Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Optimal Care Dialysis,	)	Date: May 28, 2008
CCN: 23-2595	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket Nos. C-05-474
	)	C-06-310
	)	Decision No. CR1792
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I sustain the determination by the Centers for Medicare & Medicaid Services (CMS) that Optimal Care Dialysis, Petitioner, was not pursuing network goals as required by 42 C.F.R. § 405.2134. I further sustain the determination by CMS to impose the sanctions of denial of payment for all services furnished by Petitioner to patients first accepted for care on or after July 9, 2005, as well as the termination of Petitioner's participation in the Medicare program, effective January 20, 2006.

I. Background

By letter dated December 28, 2004, CMS notified Petitioner that it was imposing the alternative sanction of denial of payment for all services furnished to patients first accepted for care on or after February 12, 2005 because Petitioner was not "pursuing network goals" as required by 42 C.F.R. § 405.2134. Petitioner was notified that this alternative sanction would remain in effect until it had achieved substantial compliance with 42 C.F.R. § 405.2134 or it was terminated from participation in the Medicare program. Petitioner's End Stage Renal Disease (ESRD) facility was brought to CMS's attention after a quality of care referral from Renal Network 11 (Network). Petitioner

was notified that it was not pursuing Network 11's[1] goal E because it failed to conduct quality improvement activities and did not demonstrate an ability to write and follow a quality improvement plan. Further, Petitioner was notified that it was not pursuing Network 11's goal L because it failed to assure that its outcomes were comparable to expected outcomes as defined by currently accepted standards of care in the areas of anemia management, hemodialysis adequacy, nutrition, renal osteodystrophy, and vascular access.

Petitioner requested an informal hearing before a CMS official who was not involved with the decision to impose the sanction. The imposition of the sanction was stayed pending the results of the informal hearing. By letter dated May 25, 2005, CMS informed Petitioner that the hearing officer, Dr. Susan Nedza, had upheld the alternative sanction, which was imposed effective July 9, 2005. Petitioner was notified that if CMS determines that Petitioner continued to fail to meet the requirements of 42 C.F.R. § 405.2134, Petitioner's participation in the Medicare program would be terminated pursuant to 42 C.F.R. § 405.2181(c). Petitioner was informed that it could appeal this decision by requesting a hearing before an Administrative Law Judge (ALJ). Petitioner requested a hearing on the imposition of the alternative sanction. Petitioner's hearing request was docketed as C-05-474. On January 20, 2006, CMS terminated Petitioner's participation in the Medicare program. Petitioner requested a hearing on the issue of termination. Petitioner's second hearing request was docketed as C-06-310. Docket numbers C-05-474 and C-06-310 were subsequently consolidated on March 24, 2006. These cases were initially assigned to ALJ Anne Blair. On August 31, 2006, these cases were reassigned to me.

A hearing was conducted in Detroit, Michigan, from February 5-9, 2007 and continued on March 13-16, 2007. The transcript of the first week of this hearing is referred to as Transcript (Tr.) and the transcript of the second week of the hearing is referred to as Transcript 2 (Tr2). At the hearing, CMS submitted 95 exhibits (CMS Exs. 1-95) into evidence and Petitioner submitted 150 exhibits (P. Exs. 1-150) into evidence.

CMS submitted its corrected post-hearing brief on July 17, 2007 with six attachments labeled A-F. By ruling dated August 27, 2007, I notified the parties that I took judicial notice of Attachment A, which is a federal payroll calendar. My ruling further informed the parties that I would not consider Attachments B-F, which are charts that CMS attached to its post hearing brief. Attachments B-F summarize evidence regarding errors in the administration of Epogen (EPO), intravenous (IV) iron, and heparin and in patients'

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[1] Petitioner is located within the service area of Network 11, which encompasses Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin.

dry weights and treatment duration. My August 27, 2007 Ruling is incorporated by reference into this Decision. On November 5, 2007, Petitioner filed its revised post-hearing brief. Subsequently, CMS sent a letter to Petitioner dated November 9, 2007, with a copy sent to this forum. In CMS's letter, it pointed out that there were a number of blanks in the citations to exhibits, places where an exhibit did not refer to a particular page number within it, and other places where patient numbers and citations to the transcript were difficult to read. CMS filed its post-hearing reply brief on December 20, 2007. I directed Petitioner to resubmit its post-hearing brief with complete and clear citations. Petitioner filed its complete and corrected brief on February 15, 2008. Petitioner's brief was received on February 20, 2008 and on that date the record in this case closed. My decision is based on the parties' submissions, including exhibits, the testimony made at the hearing, and the applicable law.

II. Applicable Law

Eligible persons with ESRD are covered by Medicare under the Social Security Act (Act). Act, section 1881; 42 U.S.C. § 1395rr. Section 1881(b)(1) of the Act provides for payment to "renal dialysis facilities which meet such requirements as the Secretary by regulation prescribe for institutional dialysis services and supplies . . . ." The regulations regarding coverage of suppliers of ESRD services are set forth at Subpart U of 42 C.F.R. § 405.2100, et seq.

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

To participate in and receive payment from Medicare, an ESRD facility must satisfy all the provisions of section 1881 of the Act and it must be in substantial compliance with Subpart U's conditions for coverage. 42 C.F.R. §§ 405.2180; 488.3(a). A "condition for coverage" represents a broad category of services. Each condition is contained in a single regulation, which is divided into subparts called standards. *See* 42 C.F.R. § 488.26(b).

With one exception,[2] the failure of an ESRD supplier to meet one or more of the conditions for coverage set forth in Subpart U will result in termination of Medicare coverage for the services furnished by the supplier. 42 C.F.R. § 405.2180(a).

If a facility is deficient with respect to one or more *standards*, it may participate in the Medicare program only if: a) it has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary; and b) the deficiencies "neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care." 42 C.F.R. § 488.28. If the facility meets these criteria, the state agency/CMS may grant it a "reasonable time" in which to achieve compliance. Ordinarily that amount of time is 60 days but depends on the nature of the deficiency and the survey agency's judgment as to the capabilities of the facility to provide adequate and safe care. 42 C.F.R. § 488.28(c). Nothing in this or any other regulation authorizes a period of correction where a facility is found out of compliance at the condition level.

Congress has established "ESRD networks in which the approved ESRD facilities collectively provide necessary care for ESRD patients." Act, § 1881(c); 42 C.F.R. § 405.2110. Among other responsibilities, the network conducts its own on-site reviews to identify facilities that fail to provide appropriate care. 42 C.F.R. § 405.2112(i). Petitioner herein is served by Network 11, which encompasses Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin. 42 C.F.R. § 405.2134 mandates that facilities "participate in network activites and pursue network goals." A facility that has consistently failed to cooperate with network plans and goals may be terminated or may have sanctions imposed on it, such as denial of payment for patients admitted to the facility after the date of notice of sanctions. 42 U.S.C. § 1395rr(c)(3). A facility that is dissatisfied with this determination shall be entitled to a hearing by an ALJ. 42 U.S.C. § 1395rr(g)(3); 42 C.F.R. § 498.3(b)(6).

A facility, before the ALJ, must prove substantial compliance by a preponderance of the evidence once CMS has established a prima facie case that the supplier was not in substantial compliance with relevant statutory or regulatory provisions. *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999). The ALJ, if the facility is found to be noncompliant, must hold CMS authorized to impose a remedy and may not review CMS's choice of remedy to impose. 42 C.F.R. § 498.3(d)(11).

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

III. Issues

The issues in this case is are: whether Petitioner was pursing network goals; and whether CMS had a basis to impose the sanctions of denial of payment for all services furnished to patients accepted for care on or after July 9, 2005 and termination, effective January 20, 2006.

IV. Discussion

Petitioner is a for-profit free standing dialysis facility located in Highland Park, Michigan. ESRD is total and permanent kidney failure. 42 C.F.R. § 405.2134 mandates that ESRD facilities "participate in network activities and pursue network goals."

Prior to discussing the findings in this case, I address other arguments made by Petitioner. Petitioner claims that Renal Network 11 and its medical review committee member, Dr. Robert Provenzano, are biased against Petitioner and demonstrate a conflict of interest because Dr. Provenzano and members of his group nephrology practice consider Petitioner as competition. Renal Network 11's practice is that all quality of care referrals are blinded when brought to the Medical Review Committee for review and any member who could possibly have a conflict of interest is recused. Petitioner's claims are unfounded because Dr. Provenzano was, in fact, recused and did not participate in the review of Petitioner's facility. CMS's Prehearing Brief at 7, n.4. Petitioner spends a great deal of time arguing that the Network's review of its facility was unfair, that it was treated differently from other facilities, and that the Network did not assist Petitioner in reaching Network goals. Whether Petitioner was treated unfairly, which it appears it was not, or assisted in reaching Network goals, is not at issue before me and is irrelevant to the issues I must decide. CMS's determination to impose sanctions against Petitioner is an independent decision made by CMS. The issue before me is whether CMS had a basis to impose sanctions against Petitioner. I make a *de novo* review of the evidence and in the matter before me, I find that CMS had a basis to impose sanctions and had the authority to impose sanctions.

Network 11 performed an on-site review of Petitioner's facility in 2004. In addition, Network 11 reviewed randomly chosen patient charts in two off-site reviews. The first off-site review covered patient charts from July to September 2004. A second off-site review of patient charts was done for the period from May to December of 2005. Petitioner moved to a new building on March 18, 2005. Network 11 did not come to perform another on-site review of Petitioner's new facility after it finalized its move to the new facility in May 2005. P. Br. at 5. Petitioner's administrator, Dr. Cynthia C. Griggs, questioned why Network 11 did not perform another on-site review at the new location. Tr2 at 923. There is no requirement that a Network conduct a second on-site

review. At both on-site and off-site reviews, Network 11 reviews patient charts, not the physical plant of a facility. An on-site review allows the Network to have access to all the patient records and not the randomly chosen patient charts it is limited to in an off-site review. Tr2 at 147. It is the state that surveys a facility's physical plant. *Id*. Therefore, Network 11's failure to conduct another on-site review of Petitioner's new facility is not relevant to the issues before me.

Petitioner argues that 42 C.F.R. § 405.2134 is vague and ambiguous by design and is, therefore, in violation of due process. I do not have jurisdiction in this matter to make decisions as to the constitutionality of the regulation applicable to this case. That matter is reserved for Petitioner to appeal to a court that has the authority to decide that issue. However, I must note that Congress left it up to the Networks to develop "criteria and standards relating to the quality and appropriateness of patient care." 42 U.S.C. § 1395rr(c)(2)(B). Networks, made up with experts in the ESRD and dialysis community, set the goals, not CMS. The goals of Network 11 are published annually. Further, the National Kidney Foundation, Disease Outcomes Quality Initiative (K/DOQI) guidelines are also public. Petitioner, as discussed later in this decision, has not met the network goals and has not complied with K/DOQI guidelines. Furthermore, Petitioner has not met such well known established standards of care, such as following physicians' orders and accurate documentation of medical records. Tr. at 242-243, 1092.

Petitioner claims that it was pursuing network goals. As evidence of this, Petitioner claims that in 2005: it moved into a new facility at considerable cost; it had administrative and organizational restructuring with the hiring of new staff; instituted new policies and procedures; instituted an improved quality improvement plan; and that it hired Minntech, a consulting team, to prepare a plan of correction (POC). P. Br. at 6-7. Although Petitioner was making some efforts at improving, it cannot show that by the end of the second review period in December 2005, it had effective processes of care in place to correct such systematic and serious problems as its medication errors. Neither can Petitioner show that it had outcomes comparable to expected outcomes as defined by currently accepted standards of care.

The first review conducted by Network 11 was of the records of nine patients for services rendered from July to September 2004. These nine patients are identified as patients 1-9. Petitioner generally had approximately 45 patients at any one time. Therefore, the first review covered approximately 20% of Petitioner's patients. The second review conducted by Network 11 was of the records of five patients for services rendered from May to December 2005. The five patients in the second review period are identified as patients 1A-5A. The second review covered approximately 11% of Petitioner's patients. The purpose of the chart reviews was to allow Network 11 to examine the processes of care delivered by Petitioner to its patients. Petitioner has argued that the 14 sample

patients were not representative of its patients. Petitioner's argument is without merit. There was no testimony or any other evidence that the 14 patient charts reviewed were not representative of the processes of care in place at Petitioner's facility. Petitioner had the opportunity to present evidence that the 14 sample patients were not representative, but did not do so. Network 11 also examined the laboratory values of **all** of Petitioner's patients to determine that Petitioner was not meeting Network goals.

Petitioner also argued that I should rely primarily on the data and charts it provided as evidence in this case. I find that I cannot rely on Petitioner's evidence. I assign the greater weight instead to the data and charts provided by CMS. Ms. Jan Deane, the Director of Quality Improvement in Consumer Services of Network 11, testified on behalf of CMS. She testified that she followed Network 11's standard procedure (using a patient's first laboratory result in the month) and used the data provided in CMS Ex. 91 to produce the charts admitted into evidence in CMS Exs. 82 and 83.[3] Tr2 at 346. Ms. Deane testified that the same procedure is used for every facility within Network 11's territory and the data and charts thus generated are used to compare one facility to another. Data must be used in the same way to allow a valid comparison to be made. Petitioner's data, however, was not calculated in accordance with Network 11's standard procedure. Instead, Nurse Paula J. Lewis, Petitioner's Director of Nurses, testified that laboratory values were used in data in different ways, either the highest value of the month (Tr. at 990-992, Tr2 at 39, 41-42), the average of patients' laboratory values (Tr2 at 39-41), or that Petitioner used the second laboratory value of the month (Tr2 at 42-43). Petitioner never laid a foundation as to the accuracy of the data and charts upon which it relies. Therefore, I do not base my decision upon the data and charts provided by Petitioner. The data displayed on Petitioner's charts essentially consist of the comparison of two numbers on two different documents and concluding that the number on one document came close to meeting, met, or surpassed the number on the other document. Petitioner made no attempt to establish that the numbers favorable to it were in fact true and accurate numbers. Thus, without that critical foundation, the evidence presented by Petitioner in using its charts simply become a meaningless comparison of numbers.

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[3] CMS Ex. 83, at 11, does include an error in the percentages for the months of October - December 2004. The percentages reflected by that part of CMS Ex. 83 really reflects the percentages for January - March 2004. I did not rely on the percentages that were in error. The correct percentages for October to December 2004, which I have used in my Decision in Part IV.2., are to be found at CMS Ex. 82, at 2.

As to the respective experts in the case, I found the expert from CMS, Dr. Jeffrey C. Fink,[4] to be more credible and analytical in his opinion and, therefore, I give his testimony the greater weight. Petitioner tried to argue that his findings and opinions were erroneous because they were not based on a valid statistical sample. CMS does not maintain that the sample of records reviewed constituted a valid statistical sample. While CMS's expert admits that the records he reviewed did not constitute a valid statistical sample, his credible opinion was based on the sample he did review. From the sample he reviewed, Dr. Fink credibly testified that in his opinion the sample demonstrated that Petitioner was not pursuing network goals.

Petitioner attempted to argue that all of the other dialysis services which were not part of the sample reviewed by Dr. Fink were correctly performed. Petitioner maintained that had the CMS expert analyzed all of the records, he would have found them correct, and thus, could not conclude that Petitioner was not pursuing network goals. When challenged as to the premise of that argument at hearing, Petitioner attempted to go through each and every service in the record to prove that all other services provided were correct. Petitioner's attempt to prove this point at hearing only served to identify additional errors and deficiencies in Petitioner's records. Petitioner finally abandoned that strategy and agreed to a stipulation with CMS, on the record, that there were other errors in records which were not part of the review conducted by the CMS expert.

Petitioner presented the expert testimony of Dr. James Sondheimer.[5] I do not give Dr. Sondheimer's testimony weight as he relied upon Petitioner's data and charts in rendering his opinion. In relying on Petitioner's data and charts, Dr. Sondheimer was simply comparing numbers on two sheets of paper. Thus, Dr. Sondheimer did not provide an expert analysis or expert opinion based on evidence that was established as being accurate or relevant to the matter in controversy. In some instances he agreed with the CMS expert opinion. For example, both expert witnesses agreed that Petitioner did not always dose EPO appropriately and failed to monitor patients whose hemoglobin results were outside the target range.

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[4] Dr. Fink was accepted as an expert witness in the area of nephrology on behalf of CMS. Tr. at 1039.

[5] Dr. Sondheimer was accepted as an expert witness in nephrology on behalf of Petitioner. Tr. at 537.

Petitioner has also argued that its patient population was sicker than the patients in other ESRD facilities. The evidence does not support Petitioner's claim. Dr. Fink noted that Petitioner's patients were about average compared to most ESRD patients. More importantly, while sicker patients might result in worse laboratory values as discussed in Part IV.2. of this Decision, sicker patients have no effect on the processes of care in place at a facility. Petitioner's most egregious failure was its failure to deal with its problem of excessive medication errors as discussed in the Part IV.1.a. of this Decision. Medication errors that happen to very sick patients can have serious, if not deadly, results. Therefore, if the patients being dialyzed by Petitioner's facility were indeed sicker, then it was even more important that they receive the medication that they require and that their physicians ordered for them. Instead, the evidence shows that Petitioner had a systematic and very serious problem concerning medication errors and failure to follow physicians' orders. Furthermore, Petitioner did not engage in continuous quality improvement (CQI) to attempt to deal with this problem.

I find that CMS has presented a *prima facie* case that Petitioner was not pursuing network goals. It is Petitioner's burden to show by a preponderance of the evidence that it was pursuing network goals. Petitioner had access to all of its patients' charts and other documents to prove that it was in fact pursing network goals. Petitioner did not meet its burden.

As preliminary medical background in analyzing this case, it must be born in mind that ESRD is total and permanent kidney failure. Anemia is a significant problem for dialysis patients. Dialysis patients are tested for hemoglobin levels and hematocrit levels, which measure whether they have adequate red blood cells. Functioning kidneys produce a hormone, erythropoetin, which helps form red blood cells. Anemia is often treated with EPO, a bioengineered erythropoetin, and with supplemental intravenous iron, if needed. Other tests performed on these individuals to monitor their condition include: transferrin saturation (TSAT), which represents the amount of protein bound iron in circulation; ferritin, which correlates to total iron stores in the body; urea reduction ratio (URR), which measure dialysis adequacy by indicating how well a patient had been dialyzed in one treatment (Tr. 111), blood albumin, which measures protein stores in the body; parathyroid hormone (PTH), which draws calcium from bones; and calcium and phosphorus. Calcium, phosphorus and PTH are measured to monitor bone health. Renal osteodystrophy is a bone disease of kidney patients.

The Kidney Epidemiology and Cost Center at the University of Michigan (UM-KECC) prepares a Dialysis Facility Report for all the dialysis facilities that participate in the Medicare program. Petitioner was found to be in the bottom fourth percentile of dialysis facilities in Michigan and Network 11. Petitioner was also noted as having had a significantly higher percentile of patients dying and suffering from complications.

Petitioner had a 36% annual observed death rate as compared to an expected death rate of 19%. CMS Ex. 34, at 3. Petitioner also had a 121% higher rate of hospitalizations for its patients than expected. *Id.* Petitioner was found to be in the bottom percentile of facilities with patients having hematocrits at or over 33. *Id.* URR was 74% while it was 91% nationally.

1. Petitioner was not pursuing Network 11's goal E because it failed to conduct effective quality improvement activities.

Network 11's goal E requires Petitioner to engage in CQI. CQI requires information gathering, identifying problems in either patient care or patient outcomes, developing an improvement plan, implementing the plan, and reviewing the results of the implementation to determine if the problem had been resolved. Tr. at 139. Dr. Sondheimer, Petitioner's own expert, testified that quality improvement requires completing all of these steps. Tr. at 764-766. Developing a quality improvement plan is a facility's responsibility. Petitioner did not provide evidence that it was conducting meaningful CQI.

Network 11 has a goal that 80% of patients would have a hemoglobin value equal to or greater than 11 gm/dl. In analyzing whether Petitioner met this goal it is critical to bear in mind that Petitioner did not calculate its data the same way that this type of data was calculated by Network 11. Petitioner used the highest hemoglobin value of the month of its patients. Using its own calculations, Petitioner determined that 55% and 70% of its patients had a hemoglobin equal to or greater than 11 gm/dl in May and June 2005 respectively. P. Ex. 57, at 1; P. Ex. 58, at 2. However, Network 11 uses the first laboratory results of the month for each patient, as it did for all the facilities within its network. In analyzing this data, Network 11 determined that 51% and 52% of Petitioner's patients had a hemoglobin equal to or greater than 11 gm/dl in May and June 2005, respectively. CMS Ex. 83, at 10.

Dr. Griggs testified that the reason for the low values were that the blood specimens were being sent to the laboratory (Satellite Labs) on Fridays, which affected their lab values. Tr2 at 506-507. However, Petitioner's records show that the blood specimens were drawn almost exclusively on Mondays through Thursdays. Furthermore, Dr. Griggs testified that blood specimens were sent to the laboratory on the same day as it was drawn. CMS Ex. 91; Tr2 at 485-6. Network 11, as previously noted, uses the first laboratory value of the month, none of which was on a Friday. Therefore, the low May results could not have been caused by sending specimens to the laboratory on Fridays.

The records disclose that a quality assurance (QA) meeting held on June 3, 2005 by Petitioner resulted in a resolution to no longer send any blood specimens to Satellite Labs on Fridays. P. Ex. 57, at 1. No laboratory specimens were drawn in June until after this resolution. This provides additional evidence that the low hemoglobin values in June could not have been caused by sending specimens to the laboratory on Fridays as alleged by Dr. Griggs. Since Network 11 determined that only 52% of Petitioner's patients had a hemoglobin value equal to or greater than 11 gm/dl in June 2005, Petitioner did not accurately analyze the root cause of the problem of low values for hemoglobin. Further, 64.1% of Petitioner's patients had a hemoglobin equal to or greater than 11 gm/dl in July 2005. Had the June 3, 2005 QA meeting resolved the root cause of the problem, there would have been a drastic increase of the percentage in July 2005.[6] The problem clearly had not been resolved, which clearly demonstrates Petitioner's inability to conduct CQI.

CMS's termination notice to Petitioner was dated January 20, 2006. Petitioner filed a 2006 POC.[7] Petitioner's POC did not schedule implementation of many portions of its POC until after the termination decision. P. Ex. 69. The POC also includes statements, such as "[a] system *will be* devised to monitor . . ." to resolve identified problems. *Id.* Such an indefinite statement cannot show compliance and implementation cannot be determined if it is to happen at some point after termination. Further, the POC did not address every finding identified by CMS. CMS Exs. 4, 83. For example, the POC does not address EPO dosing or lack of adequate monitoring of patient's hemoglobin levels. Nor does it address Petitioner's failure to individualize patients' care plans and Petitioner's failure to implement physicians' orders after the orders were noted by nurses. P. Ex. 69. Therefore, Petitioner cannot rely on its POC to show that it was pursuing network goals.

Petitioner also asserts that in-service training was given on a variety of topics. P. Br. at 63-64. However, for the most part, Petitioner does not provide evidence that these in-services took place. CMS Reply Br. at 20. Petitioner also claims that it has corrected its problem with contingent staff and has hired permanent staff, for example, its new Director of Nurses, Nurse Lewis, and Nurse McGowan and Nurse Smith. However, Petitioner's problems continued after Nurses Lewis, McGowan and Smith were hired.

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[6] Network 11 has a goal that 80% of patients would have a hemoglobin value equal to or greater that 11 gm/dl.

[7] Petitioner refers to its POC as its 2006 POC, but the actual POC submitted as P. Ex. 69 is undated.

CMS Reply Br. at 23. I find that Petitioner continued to have the problems discussed below throughout 2005 and whatever efforts it attempted to put in place were not effective by the time of its termination.

a. Failure to pursue network goals is evidenced by Petitioner's staff failing to follow and/or implement physicians' orders and its own policies and procedures and failing to create or implement any CQI to deal with this problem.

The evidence establishes that Petitioner had a systemic and very serious problem with its staff failing to follow and/or implement physicians' orders, as well as failing to follow and/or implement its own policies and procedures. Petitioner failed to pursue Network 11's goals when it failed to conduct CQI activities to deal with the huge number of medication errors that existed during the first review period and continued to exist during the second review period.

The problem of failure to follow physician orders was evident in both off-site reviews. For example, the length of time a patient is to be dialyzed is considered a prescription item. Tr. at 267. If a dialysis session is to be cut short, there should be documentation as to the reason why it was cut short. On October 10, 2005, Dr. Griggs changed the order for the length of time patient 3A was to be dialyzed from three and one-half hours to four hours. Nurse Lewis, who was Petitioner's Director of Nursing as of July 1, 2005, signed off on the treatment sheet as having noted the change made by Dr. Griggs. However, the evidence establishes that between October 14, 2005 and November 17, 2005, patient 3A was dialyzed for only three and one-half hours during each session. Tr. 1014-1016. When questioned as to this fact, Nurse Lewis testified that she had patient 3A dialyzed for three and one-half hours because she "knew her patient." Tr. 1014. Despite the assertion that Nurse Lewis "knew her patient," Petitioner finally implemented Dr. Griggs' October 10th order on November 21, 2005, six weeks after the order was made. CMS Ex. 87, at 252-263. A nurse following her own judgment instead of following a doctor's orders of which she had documented specific knowledge, is contrary to the standard of care. Petitioner did not create or implement any form of CQI to address, resolve, or prevent this type of problem.

Errors were also made by Petitioner's staff in using the wrong dialysate solution. The dialysate solutions used in dialyzing patients are not always the same. The dialysate solutions have varying concentrations of potassium and calcium and are considered a prescription medication to correspond to the patient's needs. In two instances, patient 1's dialysate had the wrong potassium level. CMS Ex. 5, at 4, 35, 43. In eight instances, patient 5's dialysate solution had the wrong calcium level. CMS Ex. 9, at 4, 5, 72, 74, 76, 78, 85, 91, 95, 99.

Petitioner's staff also made serious medication errors in the administration of antibiotics. An error involving antibiotics can result in sepsis, infection, or death in a patient with ESRD. Tr. at 1092. Patient 9 in the first review and patient 4A in the second review were the same individual. That patient will be referred to as patient 9/4A. Patient 9/4A was prescribed Vancomycin to be administered three times a week from July 16, 2004 until August 4, 2004, and the Vancomycin was to be monitored during dialysis. CMS Ex. 13, at 114. This patient was infected with Methicillin-Resistant Staphlococcus Aureas (MRSA) secondary to line sepsis. There is no record that this patient received Vancomycin as ordered. *Id.* at 45-57. The same patient was again prescribed Vancomycin for one week on June 7, 2005, and then was to be continued on Vancomycin for an additional two weeks. There is no record that this patient received any of the prescribed Vancomycin during June 2005. *Id*. at 10, 146-163. Vancomycin was again prescribed in July of 2005. However, two orders written on the same day (July 19, 2005) conflicted as to the frequency of administration of Vancomycin and there is no indication what the staff did about the conflicting orders or which order was followed. *Id*. at 5 and 11. Errors in the administration of Vancomycin again occurred in October, 2005. An October 27, 2005 order prescribed 1.5 gm of Vancomycin for 19 days. The records indicate that from the second day Vancomycin was administered, this patient received only 1 gm instead of the 1.5 gm prescribed. In addition this patient did not receive even the erroneous l gm for the full 19 days prescribed. *Id.* at 274-85, 288-91.

Petitioner's staff also made dosage errors in the administration of EPO, intravenous iron, Ferrelicit or Venofer which were identified in both the first and second review periods. On September 14, 2005, Dr. Griggs ordered 5000u of EPO to be administered every treatment for patient 5. This order was noted by a nurse on September 15th. CMS Ex. 9, at 5. Nevertheless, patient 5 did not receive the ordered EPO on September 18 or 25, 2005. *Id.* at 101, 107. When a patient had a high hematocrit value, the facility had a policy that only 1000u of EPO would be given. In August 2004, patient 5's hematocrit was over 37.2, which is considered a high hematocrit. Under Petitioner's own policy, patient 5 was to receive 1000u EPO during every session. Instead, patient 5 was given 1000u on August 12, 17, and 24, but nothing on August 14, 19, or 21. Other errors in the September 2004 review period in the administration of EPO occurred for patient 1 (CMS Ex. 5, at 5, 48-67), patient 3 (CMS Ex. 7, at 3-6, 14, 49-58, 59, 79, 95, 97), patient 4 (CMS Ex. 8, at 5, 47, 65), patient 6 (CMS Ex. 9, at 4-5, 70-80, 101, 107; CMS Ex. 10, at 4, 44), and patient 9 (CMS Ex. 13, at 6, 73, 75).

An example of a medication error identified in the second review period occurred on June 25, 2005. Dr. Griggs increased patient 9/4A's EPO dosage from 5000u to 7000u. A nurse noted this change on June 25, the same day the change was ordered. CMS Ex. 88, at 10. Nevertheless, patient 9/4A received only 5000u EPO on June 25, 30 and on July 2, 5, and 7. *Id*. at 160-170. Other errors in the second review period in the administration of

EPO occurred for patient 1A (CMS Ex. 85, at 6, 180), patient 2A (CMS Ex. 86, at 5, 7, 79, 132), patient 3A (CMS Ex. 87, at 2, 7, 81, 91, 210), and patient 5A (CMS Ex. 89, at 2-4, 81, 126, 133).

The two reviews conducted also identified numerous errors in the administration of intravenous iron. Errors in the first review period were found for patient 1 (CMS Ex. 5, at 6, 7, 69, 97), patient 2 (CMS Ex. 6, at 5, 86), patient 3 (CMS Ex. 7, at 4, 6, 59, 66, 97), patient 4 (CMS Ex. 8, at 5, 6, 47, 62), patient 6 (CMS Ex. 10, at 4, 48, 61, 63), patient 8 (CMS Ex. 12, at 3, 4, 6, 44, 49, 68. 70, 72) and patient 9 (CMS Ex. 13, at 9, 95, 97). Even though nurses had noted the medication orders on the day it was made or the day after the order was made, there were still medication errors because Petitioner had not set up a system for ensuring that physician orders were entered in patients' records where all the staff could find them and ensure that the medication orders were noted by all necessary staff and implemented.

Errors in the second review period are exemplified by the error in the implementation of Dr. Griggs' August 24, 2005 order that 125 mg of intravenous iron be given to patient 2A during each of his next 10 dialysis sessions. CMS Ex. 84, at 5. Nurse Lewis noted the order the same day. *Id*. Nevertheless, patient 2A was not administered intravenous iron seven times between August 25 and September 10. *Id*. at 64-79. Other errors relative to the failure to administer intravenous iron identified during the second review period occurred for patient 1A (CMS Ex. 85, at 6, 180, 194, 200), patient 2A (CMS Ex. 86, at 5, 6, 7, 64-79, 110-112, 119-121, 127-143), patient 3A (CMS Ex. 87, at 2, 3, 5, 83, 97, 101, 107, 117, 123, 181, 185, 187, 204), and patient 5A (CMS Ex. 89, at 7, 230).

Errors identified during the first review period relative to the administration of heparin, a blood anti-clotting agent, are exemplified by the July 19, 2004 administration of heparin to patient 7 when Dr. Griggs had in fact ordered that patient 7 was not to be given any heparin at all. CMS Ex. 11, at 4-5, 41-42; Tr. 165-166. Patient 7 suffered prolonged bleeding from his arterial site as a result of this error. *Id*. Other errors in the September 2004 review period relative to the administration of heparin occurred for patient 1 (CMS Ex. 5, at 4, 5, 6, 48, 50, 52, 56, 60, 62, 68, 70, 80, 82, 94), patient 2 (CMS Ex. 6, at 5, 35, 45, 51, 57, 59, 61, 63, 65, 67, 75, 83, 91), patient 3 (CMS Ex. 7, at 3, 6, 42, 46, 50, 52, 54, 58, 62, 66, 70, 78, 82, 88, 94, 96, 99), patient 4 (CMS Ex. 8, at 5, 48, 66), patient 5 (CMS Ex. 9, at 3-5, 61, 63, 65, 69, 71, 73, 75, 77, 79, 86, 96, 98, 102), patient 6 (CMS Ex. 10, at 3, 4, 31, 49, 62), patient 7 (CMS Ex. 11, at 4, 52, 87, 89, 93), patient 8 (CMS Ex. 12, at 3, 4, 41, 43, 45, 50, 67, 71), and patient 9 (CMS Ex. 13, at 4, 5, 7, 35, 37, 39, 41, 51, 53, 55, 63, 67, 71, 77, 80, 96).

Errors disclosed in the second review period relative to the administration of heparin occurred for patient 1A (CMS Ex. 85, at 4, 142), patient 2A (CMS Ex. 86, at 5, 67, 76, 93), patient 3A (CMS Ex. 87, at 2, 4, 92, 96, 98, 100, 142), and patient 9/4A (CMS Ex. 88, at 2, 4, 183-186; CMS Ex. 89, at 5, 6, 155, 170, 176, 180, 184, 193).

Other errors by Petitioner's staff included administration of incorrect doses of vitamin D or the failure to administer any dose of vitamin D at all. Errors were also noted in incorrect blood flow rate sheets that would mislead a dialysis tech and cause the tech to incorrectly set up the dialysis machines. There were instances identified where incorrect dry weights[8] were documented on treatment sheets as well as the entry of incorrect duration times for the dialysis sessions.

Petitioner's Quality Assurance (QA) meeting minutes during the period of the second review are silent on the issues of medication errors. P. Exs. 58-64. QA meetings do mention in-servicing of the staff but none of the in-services concerned medication errors. P. Exs. 54-64. In the last quarter of 2005, Petitioner had its nurses check the physician's order sheet in the patient's charts daily to confirm medication orders to be given during dialysis. Tr. 416-417. However, the evidence of such a vast number of medication errors shows that this system of checking medication orders was not effective. Quality assurance is designed to catch errors that occur and to develop a system to prevent errors or other areas of concern from occurring over and over again. It is clear that Petitioner had a problem with medication errors in the first review period. It is also clear that in the second review period, Petitioner still had the same problem and had not yet developed a reliable system to prevent reoccurrence of this problem. Petitioner's argument that medication errors drastically decreased in the second review period is not supported by the evidence. Tr2 at 646. Petitioner also failed to present evidence that documents that alleged processes to prevent medication errors were in place. CMS. Ex. 81; P. Exs. 54-64. The evidence has established that Petitioner was not pursuing network goals by failing to address this serious problem of systematic medication errors and failure of its staff to follow physicians orders through a CQI process at the time of its termination.[9]

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[8] Incorrect dry weights can lead to fluid overload in a patient which causes low blood pressure, loss of consciousness, and cardiac irregularities. Tr. at 252.

[9] Petitioner claims to have instituted many new changes in 2006 (Tr2 at 85), but has failed to present evidence that it did so prior to the end of the second review period that lead to the termination by CMS from Medicare participation on January 20, 2006. If Petitioner indeed did institute changes and the facility has overcome its prior problems, Petitioner's remedy at present is to reapply for participation because the issue before me is whether CMS had a basis for Petitioner's termination on January 20, 2006.

Petitioner's attempts to show that it engaged in CQI were incomplete. Petitioner provided evidence of a corrective measure that it took to remedy its staff's failure to follow medication orders. Petitioner hired a dietician, Mrs. Joyce Mooty, as a consultant. Mrs. Mooty performed audits of patient charts. An audit of a chart would entail the review of the chart to determine the contents of the chart. However, the audits before me seem to be primarily a confirmation that documents were signed and were in existence, not that the document actually addressed and corrected a certain problem. At most, an audit of a chart would help to identify the causes of numerous medication errors. CQI requires that there be an identification of a problem, an analysis of the root causes of the problem, consideration of how to correct any problems identified, and how to prevent such problems from reoccurring. Finally, CQI requires a follow-up to see that any correction that was implemented is working. An audit by itself does not address these later areas of CQI. No evidence was provided to me that shows any QA meeting minutes that discussed what the audits showed, how to correct problems identified, or any follow-up to show that any correction that was implemented was indeed successful so that medication errors would be less likely to reoccur.

Petitioner's nurses also conducted an audit of patient flow charts and treatment sheets. No reference to the results of the treatment sheet audits from late 2004 and early 2005 were documented and no plan for dealing with the problem of medication errors was documented in the minutes of the QA meetings. CMS Ex. 81, at 14-83.

In November 2005, Petitioner hired Minntech, a consulting firm, to assist it with completing a POC. Minntech identified the cause of the medication errors to be the fact that Dr. Griggs was not taking the patient's charts back into the treatment area from her office after she finished working on them in the evening. Tr2 at 649; P. Ex. 69, at 16. The Minntech POC included a start date of February 2006 for a corrective action. That corrective action date is a date after which Petitioner had already been terminated. To the extent that the POC refers to a future plan to correct a problem, it is not relevant to the matter before me. The issue in this case is whether CMS had a basis to terminate Petitioner on January 20, 2006. I am not persuaded by Dr. Griggs' testimony that the problem of keeping charts in her office overnight was already being addressed during 2005 because, had that been the case, the POC would have specifically noted that the problem had previously been addressed. The POC includes no such statement.

Many of the medication errors identified were due to staff not implementing the new orders for numerous days, not simply just the day following the writing of the new order. Although keeping charts overnight in Dr. Griggs' office might have contributed to the problem of medication errors, it could not have been the sole or primary cause of this problem. Dr. Griggs' statement that keeping charts overnight in her office was "pretty much" the only cause of medication errors is not only unpersuasive but unlikely to be

accurate. Tr2 at 649. I have previously discussed some examples where nurses noted the change in the medication orders on the same day as the order was written or the day following and still the orders were not followed for days or even longer.

The use of contingent staff was mentioned at the hearing, but not in the QA meeting minutes, as an additional cause of errors in medication orders. Contingent staff worked primarily elsewhere and came to work at Petitioner's facility on a less than full time basis. Nurse Lewis stated that contingent staff were a "major problem" and would "bring in their own practices from their own units [other facilities that they work in primarily] and it [made for] a lot of inconsistencies." Tr. at 360. Nurse Lewis also admitted that "[a]lot of the policies during that time were very ambiguous." Tr2 at 23. Dr. Griggs also alluded to ambiguous policies in her testimony. Tr2 at 769. In addition, there were multiple policies on the same subject. P. Ex. 53, at 125, 148, 150; Tr2 at 757. The use of contingent staff, ambiguous policies, and multiple policies on the same subject could also cause medication errors but those issues were not addressed in a CQI plan by Petitioner.

Petitioner attempts to claim that the large degree of medication problems that existed in its facility were merely inevitable random errors. However, the first review consisted of a review of nine charts out of approximately 45 patient charts (approximately 20% of Petitioner's patients). The second review consisted of a review of five out of 45 patient charts (approximately 11% of Petitioner's patients). The number of charts reviewed and the excessive number of medication errors found are far beyond inevitable random errors. The excessive number of medication errors reflect a systematic, serious problem at Petitioner's facility that was not addressed and not corrected by CQI procedures. Even as late as the hearing in this case, Petitioner has failed to recognize that there was a systematic, serious problem at the time the facility was terminated. A process to ensure that new medication orders were entered into the patient's chart, then noted by a nurse and then, most importantly, implemented promptly, was never addressed or put in place. I agree with Dr. Fink's conclusion that the quality of care provided to Petitioner's patients was inadequate because Petitioner's staff failed to implement physicians' orders. Tr. at 1113. The failure of Petitioner to address this serious systematic problem, by itself, justifies CMS's alternative sanction and the termination of Petitioner for not complying with network goals.

b. Petitioner did not correctly monitor dialysis patients or intervene in dangerous medical situations.

Petitioner's staff, according to its own policies, were to take vital signs and record them every 30 minutes for stable patients during their dialysis treatment. P. Ex. 53, at 162. Evidence concerning patient 9 was presented which established that Petitioner's staff did not follow this policy. CMS Ex. 13, at 37, 39, 53, 59, 61, 67, 71, 82, 86, 88, 94.

Low blood pressure in dialysis patients can cause loss of consciousness and cardiac arrest. Prior to January 2006, according to Petitioner's own protocol, Dr. Griggs was to be informed if a patient's blood pressure went below 110/60 and staff were to perform certain interventions. However, Nurse Lewis testified that, "[i]t [physician notification] doesn't always happen" when low blood pressure is identified in a patient. Tr. at 978. Petitioner's protocol, confirmed by its own expert witness, Dr. Sondheimer, requires that there should be 15 minute blood pressure checks when a patient was hypotensive. Evidence was presented that during the majority of the time there were no 15 minute blood pressure checks when patient 1A had a systolic reading of below 100. CMS Ex. 85, at 72, 155, 169, 183, 191, 195, 201, 221, 247. Similarly, patient 5A's systolic pressure was lower than 100 many times and there is no record of the staff performing any of the interventions mentioned in Petitioner's protocol. CMS Ex. 89, at 105, 131, 138, 141, 158, 160, 162, 174, 176, 197, 207, 213, 215, 228, 245, 256. Further, Nurse Lewis testified that staff would only monitor blood pressure every 15 minutes when a patient was both hypotensive and *also* symptomatic. Tr. 980. Therefore, hypotensive, but otherwise stable, patients were not having 15 minute blood pressure checks. This violates not only Petitioner's own protocol but is against good medical practice. Petitioner's own expert witness, Dr. Sondheimer, testified that 15 minute blood pressure checks on hypotensive patients was a minimum practice. Tr. 749. For example, evidence was presented that patient 6 came into the facility with a blood pressure of 120/68 and during dialysis his blood pressure dropped to either 97/56 or 91/56, but his blood pressure was not monitored for another 45 minutes. CMS Ex. 10, at 66; Tr. at 750. Petitioner attempts to argue that the protocols are optimal measures that can be taken at the staff's discretion. However, Petitioner's protocol is not written as if monitoring blood pressures every 15 minutes is optional. Tr2 at 876.

High blood pressure during dialysis puts ESRD patients at a higher risk for stoke, intra-cranial bleeding, loss of consciousness and death than patients who do not suffer ESRD. Tr. at 296. Petitioner's policy, prior to January 2006, was to monitor patients with hypertension if the blood pressure was over 160/100. P. Ex. 53, at 151; Tr2 at 755. Petitioner's policy was that after two 15 minutes checks, if the patient's blood pressure was still elevated, a patient was to receive a medication called Cateapres. P. Ex. 53, at 151. Evidence was provided that Petitioner did not monitor patients 3, 6, 7, 9, and 2A as required by its policy. CMS Ex. 7, at 76; CMS Ex. 10, at 68; CMS Ex. 11, at 40; CMS Ex. 13, at 39; CMS Ex. 86, at 57, 67, 80, 95, 120, 142. No interventions were recorded at all for patient 3 (CMS Ex. 7, at 46, 58, 62, 70, 76, 78, 96, 103), not even when patient 3 had a blood pressure of 217 (*id*. at 72). No interventions were recorded at all for patient 2A (CMS Ex. 86, at 57, 61, 63, 65, 67, 72, 78, 80, 95, 97, 109, 111, 113, 115, 128, 136, 139), not even when patient 2A had a blood pressure of 239 (*id*. at 133).

Petitioner argues that the fact that interventions were not recorded does not mean that intervention were not performed. I give absolutely no weight to Petitioner's argument on this point. It is both Petitioner's policy and the nursing standard of care that interventions, including recording blood pressures, should always be documented. Tr. at 242-243; P. Ex. 53, at 145. Medicare requires that ESRD medical records are to be complete and accurately documented, and therefore I can assume, and case law supports this assumption, that a patient's medical record accurately reflects the services provided or not provided. 42 C.F.R. § 405.2139. Thus, if the ESRD patient's record does not document that a service or treatment was performed, I must conclude that the service or treatment was not performed. Furthermore, CQI was not conducted or performed for the problem of failure to monitor dialysis patients and for the failure to intervene when necessary.

c. Petitioner failed to pursue network goals by not having complete and accurate clinical assessments, and particularly, Petitioner did not ensure that patients reached their ordered dry weight.

Although numerous examples of failure to have complete and accurate clinical assessments were provided by CMS, I mentioned only several examples here to support this finding. On September 18, 2004, patient 5's post dialysis assessment included a checked box for "Access Normal" even though the back of the treatment sheet mentions that the treatment was terminated 25 minutes early because the access was clotted. CMS Ex. 9, at 101, 102. Patient 8's post-treatment assessment documents that he would need to be admitted into the hospital for a catheter infection, yet the "S & S of infection"[10] was not checked in the Access area. CMS Ex. 12, at 49. During both review periods, brachycardia (pulse below 60) was not checked on the assessment form often in spite of the fact that the patient was experiencing brachycardia. CMS Exs. 6, 9, 85. Patients, after an extended absence from the dialysis facility, were not having complete assessments. CMS Ex. 12, at 61.

Petitioner had particular problems in ensuring that patients reach the dry weight ordered by their physicians. As noted earlier, one of the functions of dialysis is to remove excess fluid. Therefore, a patient will weigh less after a treatment session is concluded. Physicians calculate what a patient should weigh after a dialysis treatment removes the excess fluid from the patient's system. This is called a physician ordered dry weight. If a patient does not come within one kilogram of their physician ordered dry weight, then interventions should be taken. Tr. at 122-123. For example, patient 2's dry weight came within acceptable dry weight limits only once in the entire month of July 2004. CMS Ex.

[10] "S & S of infection" stands for signs and symptoms of infection.

6, at 34-56. This was not addressed and no interventions were taken. In fact the adequacy and fluid management care plans for June and July for patient 2 were blank. *Id*. at 107, 113. Patient 2 came within acceptable dry weight limits only three out of 13 times in August and 2 out of 9 times in September. *Id*. at 58-83, 84-105. The same problems were identified during the second review period. For example, patient 9/4A met her dry weight only once during the month of May, and did not meet her dry weight a majority of the times in June. CMS Ex. 88, at 104-30, 133-163. However, her adequacy and fluid management care plan for both May and June indicate, contrary to treatment records, that her goal was met. *Id*. at 310.

d. Petitioner failed to properly complete care plans for its patients.

The regulations require a personalized care plan for each patient which documents psychological, social and functional needs. 42 C.F.R. § 405.2137(b)(1).

The evidence shows that care plans prepared by Petitioner, were not personalized and portions of many of the care plans were left blank. CMS Ex. 5, at 107-111, CMS Ex. 11, at 94-105, CMS Ex. 89, at 259-264. In many instances the patient goal was not met but the care plan was silent as to how to go about meeting the specific patient needs. CMS Ex. 5, at 107, 114; CMS Ex. 13, at 102, 103; CMS Ex. 87, at 265, 271; CMS Ex. 89, at 265.

In addition there were many instances where required signatures in the care plans were missing. CMS Ex. 11, at 99. The December 2005 review concluded that Petitioner's care plans "were predominately a record of clinical outcomes and did not address a plan of care for improving a substandard outcome." CMS Ex. 83, at 6. Based on the evidence CMS presented in this case, I must agree with that conclusion.

e. Petitioner failed to maintain a system for determining medications taken by patients at home.

The first review in September 2004 disclosed that one- third of the patients reviewed (patients 2, 3, 7) did not have a monthly record of their outside medications in their charts. Tr. at 136-137. The first review also identified that for patients 1, 4, 5, 8, and 9 outside medication records were not consistently updated. *Id*. Although the second review found that all the patients had medication review forms in their charts, Petitioner still did not consistently update the records. CMS Ex. 5, at 5; CMS Ex. 87, at 19; CMS Ex. 86, at 14. Petitioner did not attempt to obtain the medication information from the patient's pharmacy or their primary care physicians. In most cases, Petitioner failed to

even determine the pharmacies being used by each patient as a predicate step to getting this necessary information. Petitioner's failure to keep accurate and updated records of medications for their patients is medically significant since the effect of medications can be altered by dialysis.

f. Petitioner failed to obtain hospital records for its patients following a hospitalization.

Evidence was presented by CMS which established that during the first review period, Petitioner failed to obtain hospital records after patient 4's hospitalization and patient 6's hospitalization. CMS Exs. 8, 10.

This failure continued during the second review period. Patient 2A was hospitalized to remove a transplanted kidney that failed in October 2005. Petitioner merely obtained the operative note, not the entire hospitalization record as Petitioner should have. CMS Ex. 86, at 177-8. Petitioner also failed to obtain the record of the same patient's hospitalization of November 3-7, 2005. CMS Ex. 86. Further, Petitioner failed to obtain hospital records from the hospitalization of patient 1A on July 1, 2005. P. Ex. 59, at 26; CMS Ex. 85, at 118. Petitioner also failed to obtain the hospitalization records for patient 4A's hospitalization on May 27-June 2, 2005. CMS Ex. 88; P. Ex. 57, at 33; P. Ex. 58, at 29.

2. Petitioner failed to pursue Network 11's goal L in that it failed to ensure that its outcomes were comparable to expected outcomes as defined by currently accepted standards of care.

Petitioner has maintained that it had made improvements in it procedure and processes that demonstrated that it was pursuing Network 11's goal L. Nurse Lewis, Petitioner's Director of Nursing, was hired in July of 2005. She admitted that many of the alleged improvements made by Petitioner in its systems and processes of care were not made until after Network 11 had completed its second review in December of 2005. According to Nurse Lewis, many of Petitioner's policies were ambiguous, in 2005. Tr2 at 23. Nurse Lewis admitted that during the second review "things were not like they should have been." Tr2 at 89-90. She admitted that there were discrepancies and documentation "was not as it should have been." *Id*. CMS's termination in January 2006 was based on Network 11's first and second reviews. At most, Petitioner was only beginning to make corrections and improvements by the time Petitioner was terminated. Petitioner's POC shows that many corrections were not expected to take place until after January 2006. Nurse Lewis admitted that these corrections and improvements did not take place until January 2006. Tr2 at 23. If these corrections and improvement were actually implemented and were effective, Petitioner may be able to reapply for Medicare

participation. However, the issue before me is whether CMS had a basis to terminate Petitioner based on the evidence it had before it at the time it terminated Petitioner. The evidence clearly shows that it did.

I find the patient outcome data presented by CMS and Network 11 in this case to be more credible and warrants the greater evidentiary weight. CMS Ex. 82, 83; P. Ex. 65. Petitioner compares the patient outcome data it compiled to the 2005 Dialysis Facility Report prepared by the University of Michigan in an attempt to show that its patient outcomes improved from 2004 to 2005. CMS Ex. 34, at 12. However, the 2005 Dialysis Facility Report does not cover all of Petitioner's patients. CMS Ex. 38, at 21. I find the data presented by Network 11 to be more persuasive for the following reasons: Petitioner did not calculate its data in the standard method used by Network 11 to calculate data received from all the facilities within its network; in reviewing Petitioner's performance, Network 11 was comparing Petitioner to all the other facilities within its Network; the 2005 Dialysis Facility Report Petitioner utilized does not use data from all of Petitioner's patients (data from only 39 patients were used for hematocrit values; data from only 31 patients were used for URR values while Petitioner had between 41 to 45 patients in 2005); the 2005 Dialysis Facility Report uses hematocrit results which do not strictly correlate to the hemoglobin results used by Network 11; hemoglobin results are a more accurate way to measure anemia; and Petitioner's 2005 data were obtained from a different patient population than its 2004 patient population.[11]

a. Petitioner failed to properly manage its patients' anemia. Petitioner failed to pursue Network 11 goals that at least 80% of its patients have a mean hemoglobin value of greater than or equal to 11 g/dl.

Petitioner did not meet Network 11 goals for anemia management. Network 11's goal for anemia management was that at least 80% of patients would have a mean hemoglobin value of 11gm/dl or greater. The target range for hemoglobin is actually between 11-12 gm/dl because if hemoglobin becomes higher than 13 gm/dl, a patient's blood becomes more viscous, which is dangerous for a dialysis patient. Tr. at 1046. Network 11 also expects facilities to maintain and follow a policy of supplemental iron administration based on K/DOQI guidelines. CMS Ex. 45, at 32. The evidence established that Petitioner did not treat anemia in its patients with EPO, a bioengineered erythropoetin, according to its own protocols and K/DOQI guidelines.

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[11] Petitioner moved into a different physical facility on March 18, 2005. In its new location, Petitioner had no stretcher patients and the number of nursing home patients it had likely decreased greatly because it was no longer adjacent to a nursing home. Tr. at 390.

By letter dated April 30, 2003, Network 11 placed Petitioner on notice that it had to make significant improvements in anemia management including hemoglobin values equal or greater than 11 gm/dl. Petitioner was also informed that it was required to submit a quality improvement plan. By letter dated December 29, 2003, Network 11 informed Petitioner that as a result of a review of four active patients and seven deceased patients, that Petitioner was giving inadequate EPO dosing and anemia related problems were not being adequately assessed.

On January 20-21, 2004, Network 11 conducted an on-site review and found that, among other things, EPO and iron were not being administered in accordance with Petitioner's protocol and there were discrepancies between the ordered dose of dialysis medications (EPO and heparin) and the dose that was documented as actually administered. Network 11 requested that Petitioner prepare a corrective action plan, which Petitioner subsequently submitted in April, 2004. In spite of the corrective action plan, Petitioner did not sustain an improvement in anemia management. The failure to improve anemia management is demonstrated by the hemoglobin values of Petitioner's patients. The percentages of Petitioner's patients that had a hemoglobin value of greater than or equal to 11 gm/dl fluctuated as follows:

53.1% in January 2004
60% in February 2004
60% in March 2004
54% in April 2004
69.5% in May 2004
80.1% in June 2004
74.4% in July 2004
88.8% in August 2004
52.3% in September 2004
57.9% in October 2004
75.8% in November 2004
64.5% in December 2004
73.3% in January 2005
83% in February 2005 (based on results for 35 out of 40 patients)
84% in March 2005 (based on results for 19 out of 40 patients)
67% in April 2005
51% in May 2005
52% in June 2005
64.1% in July 2005

73% in August 2005
81% in September 2005
79% in October 2005
72.1% in November 2005
73.1% in December 2005

CMS Ex. 27, at 7; CMS Ex. 82, at 1; CMS Ex. 83, at 10.[12]

Only twice in 2004 did Petitioner meet network goals. The average percentage of patients with hemoglobin values greater or equal to 11 gm/dl for 2004 was 65.8%. Only once in 2005, for months that Petitioner had submitted data on all of its patients, did Petitioner meet network goals. The average percentage of patients with hemoglobin values greater or equal to 11 gm/dl for 2005 was 68.6%. The calculation of this percentage does not include the months of February or March for which Petitioner submitted incomplete results.

b. Anemia was not managed properly.

Evidence was presented that Petitioner was not following its own protocols in anemia management during the first review period. For example, patient 1 was not monitored bimonthly as required by the protocol (CMS Ex. 91, at 23, 25, 27), patient 1's EPO dosage did not follow Petitioner's protocols (CMS Ex. 5, at 5-7, 9), and patient 1's EPO was not held in accordance with Petitioner's protocols (CMS Ex. 5, at 49-67). Patient 3's anemia management is an example of Petitioner's staff not following Dr. Griggs' orders (CMS Ex. 7, at 14, 49-57; Tr. at 146-148). In addition, Dr. Fink testified that in his expert opinion, Petitioner's management of patient 3 was inadequate because there was no significant effort to reduce her EPO dose or increase the monitoring of her hemoglobin level when her hemoglobin was above her target range. Having a hemoglobin value above her target range was dangerous because patient 3 had a form of ischemic heart disease. Tr. at 1071-1072, 1083-86.

The evidence also establishes that patient 6 had very low hemoglobin values. For example, his hemoglobin was only 8.2 on July 28, 2004. Patient 6 is also another example of Petitioner's improper management of anemia. During the first review period,

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[12] Network 11 calculated its data using each patient's first reported hemoglobin value for each month. When Petitioner submitted hematocrit values, Network 11, in accordance with its practice, divided the hematocrit values by three and used that number. Network 11 used the same methodology with Petitioner's data as it did with all other facilities within the Network.

Dr. Griggs reduced patient 6's dosage of EPO from 15,000u to 8,000u, despite the fact that patient 6 had a very low hemoglobin value indicative of severe anemia. The reduction in EPO dosage is contrary to Petitioner's own protocol and K/DOQI guidelines. CMS Ex. 10, at 4, 5, 28-42, 80-85. Patient 6's records indicate inadequate hemoglobin monitoring as well. CMS Ex. 91, at 24, 26, 28. As a defense, Dr. Griggs claimed that patient 6 was a classic case of EPO resistance. Tr2 at 464. However, Dr. Sondheimer, Petitioner's own expert witness, testified that the dosage of EPO should escalate if a patient has an anemia that does not respond. Tr. at 774, 788.

On July 28, 2004, Dr. Griggs reduced patient 9/4A's EPO to 8000u. CMS Ex. 13, at 5. However, staff did not follow Dr. Griggs' order. Thus, on August 10, when patient 9/4A's hemoglobin was 10.2, she was given only 1000u EPO, not the 8000u as ordered. This incorrect dosage was continued for five treatments and during the sixth treatment no EPO was administered at all. *Id*. at 62, 64, 66, 68, 70, 73,

During the second review period, Petitioner's 2005 EPO protocol was in place. P. Ex. 58, at 23; Tr2 at 838-839. The third paragraph of that protocol states "initiate the Epogen dose at 100U/kg IV TIW." P. Ex. 58, at 23. At the hearing, Dr. Griggs could not explain the meaning of the protocol. She could not testify whether the initiating dose was to be given once or three times a week. Tr2 at 844-847. In response to CMS's question on cross examination as to the meaning of the term TIW, Dr.Griggs' responsed that the term TIW was "Total Ideal Weight." Tr2 at 844. However, the acronym TIW means, in standard medical terminology, "three times a week."[13] If Dr. Griggs could not explain Petitioner's protocol then it is not surprising that Petitioner's staff was confused about the protocol, which would lead to inadequate anemia management for Petitioner's patients.

The evidence presented by CMS established that Petitioner's anemia management practices did not follow its own protocols or K/DOQI guidelines. CMS Exs. 53, 54, 64, at 30; P. Ex. 58, at 23. Both Dr. Fink (Tr. at 1095-1098) and Dr. Sondheimer (Tr2 at 379, 382) testified that Patient 1A's hemoglobin was documented as too high and her EPO dose was not reduced as it should have been. CMS Ex. 85, at 4, CMS Ex. 91, at 66; Tr2 at 381. In addition, Petitioner did not monitor patient 1A's hemoglobin weekly or biweekly. Instead, patient 1's hemoglobin was checked once a month. CMS Ex. 85, at 5, 7, 18. Similarly, when patient 3A's hemoglobin was documented as being high and his EPO dosage was being changed, patient 3A's hemoglobin was checked only once a month on September 7, October 5, and November 2. CMS Ex. 87, at 4, 5, 6, 7, 18. Dr. Fink testified that he considered Petitioner's monitoring to be "really inadequate." Tr. at

[13] The acronym TIW is defined at http://acronyms.thefreedictionary.com/Tiw.

1112. Dr. Sondheimer also testified that when adjusting the dose of EPO for a patient, a facility should test hemoglobin every two weeks. Tr. at 807, 381. Petitioner, however, generally tested hemoglobin values once a month. CMS Ex. 91; Tr. at 991-2.

It must also be noted that, as discussed in Part IV.1.a. of this Decision, Petitioner's anemia management was also deficient because of medication errors and because Petitioner did not have a system in place to ensure that new orders were implemented correctly or promptly.

c. Petitioner did not provide adequate dialysis to its patients and did not meet network goals that 80% of URR (urea reduction ratio) values be greater than or equal to 65%.

Network 11's goal requires that at least 80% of a facility's patients have a URR value of greater than or equal to 65%. URR measures dialysis adequacy and is based on a ratio of blood tests for urea taken just before treatment begins and then just after a dialysis treatment is completed. K/DOQI guidelines also require that at least 80% of a facility's patients have a URR value of greater than or equal to 65%. In determining whether a facility met the goal, Network 11 used the first reported URR value of the month and did not use any URR results that are greater or equal to 90% or URR results less than or equal to 10%. Petitioner's monthly data for 2004 shows acceptable URR values for the following percentages of patients:

63.6% in January 2004
69.8% in February 2004
78.6% in March 2004
88% in April 2004
76.7% in May 2004
86.8% in June 2004
75.7% in July 2004
80.6% in August 2004
69.7% in September 2004
81.1% in October 2004
86.7% in November 2004
78.6% in December 2004

CMS Ex. 82, at 2.

Based on data submitted by Petitioner it appears that Petitioner reached Network 11 goals for only five months in 2004. However, the evidence presented by CMS established that Petitioner did not provide valid data for all of the months reviewed. In fact, Petitioner only provided valid data for all of its patients for a total of four months: February, April, August and September.[14] *Id*. Thus, only for April and August of 2004, did Petitioner meet Network 11 goals with valid data for all of its patients.

Petitioner's monthly data for 2005 shows acceptable URR values for the following percentages of its patients:

81.5% in January 2005
87% in February 2005
62% in March 2005
85% in April 2005
67.7% in May 2005
65% in June 2005
79.5% in July 2005
69% in August 2005
77% in September 2005
70.5% in October 2005
76.7% in November 2005
78.6% in December 2005

CMS Ex. 83, at 11.

In 2005, Petitioner reached network goals for only three months (January, February, and April). In the last eight consecutive months of 2005, Petitioner consistently did not meet network goals.

During the first review period, Petitioner failed to draw blood for some patients who were absent on the regularly scheduled blood drawing days and, contrary to its own policy, did not draw blood at the next treatment date. CMS Ex. 4, at 3; P. Ex. 53, at 212. This resulted in a failure to monitor whether those patients were receiving adequate dialysis. For example, Petitioner failed to have any URR values for patient 2 between May 6, 2004 and April 5, 2005. CMS Ex. 6, at 10, CMS Ex. 91, at 17, 21, 23, 25. Similarly, patient 3 did not have any URR values between May 6, 2004 and July 8, 2004, even though her

[14] For example, in the month of March, only 42 out of 50 results submitted by Petitioner were valid which only accounts for 84% of all of the URR data for that month. CMS Ex. 82, at 2.

URR value in May was 27.94%, indicating severe dialysis inadequacy. CMS Ex. 7, at 11, 12. Further, Petitioner did not always provide its patients with the correct blood flow rate (BFR) during their dialysis treatment. An example of this failure was demonstrated by CMS in patient 6 during the first review period. CMS Ex. 10, at 3-5, 28-54.

CMS also established that Petitioner failed to provide its patients dialysis for the prescribed period of time. Patient 3A and 5A are examples of patients who received inadequate dialysis treatment time. On October 10, 2005, Dr. Griggs ordered that patient 3A's treatment time be increased from 3.5 hours to 4 hours because of low URR values. CMS Ex. 87, at 7. Nurse Lewis signed off on the October 10th change of orders. Nevertheless, patient 3A received dialysis for only 3.5 hours per session from October 10 until November 18 instead of the 4 hours prescribed. Patient 3A received inadequate dialysis treatment time despite the fact that Nurse Lewis signed off on Dr. Griggs' October 10th order and that same order was repeated on November 8, 2005. *Id*. at 7, 210-252. The evidence presented by CMS also established that patient 5A's dialysis treatment times ended earlier than the treatment time ordered a total of 14 times. In addition, the blood flow rate used for patient 5's treatment was below that set by Dr. Griggs. The failure to use the correct blood flow rate occurred in patient 5A treatment a total of 28 times during the second review period. CMS Ex. 89, at 73-258.

As previously noted, Petitioner argued that it had sicker patients, with a greater number of comorbidities, than other dialysis facilities.[15] Tr2 at 475, 482, 602-603. Petitioner maintains that because it treated sicker patients substandard outcomes were inevitable. However, Dr. Fink and Ms. Deane testified that the types of patients that were the subjects of the first and second reviews were consistent with typical dialysis patients as a whole. Tr. at 1042; Tr2 at 149. I find Petitioner's argument to be unpersuasive because the Standard Mortality Ratio (SMR) provides adjustments for comorbidites. P. Ex. 66, at 3. Petitioner's mortality ratio, even adjusting for the impact of comorbidities, in 2001-2004, was **almost twice** what would be expected, which would place Petitioner in the category of the worst 2% of facilities in the country. *Id*. Comorbidities and poor outcomes are not a justification for providing poor care.

It is important to realize that medical errors are least tolerated by very sick patients. Very sick patients require excellent or, at the very least, adequate care that comports with professionally recognized standards. I take note that requiring medical staff to follow a physician's medication orders is considered a basic in providing proper care to patients. I find that the weight of the evidence presented by CMS in this case clearly establishes that

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[15] A comorbidity is the presence of one or more diseases in addition to end stage renal disease.

Petitioner did not provide proper care to its patients.

Finally, CMS presented evidence that established the following deficiencies:

> Petitioner's management of patient's phosphorus levels was inadequate;
> Petitioner's administration of vitamin D analogues was not in accordance with physician orders;
> Petitioner did not meet Network 11 albumin goals;
> Petitioner failed to properly monitor patients' nutritional status;
> Petitioner did not manage patients' vascular access in accordance with K/DOQI guidelines; and
> Petitioner did not pursue Network 11 goals of increasing the use of fistulas for vascular access, and failed to monitor patients' accesses.

However, I do not discuss theses issues in my decision. The issues I have already discussed more than supports CMS's imposition of a denial of payment for all services furnished to patients first accepted for care on or after July 9, 2005 and its decision to terminate Petitioner from participation in the Medicare program on January 20, 2006.

V. Conclusion

Based on my review of all of the evidence and testimony in this case, I sustain CMS's determination to impose the sanctions of denial of payment to Petitioner for all services furnished to patients accepted for care on or after July 9, 2005. I further sustain CMS's determination to terminate Petitioner from participation in the Medicare and Medicaid programs effective January 20, 2006.

/s/
Alfonso J. Montano
Administrative Law Judge