Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Advance Rehabilitation Clinic,
(CCN: 23-6597)

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-1974

Decision No. CR4390

Date: November 4, 2015

DECISION

I sustain the determination made by the Centers for Medicare & Medicaid Services (CMS) to terminate Petitioner's participation as a provider of services in the Medicare program.

I. Background

Petitioner, Advance Rehabilitation Clinic, operates a rehabilitation agency whose primary location is in Farmington Hills, Michigan.[1] CMS Exhibit (CMS Ex.) 1 at 1. The services offered by Petitioner include outpatient physical therapy services. CMS Ex. 2 at 1. A recertification survey completed by the Michigan Department of Licensing and Regulatory Affairs (state agency) on October 8, 2014, found that the clinic was closed during business hours and documented that Petitioner was not in compliance with one condition of participation (CoP) at 42 C.F.R. Part 485, Subpart H (specifically 42 C.F.R. § 485.709). CMS Exs. 1, 2. Petitioner submitted a plan of correction, and the state

[1] Petitioner also operates an extension site in Clinton Township, Michigan. CMS Ex. 10 at 1.

agency conducted a revisit survey of Petitioner on November 20, 2014. CMS Exs. 3, 4. The resurvey found that Petitioner was not in compliance with five CoPs: 42 C.F.R. §§ 485.709 (administrative management), 485.711 (plan of care and physician improvement), 485.719 (conditions), 485.725 (infection control), and 485.729 (program evaluation). CMS Ex. 4. CMS notified Petitioner by letter dated December 4, 2014, that it would be terminating Petitioner's provider agreement effective January 6, 2015, based on the findings of both surveys. CMS Ex. 5. Petitioner submitted a second plan of correction on December 12, 2014. CMS Exs. 6, 7. At the request of CMS (CMS Ex. 8), a second revisit survey was conducted on January 22, 2015. CMS Ex. 10. Following this survey, CMS notified Petitioner that, effective February 22, 2015, its Medicare provider agreement would be terminated. CMS Ex. 13. CMS explained that in addition to the deficiencies addressed through the two previous surveys, the second revisit survey found that Petitioner once again did not meet the CoPs for administrative management and infection control. In its February 18, 2015 letter, CMS explained that it had "determined that these deficiencies limit the capacity of [the] facility to render adequate care and ensure the health and safety" of Petitioner's patients. *Id.*

Petitioner requested a hearing by letter dated April 7, 2015.[2] The case was assigned to Administrative Law Judge Joseph Grow for hearing and decision on May 6, 2015, and Judge Grow issued an Acknowledgment and Prehearing Order (Order) on that same date.[3] CMS filed a motion for summary judgment and prehearing brief (CMS Br.), accompanied by 20 exhibits. Petitioner filed a response (P. Br.). In the absence of any objections, I admit CMS Exs. 1-20 into evidence.

Petitioner does not present anything more than a generic dispute with CMS's determination that it was not in substantial compliance with all Medicare conditions of participation. Although CMS requests summary judgment, I am deciding this case on the written record. CMS proposed two witnesses, but Petitioner did not ask to cross-examine these witnesses as required by Judge Grow's Order. A hearing therefore was unnecessary. Order at ¶¶ 8-10. I find that CMS was authorized to terminate Petitioner's Medicare provider agreement. For purposes of judicial economy, I will focus my discussion on the CoPs that were addressed in the second revisit survey which was conducted after Petitioner submitted its second plan of correction.

II. Background Law

Medicare-participating facilities may be surveyed on behalf of CMS by state survey agencies in order to assess compliance with federal participation requirements. 42 C.F.R. pt. 488, subpt. A. CMS may determine that a provider does not qualify to participate in

[2] Petitioner was represented by counsel at the time of this filing, but is currently *pro se.*

[3] This case was reassigned to me on October 28, 2015.

Medicare and/or Medicaid programs if it is not in compliance with the CoPs. 42 C.F.R. § 488.24. CMS may terminate a provider agreement if it determines that the provider no longer meets the CoPs. 42 C.F.R. § 489.53.

CMS, acting on behalf of the Secretary, may terminate a provider agreement based on the provider's failure to comply with the provisions of section 1861 or its failure to comply with *all* applicable CoPs. Act § 1866(b)(2); 42 C.F.R. § 489.53(a); *Cmty. Home Health*, DAB No. 2134, at 13 (2007). To monitor compliance, CMS contracts with state agencies that conduct periodic surveys. Act § 1864(a); 42 C.F.R. § 488.20. For facilities that are not skilled nursing facilities (SNFs), nursing facilities (NFs), or home health agencies, the State Agency must survey "as frequently as necessary to ascertain compliance. . . ." 42 C.F.R. § 488.20(b)(1).

Petitioner provides physical therapy services as a rehabilitation agency, which is defined by regulation as an agency that:

> (1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
>
> (2) Provides at least physical therapy or speech-language pathology services.

42 C.F.R. § 485.703. Section 1861(p)(4) of the Act specifies that a rehabilitation agency must meet and maintain certain CoPs. 42 C.F.R. § 485.701. These CoPs are found in 42 C.F.R. Part 485, Subpart H. Each "condition of participation" is contained in a single regulation, which is divided into subparts called standards. 42 C.F.R. pt. 485. Compliance with a CoP is determined by the manner and degree to which the provider satisfies the standards within the condition. 42 C.F.R. §§ 488.1; 488.26(b). If deficiencies are of such character as to "substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients," the provider is not in compliance with CoPs. 42 C.F.R. § 488.24(b). Noncompliance with even one of the standards making up a CoP may constitute a violation of that CoP if the violation is significant enough. *Sonali Diagnostic Lab.*, DAB No. 2008 (2006); 42 C.F.R. § 488.26(b).

If a provider appeals CMS's action, then CMS must on appeal make a *prima facie* case that the provider has failed to comply substantially with participation requirements. Once CMS has established its *prima facie* case, a provider must overcome CMS's case by a preponderance of the evidence. *MediSource Corp.*, DAB No. 2011 (2006); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 Fed. Appx. 664 (6th Cir. 2005) (unpublished); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. U.S. Dep't of Health & Human Servs.*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). When a provider's

Medicare participation is terminated because of alleged noncompliance, "the critical date for establishing compliance is the survey date, not the subsequent effective date of the termination." *Carmel Convalescent Hosp.*, DAB No. 1584, at 12 (1996); *Rosewood Living Ctr.*, DAB No. 2019, at 11 (2006). A provider's efforts to bring itself into compliance after the date of the resurvey is "completely irrelevant to the facility's appeal of [CMS's] determination to terminate." *Carmel*, DAB No. 1584, at 13.

The Act and regulations allow a provider the opportunity for a hearing before an Administrative Law Judge (ALJ) in cases in which CMS has terminated its provider agreement. The scope of the hearing is limited to whether the initial determination CMS made is correct. 42 C.F.R. § 498.3(b)(8). The hearing is a *de novo* proceeding. *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991).

III. Findings and Discussion[4]

1. Petitioner failed to maintain substantial compliance with all Medicare conditions of participation and CMS properly terminated Petitioner's participation in Medicare.

While Petitioner broadly argues in its brief that "some of these findings contain inaccuracies," it does not question the evidentiary basis for CMS's determination that it failed to comply with the CoPs. Likewise, in its request for hearing, which was filed by its former counsel, Petitioner makes only vague assertions of error without specifically identifying any findings of fact that it feels are erroneous with the reason(s) in support thereof. *See* 42 C.F.R. §§ 498.40(b)(1) and (2) (requiring that a request for hearing "[i]dentify the specific issues and the findings of fact and conclusions of law with which the affected parties disagrees" and that the affected party specify the basis why those findings and conclusions are incorrect); *see also* Order, at ¶ 4(c)(i) (directing the parties to each file a "brief addressing all issues of law and fact"). In both its request for hearing and its brief, Petitioner has not asserted any specific allegation of error regarding CMS's determination that it failed to meet the CoPs. Petitioner has not contended that it was in full compliance with the CoPs for administrative management and infection control at the time of the January 2015 survey; rather, it has contended that a fourth survey is warranted in order to assess whether, following submission of its third plan of correction in the span of less than six months, it is now in compliance with the CoPs.

The CoP pertaining to administrative management, 42 C.F.R. § 485.709, requires that a rehabilitation agency must have an effective governing body that is legally responsible for the conduct of the agency, and that the governing body designate an administrator and establish administrative policies. In the third survey, which was the second revisit survey, CMS identified deficiencies under this CoP in the areas of "Administrator" and

[4] My findings of fact and conclusions of law are listed in bold and italics.

"Patient care policies." CMS Ex. 10; *see* 42 C.F.R. §§ 485.709(b) and (d). With regard to administrative management, a clinic or rehabilitation agency's governing body "[a]ppoints a qualified full-time administrator" and "[d]esignates a competent individual to act during temporary absence of the administrator." 42 C.F.R. § 485.709(b). Furthermore, "[p]ersonnel records include the qualifications of all professional and assistant level personnel." Petitioner did not meet the CoP for administrative management at the second revisit on January 22, 2015.

At the time of the January 22, 2015 survey, the administrator was unavailable. CMS Ex. 10 at 1-5. Petitioner has admitted there was "confusion" on the part of Petitioner at the time of the survey, in that the office staff gave the surveyors conflicting information regarding who was actually designated to act as the administrator during the administrator's absence. CMS Ex. 14 at 1; P. Br. at 2. Petitioner has conceded that the designated alternate administrator was at a different location and unable to meet with the surveyors on January 22, 2015 (CMS Ex. 14 at 68). In its subsequent plan of correction, Petitioner indicated that it would educate its staff "on the role and identity of the alternate administrator prior to working their next shift." CMS Ex. 14 at 2. In this second plan of correction, Petitioner further stated that the "alternate administrator will also be re-inserviced on his administrative responsibilities," and that a second alternative administrator who is "a full-time employee [and] not a therapist" would be hired. CMS Ex. 14 at 2, 3.

With respect to the CoP for administrative management, the survey also revealed that although Petitioner's policy indicated that a physical therapist aide is a non-licensed worker who has completed an on-the-job training program, the personnel files for two physical therapist aides contained no documentation of training or competency to provide services to patients. CMS Ex. 10 at 9-11. While Petitioner submitted a revised job description and records pertaining to those individuals' competency and training (CMS Ex 14 at 7), these records were not available for review by the surveyors at the time of second revisit survey on January 22, 2015.

Petitioner's failure to meet the CoP of administrative management on January 22, 2015, was the third consecutive occasion in which it failed to meet this CoP: Two previous surveys in October and November of 2014 documented that Petitioner did not meet the CoP of administrative management, as well. CMS Exs. 1, 4. At approximately 10:00 am on October 8, 2014, a surveyor visited the office and determined that "the agency failed to have an effective governing body that is legally responsible for the operation and conduct of the agency, failed to designate an administrator, and failed to establish administrative policies." CMS Ex. 1 at 1, 3, 4. At that time, the clinic was closed during the business hours that were listed on its website and there were no hours posted on the door. The surveyor also observed that on October 8, 2014, a United States Postal Service

delivery notice, dated October 3, 2014, was on the door even though Petitioner's website indicated the clinic was open on Monday, Wednesday, Thursday, and Friday from 7:30 am to 7:30 pm. CMS Ex. 1 at 3.

Following this failed survey attempt during advertised business hours, Petitioner submitted a plan of correction on October 22, 2014 (CMS Ex. 3), and a follow-up survey was conducted on November 20, 2014. CMS Ex. 4. At that time, an administrator was once again not available. CMS Ex 4 at 4. The surveyors also determined that "[t]he clinic failed to ensure all contracted personnel were qualified to provide services to its patients." CMS Ex. 4 at 10. Specifically, the surveyors documented that of the two staff members in the office at the time of the visit, one did not have a personnel record on file and the other staff member's records contained only a copy of a driver's license and a letter indicating that he was an independent contractor. CMS Ex. 4 at 5.

The January 22, 2015 survey also found deficiencies with respect to the CoP of infection control. CMS Ex. 10 at 15-17. The CoP for infection control requires that "[t]he infection control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed." 42 C.F.R. § 485.725(a). It further requires that "[a]ll personnel follow written procedures of effective aseptic techniques." 42 C.F.R. § 485.725(b). Additionally, the CoP requires that "[l]inens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection." 42 C.F.R. § 485.725(c).

At the time of the third survey, conducted after Petitioner submitted its plan of correction for the CoP of infection control, the surveyors again documented several infection control deficiencies that violated the CoPs. First, surveyors documented that a refrigerator contained a bottle of expired medication, ice packs used for treatment of patients, and employees' food and beverage items. CMS Ex. 10 at 4. The surveyors documented that the clinic did not follow proper aseptic techniques for storage of cold packs. CMS Ex. 10 at 15-21. With regard to hot packs, the surveyors noted deficiencies, as well. Even though the Petitioner's policy was to clean the hydrocollator once per month and to launder hot pack covers every other week, the surveyors could find no documentation of when the hydrocollator was last cleaned and the hot pack covers were last laundered. CMS Ex. 10 at 18-20. In response to surveyor questions, one employee stated that the hydrocollator "was probably cleaned and emptied last month" and that he would "throw Clorox in there occasionally." CMS Ex. 10 at 18. Although the Administrator was out of the clinic at the time of this survey, the Administrator, via a telephone conversation, informed the surveyors that the cleaning log was posted on the wall. However, the surveyors observed that the only log posted on the wall did not document cleaning of the hydrocollator. CMS Ex. 10 at 19. Finally, although Petitioner's policy was that linens "are stored, processed, and transported in such a manner as to prevent the spread of infection" and that "[u]sed linen will be stored in a closed lined hamper and will be

washed at the end of the day," CMS Ex. 10 at 20-21, the surveyors documented that "dirty linens were stored in an open, uncovered canvas hamper next to the Hydrocollator." CMS Ex. 10 at 21.

Petitioner had previously been given an opportunity to correct deficiencies that were found to not meet the infection control CoPs. CMS Exs. 4, 6. After being notified that it no longer met the CoPs for, *inter alia*, infection control and that its provider agreement would terminate on January 6, 2015, Petitioner submitted a corrective action plan for infection control in which it informed CMS that it had "inserviced" its employees regarding infection control and that its infection control committee would inspect the clinic to make sure it maintained a sanitary environment and prevented the transmission of infection. CMS Ex. 6 at 16-17. CMS determined, at the November 2014 survey, that Petitioner "failed to establish required infection control procedures for aseptic technique" (CMS Ex. 4 at 16-17); nevertheless, the same deficiency was observed at the subsequent January 2015 survey after Petitioner had submitted a plan of correction for this CoP. CMS Ex. 6; CMS Ex. 10 at 17.

I find Petitioner was out of compliance with participation requirements at 42 C.F.R. §§ 485.709 and 485.725 at the condition level. Moreover, if even one CoP is out of compliance, CMS is justified in terminating Petitioner's provider agreement. Here, I sustain CMS's determination of deficiencies at 42 C.F.R. §§ 485.709 and 485.725, and find that the condition-level deficiencies alone justify CMS's decision to terminate. I do not address the other CoP deficiencies addressed by CMS at 42 C.F.R. §§ 485.711, 485.719, and 485.729, or other standard-level deficiencies addressed at the time of the January 22, 2015 survey, because it is not necessary that I do so to sustain CMS's decision to terminate Petitioner's provider agreement.[5] *Golden Living Ctr. – Frankfort*, DAB No. 2296, at 3 n.2 (2009); *Cmty. Skilled Nursing Ctr.*, DAB No. 1987 (2005); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904.

Furthermore, I acknowledge that CMS has the discretion to give providers an opportunity to correct deficiencies prior to termination. *See* 42 C.F.R. § 488.28 (noting that a deficient provider may continue to participate only if the facility has "submitted an

[5] Owing to the significant number of deficiencies identified by CMS, I have focused on the condition-level deficiencies in administrative management and infection control that were not corrected by Petitioner despite having submitted a plan of correction pertaining to both of those CoPs prior to the second revisit survey on January 22, 2015. I have taken this approach out of judicial economy and I do not intend to minimize Petitioner's other failures, including standard-level deficiencies in the areas of safety of patients, 42. C.F.R. § 425.723, that were found at the time of the January 22, 2015 second revisit survey, and condition-level deficiencies relating to the CoPs of plan of care and physician involvement, conditions, and program evaluation that were found at the time of the November 20, 2014 revisit survey.

acceptable plan of correction for achieving compliance within a reasonable time." In this case, CMS gave Petitioner two opportunities to correct its deficiencies. CMS Ex. 3, 6. While Petitioner submitted a third plan of correction on March 2, 2015 (P. Ex. 14), CMS was not required to afford Petitioner another opportunity to correct its condition-level deficiencies before terminating its program participation. 42 C.F.R. §§ 488.24, 488.28. A provider that is dissatisfied with an initial determination, such as the termination of a provider agreement in accordance with 42 C.F.R. § 489.53, may request an ALJ hearing pursuant to 42 C.F.R. Part 498. CMS's rejection of a plan of correction (and in this case a third plan of correction) however is not an initial decision that is reviewable by me. *See* 42 C.F.R. § 498.3; *see also Apollo Behavioral Health Hosp., L.L.C.*, DAB 2561 at 8 (2014) (stating that "section 488.28 permits a provider found to have deficiencies to submit an acceptable plan of correction only where CMS has determined that the deficiencies are at *less than the condition level*" and that "section 488.28 provides no opportunity to correct condition-level deficiencies").

I agree with CMS that Petitioner's deficiencies constitute condition-level noncompliance. The deficiencies substantially limit Petitioner's capacity to furnish adequate care and may adversely affect the health and safety of patients. Petitioner's administrative failures show that it lacked the necessary control and oversight of its staff, despite having more than one opportunity, to correct its deficiencies. Likewise, Petitioner continued to fail to ensure that its infection control policies and procedures were followed.

Pursuant to 42 C.F.R. § 489.53(a), CMS may terminate a provider agreement with any provider if CMS finds the provider no longer meets the appropriate CoPs. As I have found Petitioner in violation of two conditions of participation, CMS is authorized to terminate Petitioner's provider agreement.

IV. Conclusion

For the reasons set forth above, CMS properly terminated Petitioner's participation as a provider of services in the Medicare program.

/s/
Leslie C. Rogall
Administrative Law Judge