Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
St. Vincent's Catholic Medical Centers of New York, (CCN: 33-0290),	)	Date: February 7, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-336
	)	Decision No. CR1734
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION REMANDING CASE

I conclude that the Centers for Medicare & Medicare Services (CMS) has not provided a rational basis for determining that Petitioner's Comprehensive Cancer Center (Cancer Center) does not qualify for designation as an on-campus provider-based department of St. Vincent's Catholic Medical Centers of New York (Petitioner or St. Vincent's). Therefore, for the reasons that follow, I hereby remand this case to CMS for further proceedings.

I. Background

Petitioner is a non-profit provider of health care services in the greater New York metropolitan area. Petitioner operates, among other facilities, a general hospital that provides acute care and certain specialty services in Manhattan. Pertinent to the issue present in this case is Petitioner's Cancer Center, which is located within walking distance from the hospital's main buildings in the Greenwich Village neighborhood of New York City. P. Br. at 1.

By letter dated December 12, 2003, Petitioner requested a determination by the CMS New York Regional Office that its Cancer Center is located on the campus of Petitioner for purposes of the provider-based regulations. The letter went on to say that the Cancer Center is located at 325 West 15th Street and 8th Avenue, a distance of approximately 327

yards ("as the crow flies" according to P. Br. at 3) from St. Vincent's main buildings, located at 13th Street and 8th Avenue. P. Ex. 4.

By letter dated November 10, 2005, the CMS New York Regional Office determined that the Cancer Center located at 325 West 15th Street, New York, N.Y. 10011, did not qualify as an on-campus provider-based department of St. Vincent's. P. Ex. 6.

Petitioner sought reconsideration of the initial denial by letter dated January 13, 2006. P. Ex. 7. In a letter dated January 26, 2007, CMS affirmed the initial determination. P. Ex. 9. On March 27, 2007, Petitioner filed a timely request for hearing before an administrative law judge (ALJ) of the Departmental Appeals Board, and the case was assigned to me for hearing and decision.

On July 17, 2007, the parties filed a joint Notice of Issues contending that the material facts are not in dispute and that each side was entitled to judgment as a matter of law. Accordingly, they proposed to submit their respective motions for summary judgment on September 28, 2007. The parties subsequently submitted a joint motion, dated September 21, 2007, waiving their right to an in-person hearing. Consequently, I hereby issue this decision without regard to the rules applicable to summary judgment.[1]

In compliance with my order of October 9, 2007, establishing a briefing schedule, the parties filed their respective briefs (P. Br. and CMS Br.) on November 9, 2007. Petitioner proffered 11 exhibits, which I have entered into the record without objection as P. Exs. 1–11. CMS proffered one exhibit, which I have entered into the record as CMS Ex. 1. The parties submitted their reply briefs (P. Reply Br. and CMS Reply Br.) on November 29, 2007.

Based on the arguments of the parties, the documentary evidence admitted into the record, and the applicable law and regulations, I find that it is appropriate to remand this case to CMS.

II. Applicable Law and Regulations

The following definitions set forth at 42 C.F.R. § 413.65(a) are pertinent to the issue in this case:

- *Main provider* means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

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[1] The parties have continued to mistakenly refer to the adjudication of this case as one based on summary judgment.

- *Provider-based entity* means a provider of health care services, . . . that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider.

- *Provider-based status* means the relationship between a main provider and a provider-based entity or a department of a provider, . . . that complies with the provisions of [the regulations].

- *Campus* means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

42 C.F.R. § 413.65(b)(3)(i) provides that if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of 42 C.F.R. § 413.65, and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of 42 C.F.R. § 413.65.

42 C.F.R. § 413.65(d) establishes that a facility for which provider-based status is sought, whether located on or off campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

> (1) *Licensure*. The facility must operate under the same license as the main provider, except where state law requires separate licensure.
>
> (2) *Clinical services*. The facility's clinical staff must have privileges at the main provider, there is monitoring and oversight of the facility by the main provider, medical records must be integrated with those of the main provider, and patients must have full access to care at both facilities.
>
> (3) *Financial integration*. The subordinate facility's financial operations must be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the subordinate facility.
>
> (4) *Public awareness.* The public and other payers must be aware that the entity is part of the main provider.

> (5) *Obligations of hospital outpatient departments and hospital-based entities*. In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of 42 C.F.R. § 413.65.

A party against whom CMS has issued an adverse determination may request a hearing before an ALJ of the Departmental Appeals Board, pursuant to 42 C.F.R. § 498.40, *et seq*.

III. The parties' contentions

Petitioner contends that CMS has misinterpreted its own regulations, and has arbitrarily and capriciously refused to apply its discretion to confer on-campus provider-based status on Petitioner's Cancer Center located beyond 250 yards from the main hospital.

CMS, on the other hand, maintains that its Regional Office's decision to deny Petitioner's Cancer Center on-campus provider-based status is not arbitrary and capricious. In that regard, states CMS, the New York Regional Office concluded that the Cancer Center is 77 yards beyond the limit given in the regulation's definition of "campus." Additionally, CMS argues that in arriving at its determination, the Regional Office considered the distance between the Cancer Center and the main campus, the number of streets that must be crossed to walk between them, the lack of a clear line of sight between the two facilities, and the numerous non-medical businesses and residences separating the Cancer Center from the main hospital.

IV. Discussion

CMS's letter to Petitioner dated November 10, 2005, merely states that the denial of on-campus provider-based status for the Cancer Center was grounded on the fact that the distance between the Cancer Center and the main provider was 327 yards. P. Ex. 6. That distance is greater than the 250 yards established in the regulation.

In the reconsideration determination dated January 26, 2007, the CMS New York Regional Office stated the following additional reasons for denying Petitioner's request for on-campus designation of its Cancer Center:

- the dense urban nature of the location is a negative factor with regard to the request;

- the street plan shows that there is no direct line of sight between the Cancer Center and the Medical Center;

- to travel from one facility to the other requires a walk of over 400 yards across three busy streets and a major avenue; and,

- between the facilities there are other businesses, residences and activities.

P. Ex. 9, at 1.

In the reconsideration determination, CMS recognizes that Petitioner's Cancer Center services had been provided on campus, but the facility was moved because of the need for additional space, and that the Medical Center would have chosen a closer site if a suitable one had been available. However, CMS considered that these factors are of no consequence. P. Ex. 9, at 1.

In its discussion of the regulations on provider-based status, the Federal Register states the following:

> The Medicare law (section 1861(u) of the [Social Security] Act) lists the types of facilities that are regarded as providers of services, but does not use or define the term "provider-based."[2] However, from the beginning of the Medicare program, some providers, which [CMS] refer[s] to . . . as "main providers," have owned and operated other facilities, such as [skilled nursing facilities] or [home health agencies], ... The subordinate facilities may have been located on the main provider campus or may have been located away from the main provider. In order to accommodate the financial integration of the two facilities without creating an administrative burden, [CMS] [has] permitted the subordinate facility to be considered provider-based.

65 Fed. Reg. 18,434, 18,504 (April 7, 2000).

The Federal Register states that the objective in issuing specific criteria for provider-based status is to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles or coinsurance (which can all be associated with provider-based status) are limited to situations where the facility or organization is clearly and unequivocally an integral and subordinate part of a provider. 65 Fed. Reg. 18,434, 18,506 (April 7, 2000). CMS asserts that while there may be numerous administrative

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[2] There is no direct statutory requirement to maintain explicit criteria for determination of provider-based status.

advantages for a hospital in receiving provider-based status for a subordinate facility, there is no difference in treatment by CMS of on-campus provider-based and off-campus provider-based facilities. The level of Medicare reimbursement paid for services at on-campus and off-campus facilities is the same. CMS Br. at 3. Petitioner agrees with CMS's assertion regarding reimbursement implications, but adds that the distinction is crucial here because off-campus facilities are subject to additional administrative requirements and restrictions (which can inhibit a main provider's ability to operate its facility efficiently), not imposed upon on-campus facilities. P. Br. at 7.

In order for CMS to determine whether a facility may be classified as on-campus provider-based, it must find that the subordinate facility is within 250 yards of the main provider, and, in addition, satisfy all of the requirements of 42 C.F.R. § 413.65(d). If the facility is not within 250 yards of the main provider, the definition of "campus" set out at 42 C.F.R. § 413.65(a) grants a CMS regional office the discretion to consider such facility as on-campus. The Federal Register states that the definition of "campus" encompasses "not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets." 65 Fed. Reg. 18,434, 18,511 (April 7, 2000). The Federal Register notes that such a definition gives the regional offices discretion to make determinations, on a case-by-case basis, as to what constitutes a hospital's campus. *Id.*

In the case at hand, CMS did not consider whether Petitioner satisfied the conditions set forth at 42 C.F.R. § 413.65(d). In the initial determination, CMS's analysis was limited to whether the subordinate facility satisfied the 250-yard distance contained in the definition of "campus." That analysis was insufficient because the CMS regional offices have been granted discretion in the regulation to consider a facility to be on-campus provider-based, even if it is beyond the 250 yard limit. As stated above, in the reconsidered determination, CMS added other reasons for denial of on-campus status to Petitioner's Cancer Center. These included the dense urban nature of the location, the absence of a direct line of sight between the main provider and the Cancer Center, the need to cross busy streets over a distance exceeding 400 yards, and the existence of businesses, residences, and other activities along the way. The absence of a direct line of sight has no correlation to the distance between the facilities or the need to cross busy streets. Structures that are within 250 yards of each other may require the crossing of busy streets to get from one to the other while providing no line of sight. In contrast, structures that are greater than 250 yards apart and do not require the crossing of busy streets when walking from one to the other, may very well have a line of sight between them.

The other factors considered by CMS in the reconsideration denial as being negative are precisely the factors mentioned in the Federal Register commentary that CMS acknowledges as possibly existing where a regional office considers exercising discretion to award on-campus provider-based status to a facility that is beyond 250 yards from a main provider. 65 Fed. Reg. 18,434, 18,511 (April 7, 2000). It is worthy of note that although the regulations contemplate the possibility of having to travel more than 250 yards on foot, across streets, and past businesses and residences, there is no mention as to whether the streets are busy or not. However, I do not see the busy nature of the streets necessarily as a negative factor, because such streets would have traffic signals at the intersections for pedestrian crossing. CMS argues that a hospital's location in an urban setting would not, in and of itself, give rise to the presumption of a need for more flexibility when it comes to the 250 yard rule. CMS Reply Br. at 6. Assuming that to be a correct rendering of the regulation, it does not lead, however, to the conclusion that location in an urban setting, with its known urban density and scarcity of available real estate for expansion of services in contiguous areas, is necessarily a negative factor. In sum, CMS's reasoning does not address the intent behind the adoption of regulatory criteria for on-campus provider-based designation of facilities that are subordinate to main providers. The determination whether to grant or deny an application for on-campus provider-based status must hinge on the objective to be achieved by the regulation, and the legitimate interests to be protected. Whether it is added beneficiary financial liability, quality of service, or personal safety, CMS must articulate, in precise terms, the basis for denial of a request for an on-campus provider-based designation. CMS has failed to do so here.[3]

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[3] In the affidavit of Peter Reisman, Associate Regional Administrator of the Division of Medicare Financial Management and Fee For Services Operations (CMS Ex. 1), Mr. Reisman states that in making the determination to deny on-campus provider-based designation to the Cancer Center, he consulted with other administrators, and, while the regulations do permit exceptions to the policy that a provider-based facility must be located within 250 yards of the main building to be considered on-campus, none of the CMS administrators could cite an instance where an exception had been granted under circumstances such as the ones present in this case. CMS Ex. 1, at 2. Mr. Reisman does not say whether no exception exists because no request had ever been made or whether a request was in fact made and a denial was issued. If such a decision was issued, Mr. Reisman chose not to share the details of that case. Furthermore, that rationale was not included in CMS's initial or reconsidered determination, nor does it suggest that a case-by-case approach as contemplated by the regulation was used.

It is not for me to establish guidelines in matters delegated by statute or regulation to a regulatory agency or one of its components. Therefore, it is my decision to remand this case to CMS, in order that it may articulate a reason or reasons for denial of Petitioner's request for designation of its Cancer Center as an on-campus provider-based entity. It does not suffice for CMS to say that the subordinate facility is more than 250 yards from the main provider, because the regulation acknowledges that a facility so situated may still qualify as an on-campus provider-based entity. Additionally, CMS cannot base a denial merely on grounds that there are other buildings and residences along the route from one entity to the other, because the regulations also acknowledge that this may be a possibility with respect to a facility that is designated as on-campus provider-based. If the dense urban conditions are a factor considered by CMS, it must state in clear and thoroughly articulated terms *why* approval would be to the detriment of beneficiaries of the program or in some way run counter to the regulatory purpose of 42 C.F.R. § 413.65.

Petitioner argues that CMS has failed to exercise the discretion delegated by regulation, and that, therefore, denial of on-campus provider-based status to its Cancer Center is arbitrary and capricious. I disagree. In denying Petitioner's request, CMS did exercise its discretion. Of course, such exercise of discretion need not necessarily be favorable to Petitioner. However, I agree with Petitioner that CMS "failed to articulate a satisfactory explanation with a rational connection between the facts found and the choice made." P. Br. at 30-31. My ruling here is that in denying the request, CMS must set forth cogent reasons consistent with the letter and spirit of the applicable regulations. Although this issue is different than the one raised by Petitioner, I have the authority to remand this case to CMS, on my own motion, for consideration of this new issue, issuance of a new determination, and, if necessary, to direct the return of the matter to me for further proceedings. 42 C.F.R. § 498.56(d).

V. Conclusion

In view of the foregoing, this case is remanded to CMS for re-issuance, within 30 days, of a determination that articulates a rational basis for its conclusion. Failure to re-issue its determination within the time provided may lead to the inference that no basis exists for the adverse determination that is the subject of this request for hearing.

/s/
José A. Anglada
Administrative Law Judge