Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
National Rehab Services, Inc.,	)	
(CCN: 23-6772)	)	Date: September 16, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-14
	)	Decision No. CR1840
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to terminate National Rehab Services, Inc.'s (Petitioner or facility) provider agreement for failure to comply substantially with federal requirements governing participation of outpatient rehabilitation facilities in Medicare and State Medicaid programs. For the reasons that follow, I uphold termination of Petitioner's participation from Medicare and Medicaid programs, effective August 19, 2006.

I. Background

This case is before me pursuant to a request for hearing filed by Petitioner dated September 14, 2006. Petitioner is an outpatient physical therapy provider located in Taylor Michigan.

By letter dated May 23, 2006, CMS informed Petitioner that based on a re-certification survey conducted by the Michigan Department of Community Health (State Agency) on March 15, 2006, and a revisit completed by the State Agency on April 20, 2006, it was terminating Petitioner's participation in the Medicare program effective June 23, 2006, due to Petitioner's failure to be compliant with the conditions of participation for outpatient physical therapy facilities. During those surveys, Petitioner was cited for noncompliance with six conditions of participation and noncompliance with five conditions of participation, respectively. Petitioner had previously submitted a plan of correction to CMS addressing the noncompliance cited in the March survey and on May 31, 2006, Petitioner submitted a plan of correction to CMS addressing the noncompliance cited in the April survey. On July 19, 2006, CMS sent Petitioner a notice accepting

Petitioner's plan of correction and notified Petitioner that it was administratively extending Petitioner's termination from June 23, 2006 to August 19, 2006. On August 7, 2006, the State Agency completed a revisit survey and found that Petitioner was still out of compliance with the Program Evaluation condition of participation (42 C.F.R. § 485.729). By letter dated August 18, 2006, CMS notified Petitioner that its Medicare provider agreement would be terminated effective August 19, 2006, and that Petitioner was informed of its appeal rights in CMS's May 23, 2006 letter. By letter dated September 14, 2006, Petitioner requested a hearing to contest whether its citation for noncompliance with 42 C.F.R. § 485.729 (Program Evaluation) warrants a condition level deficiency.

On April 2, 2008, Petitioner and CMS submitted its "Joint Statement Waiving In-Person Hearing." By Order dated April 5, 2008, I vacated the April 8, 2008 hearing date scheduled for this case and instructed the parties to submit a written brief (CMS Br. and P. Br.), witness declarations and proposed exhibits by May 8, 2008, and simultaneous replies (CMS Reply and P. Reply) by May 23, 2008. Along with CMS's brief, CMS offered 7 exhibits, identified as CMS Exhibits (Exs.) 1-7. I receive CMS Exs. 1-7 into evidence without objection. Along with Petitioner's brief, Petitioner offered 1 exhibit, identified as P. Ex. 1. I receive P. Ex. 1 into evidence without objection.

Based on the documentary evidence, the arguments of the parties, and the applicable law and regulations, I find that Petitioner was not in compliance with 42 C.F.R. § 485.729 (Program Evaluation), on the date determined by the State Agency and CMS. I further find that CMS was authorized to terminate Petitioner for non-compliance of this Condition of Participation, effective August 19, 2006.

II. Applicable Law and Regulations

Petitioner is considered a rehabilitation facility that provides outpatient physical therapy services (outpatient physical therapy facility) under the Social Security Act (Act) and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory requirements for participation by a provider of outpatient physical therapy services are found at section 1861(p) of the Act, and at 42 C.F.R. Part 485, Subpart H. Section 1861(p)(4) of the Act specifies that rehabilitation facilities that provide outpatient physical therapy services participating in Medicare and Medicaid programs must meet and maintain certain conditions of participation. These conditions of participation are further promulgated in 42 C.F.R. Part 485, Subpart H.

Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28; 42 C.F.R. §§ 488.300 - 488.335. Pursuant to 42 C.F.R. Part 488, CMS may determine that an institution or agency does not qualify for participation in the Medicare or Medicaid programs or coverage because it is not in compliance with the conditions of participation or the conditions of coverage. 42 C.F.R. § 488.24. The regulations provide that CMS may terminate the agreement with

any provider if CMS finds that the provider no longer meets the conditions of participation. 42 C.F.R. § 489.53(3).

In provider appeals under 42 C.F.R. Part 498, the Departmental Appeals Board has determined that CMS must make a prima facie case that an entity has failed to comply substantially with federal requirements. *See MediSource Corporation*, DAB No. 2011 (2006). *"*Prima facie*"* means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004); *see also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). Once CMS has established its prima facie case, the entity must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman*, DAB No. 1611 (1997).

The Act and regulations make a hearing before an ALJ available to a provider against whom CMS has terminated its provider agreement. But the scope of such hearings is limited to whether an *initial determination* made by CMS is correct. 42 C.F.R. § 498.3(b)(8). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*., DAB CR65 (1990), *aff'd* 941 F.2d 678 (8th Cir. 1991). An ALJ may review the basis for CMS's imposition of remedies, however, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 498.3(b)(11); *see also Belmont Nursing & Rehab Ctr. v. HCFA*, DAB CR507 (1997).

III. Issue

Whether the facility was not in compliance with conditions of participation for outpatient physical therapy facilities.

IV. Findings and Discussion

The findings of fact and conclusions of law noted below, in italics, are followed by a discussion of each finding.

A. Petitioner was not in compliance with Medicare conditions of participation for 42 C.F.R. § 485.729 (Program Evaluation) during the August 7, 2006 Survey.

Subpart H of 42 C.F.R. Part 485 implements section 1861(p)(4) of the Act which defines outpatient physical therapy and imposes requirements on facilities offering this service with respect to adequate program, facilities, policies, staffing, and clinical records. 42 C.F.R. § 485.701. Several conditions of participation for rehabilitation agencies as providers of outpatient physical therapy facilities are required under Subpart H of 42 C.F.R. Part 485. One of the conditions of participation is program evaluation at 42 C.F.R.

§ 485.729. The regulation at 42 C.F.R. § 485.729 requires that a rehabilitation agency that provides outpatient physical therapy services complete a clinical-record review and an annual statistical evaluation. According to the regulations, the standard for a rehabilitation agency that offers outpatient physical therapy services is that:

> An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

42 C.F.R. § 485.729(b).

CMS alleges that Petitioner did not meet the Annual Statistical Evaluation standard of the Program Evaluation condition of participation during the August 7, 2006 survey. In support of this allegation, CMS offers the declaration of the State Agency surveyor, Rick Brummette. Surveyor Brummette completed re-visit surveys of Petitioner's facility on April 20, 2006 and August 7, 2006. CMS asserts that Surveyor Brummette visited the provider, reviewed the relevant provider records, and interviewed Petitioner's administrator and alternate administrator. CMS Br. at 6. According to Surveyor Brummette, Petitioner remained out of compliance with the federal requirements for program evaluation for 2005. CMS Ex. 4 (Rick Brummette Declaration). CMS acknowledges that Petitioner did produce various records and statistics related to the ongoing operations of the facility. However, CMS contends that although clinical record review and statistical analysis are important parts of the annual evaluation, "the dominant requirement of [42 C.F.R. § 485.729(b)] is aimed at ensuring systemic evaluation of each organization's 'total program.'" CMS Br. at 7-8. CMS further contends that "mere completion of any one evaluation component is insufficient to meet the full condition of participation." CMS Br. at 8.

In its brief, Petitioner argues that it met both of the standards of 42 C.F.R. § 485.729 for Program Evaluation of outpatient physical therapy agencies. Petitioner asserts that it completed clinical record reviews and compiled its annual statistical evaluation. Petitioner contends that these two components of the Program Evaluation condition of participation were further buttressed by numerous components of the two standards related to statistical analysis and subdivisions within the report. P. Br. at 1. According to Petitioner, its noncompliance with 42 C.F.R. § 485.729 was not addressed in the April 20, 2006 survey or the State Agency's review of Petitioner's correction plan. P. Br. at 2.

I find that Petitioner was not in compliance with 42 C.F.R. § 485.729 (Program Evaluation). I agree with CMS that the documents that Petitioner presented as its program evaluation do not constitute an evaluation of its total program as required by the regulations and the Act. Petitioner does not meet the standard of Annual Statistical Evaluation as required in 42 C.F.R. §485.729(b).

Petitioner submitted its annual statistical evaluation as P. Ex. 1. Petitioner's statistical evaluation consists of:

- A chart entitled "Patient's Doctor 2005" that divides a list of patients by first and last name next to one of thirteen treating physicians. P. Ex. 1, at 1, 2;

- A chart entitled "Diagnosis Statistics 2005" that lists each patient by first and last name along with abbreviations for nine different diagnoses and the patient's physician. P. Ex. 1, at 3, 4;

- A monthly chart that breaks down the number of visits, the payment and the cost per visit of the patients that were treated at the facility. P. Ex. 1, at 5; and

- A chart entitled "PT Visits" which provides a monthly and yearly total of the number of visits by patients to the facility. P. Ex. 1, at 6.

There is no written report accompanying these charts that interprets what these numbers mean to the facility or anyone reviewing them. Any type of evaluation of these numbers, statistics, and names is absent from the document as presented. Numbers, statistics, and names alone cannot be considered as an evaluation within the meaning of 42 C.F.R. § 729(b). What Petitioner appears to have submitted as its annual statistical evaluation is what can only be considered as the first step in a multi-step process. The program evaluation regulation requires that a facility must go beyond compiling names and numbers in its statistical evaluation and that the raw data must be interpreted and evaluated in written form in order that appropriate utilization of the facility's services can be ensured and whether the facility's policies are followed in providing services to patients through employees or under arrangements with others can be determined. 42 C.F.R. § 485.729. Also, it appears from the documents submitted as its annual statistical evaluation by Petitioner that the documents only included some of the suggested data; information such as number of new patients and total staff days or work hours by discipline were not included in Petitioner's report. While each form of data that is listed may not be required, these types of data are listed so that a facility's total program can be properly evaluated. Each of the forms of data listed in section 485.729(b) of 42 C.F.R. would contribute to a complete and total program evaluation. Petitioner's submitted documents fail to meet the standard and are lacking as to what can be considered a complete and total program evaluation.

Petitioner has not given any reasonable explanation as to why a comprehensive written statistical evaluation was not completed. Petitioner argues that it was not aware of the gravity of the noncompliance because the Program Evaluation Condition of Participation was not "addressed" in the facility's April 20, 2006 survey or in the State Agency's review of the correction plan. P. Br. at 2. However, during Petitioner's annual recertification survey completed on March 15, 2006, Petitioner was cited for not meeting the annual statistical evaluation standard. This deficiency is documented on the March

20, 2006 Statement of Deficiencies as well as Petitioner's plan of correction for this deficiency. CMS Ex. 1, at 17, 18. Petitioner's plan of correction states that:

> We are currently compiling data for our annual statistical evaluation for 2005, and it will be complete within the next 2 weeks. It will be the responsibility of the Administrator, to begin collecting data at the close of each fiscal year, in order to complete this report by the end of each March, in accordance with our policies. He will monitor this annually.

Id. at 17. During the April 20, 2006 re-visit survey, Petitioner was again cited for not meeting the annual statistical evaluation standard. CMS Ex. 2, at 15. Also, during the April 20, 2006 survey, Petitioner was cited for failing to document measures for ensuring the completion of an annual program evaluation. CMS Ex. 2, at 14, 15. Furthermore, as CMS argues, Petitioner has "an on-going duty to comply with the Medicare Conditions of Participation . . ." and "this duty exists independent of the survey process." CMS Br. at 4.

Petitioner contends that it met both the standards of 42 C.F.R. § 485.729 and attempts to support its contention by describing how it provides a breakdown of the statistical data and subdivides the raw data. P. Br. at 1. But it is in this description that it is apparent that Petitioner does not demonstrate a full appreciation of the Program Evaluation Condition of Participation. Petitioner describes this breakdown of data as being presented in a summary numerical format. *Id*. But even Petitioner acknowledges in its submission that "the only thing missing was the results were not summarized in a statement." *Id*. Although a written summary of the results is not the only thing missing, it is a key component of 42 C.F.R. § 485.729. Surveyor Brummette, stated in his declaration that "merely producing the individual data components without any evidence of overall analysis is not sufficient to demonstrate a systemic evaluation of a provider's total program." CMS Ex. 4, at 5. I find the surveyor's opinion persuasive. A statistical evaluation should include a written summary and analysis of the data provided concerning a facility's total program. Despite Petitioner's contention that the results not having been summarized in a statement as being a "minor omission;" I disagree. Without these components it is much more difficult to evaluate whether a facility's policies are followed and whether there is an appropriate utilization of services as required in the regulations. I infer from Petitioner's argument that the program evaluation condition of participation may be complied with by merely reciting in narrative from what is shown in the statisical compilation. Such understanding is a misconception of the regulatory requirement. A facility that does not *interpret* its collected data through a written statistical evaluation falls short of the requirements in 42 C.F.R. § 485.729.

CMS has presented additional evidence that Petitioner should have known that an annual statistical evaluation was required in order to achieve compliance with the relevant Conditions of Participation. As part of Petitioner's approved policies and procedures that

Petitioner submitted along with its hearing request is a policy entitled "Program Evaluation" that has an effective date of 3/28/06. Part of this policy is the statement that:

> In order to assure appropriate utilization of services and to determine whether the organization's administrative and clinical policies are followed, a systematic evaluation of the total program will be conducted on an annual basis by members of the Governing Body.

CMS Ex. 5, at 18.

In the procedure section of the policy statement, Petitioner's statement sets out that:

> 2. At a minimum, the review will include:
>
> A. Administrative policy and procedure review
> B. Clinical policy and procedure review
> C. Number of referring physicians
> D. Number of new patients & different patients
> E. Number of discharged patients
> F. Patient outcomes
> G. Number of patients per diagnosis
> H. Cost per unit of service
> I. Number of staff days per discipline
>
> 3. The evaluation report will include a statement of the organization's current standing future plans, summary and conclusions with recommendations.

CMS Ex. 5, at 18. Petitioner's Policies and Procedures appear to have the necessary components that, if followed, would have satisfied the Program Evaluation conditions of participation. According to Surveyor Brummette, he conducted telephone interviews on August 7, 2006 with Petitioner's Administrator and Alternative Administrator and was told that as of that date, no report had been generated for the most recent calendar year, 2005. Petitioner had five months from when it was first cited for not completing an annual statistical evaluation and four months from the effective date of its "Program Evaluation" policy to come into compliance with 42 C.F.R. § 485.729 by completing an evaluation report. It was Surveyor Brummette's opinion that had National Rehab actually followed its own Program Evaluation policy and completed a report that included all of the components and analysis required by the policy, that such a report would have probably met the condition of participation regarding Program Evaluation. *Id*., at 4-5.

B. Petitioner's Medicare provider agreement may be terminated by CMS.

Pursuant to 42 C.F.R. § 489.53(a) CMS may terminate the agreement with any provider if CMS finds that the provider no longer meets the appropriate conditions of participation. In this case, Program Evaluation is a condition of participation for outpatient physical therapy agencies. One of the two standards for the program evaluation condition of

participation is that the provider conduct an annual statistical evaluation. Petitioner did not provide the State Agency with a credible annual statistical evaluation, thus, it was not in compliance with the condition of participation for outpatient physical therapy agencies. Therefore, CMS is authorized to terminate Petitioner's provider agreement.

V. Conclusion

Based on the documentary evidence, the arguments of the parties, and the applicable law and regulations, I find that Petitioner was not in substantial compliance with the conditions of participation for rehabilitation agencies that provide outpatient physical therapy services and that CMS is authorized to terminate Petitioner's provider agreement.

/s/
José A. Anglada
Administrative Law Judge