC Exs. 4, at 2 and 1, at 19-20. The ALJ relied on survey findings that Patient 5's plan of care did not address problems with her catheter and that Patient 19's plan of care did not address problems that might be associated with her pacemaker as well as blood clots she developed in connection with a graft. ALJ Decision at 4-5 and CMS exhibits cited therein. AKC argues that these patients did not "require a Patient Plan of Care as the patients were not unstable." RR at 15, citing AKC Ex. 4, at 2. AKC asserts that "[a]ccording to the Medical Director's knowledge and CMS Guidelines, . . . for a patient to be listed as unstable and subsequently require a Patient Plan of Care, the patient must have more than one abnormal lab value[.]" *Id*., citing AKC Ex. 1 (ESRD Surveyor Training Interpretive Guidance" dated October 3, 2008) at 19-20.[12]

AKC's argument ignores the plain language of sections 494.90 and 494.90(a)(1) requiring a dialysis facility to develop an "individualized" plan of care for "each patient" as well as the fact that AKC did have a plan of care for each of the two patients at issue. *See* CMS Ex. 6, at 18-23 (Patient 5's Plan of Care dated 10/8/14); CMS Ex. 12, at 57-59 (Patient 12's Assessment/Plan of Care dated 1/2014). Section 494.90 further requires the plan of care to specify "the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition[.]" It follows that a plan of care must be updated to reflect changes in a patient's condition. However, even if AKC intended to argue that there were no changes in condition requiring it to update its plans of care for Patients 5 and 19 because these patients did not have more than one abnormal lab value, CMS's interpretive guidance provides no support for that argument. That guidance specifies the circumstances under which a facility's

[12] AKC incorrectly identifies its Exhibit 4 as the declaration of its medical director instead of its registered dietician. RR at 14-15.

interdisciplinary team should perform a comprehensive assessment and states that "the plan of care is built upon the patient assessment . . . [and] is revised after each patient assessment[.]" AKC Ex. 1, at 16, 19-21. While the guidance also states that a facility should perform a comprehensive assessment "[a]t least monthly for unstable patients" and specifies "minimum criteria for classifying patients as 'unstable,'" the minimum criteria are comprehensive and do not specifically refer to abnormal lab values, much less limit the criteria for such a classification to abnormal lab values. *Id*. at 19.

Accordingly, AKC has not shown that the ALJ erred in concluding that it did not meet the requirements for a plan of care in sections 494.90 and 494.90(a)(1).

Conclusion

For the reasons explained above, we affirm the ALJ Decision upholding CMS's termination of coverage of AKC's services.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Leslie A. Sussan
Presiding Board Member