

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

SUBJECT: Shady Grove Adventist Hospital
Docket No. A-08-114
Decision No. 2221

DATE: December 31, 2008

DECISION

In August 2006, Shady Grove Adventist Hospital (Shady Grove), an acute-care hospital and Medicare provider located in Rockville, Maryland, opened an emergency care center nine miles away in Germantown, Maryland. Shady Grove sought a determination by the Centers for Medicare & Medicaid Services (CMS) that the Germantown emergency center had a "provider-based" relationship with Shady Grove for purposes of determining the appropriate amount of Medicare payment for Medicare-covered services provided at the center. CMS denied the application for provider-based status, whereupon Shady Grove requested and received a hearing before an administrative law judge (ALJ). In a decision dated May 8, 2008, ALJ Keith W. Sickendick held that the Germantown emergency center met the Medicare program's conditions and requirements for "provider-based status" in 42 C.F.R. § 413.65. Shady Grove Adventist Hospital Emergency Center at Germantown, DAB CR1783 (2008) (ALJ Decision).

CMS now appeals the ALJ Decision, contending that it properly denied provider-based status for the Germantown emergency center under a federal regulation which states that CMS will not recognize a facility as provider-based if a state agency with authority to regulate hospital rates in the state finds that the facility is "not part of a provider." CMS further contends that the Maryland rate-setting entity made such a finding within the meaning of that federal regulation.

For the reasons discussed below, we conclude that the ALJ's findings of fact resulted from his misreading of the applicable regulation. Based on the correct reading of that regulation, we conclude that the Maryland Health Services Cost Review Commission (HSCRC) made the requisite "finding" and that the Germantown

emergency center was therefore not eligible for provider-based status. Accordingly, we reverse.

Legal Background

1. Medicare payment to Maryland hospitals

Since the 1970s, Maryland hospitals have received payments from the Medicare program under a waiver of the program's payment rules. Under this waiver, which is authorized by section 1814(b)(3) of the Social Security Act (Act),¹ Medicare pays Maryland hospitals for inpatient and outpatient hospital services furnished to Medicare beneficiaries based on rates established by Maryland's hospital rate-setting agency, the HSCRC, in lieu of rates established by CMS under the Medicare inpatient and outpatient prospective payment systems (PPS). See CMS Exs. 5-11; 65 Fed. Reg. 18,434, 18,530 (April 7, 2000). Maryland is currently the only state in the country that operates under a section 1814(b)(3) waiver of Medicare hospital payment rules.²

Maryland law provides that the HSCRC has "jurisdiction" over "hospital services." Md. Code Ann., Health-Gen. § 19-211(a)(1). For jurisdictional purposes, the term "hospital services" is defined in Maryland law to include "[o]utpatient services provided at the hospital." *Id.* § 19-201(d)(1). Maryland's definition of the term "hospital services" also includes inpatient hospital, emergency services, and "identified physician services for which a facility has Commission-approved rates on June 30, 1985." Md. Code Ann., Health-Gen. § 19-201(d)(1).

¹ The Medicare program is governed by title XVIII of the Social Security Act, which can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

² The waiver remains in effect as long as two principal conditions are met: (1) all third-party payors (i.e., Medicare, Medicaid, private insurers) of hospital services make payments to hospitals in accordance with HSCRC-set rates; and (2) the rate of growth in Medicare payments to Maryland hospitals does not exceed certain benchmarks specified in the law. See Act § 1814(b)(3); CMS Ex. 11.

2. "Provider-based" status under Medicare

The Medicare program pays health care "providers"³ for the medical items and services they furnish to Medicare beneficiaries. Act §§ 1811-12. For program payment purposes, Medicare has long recognized that a provider, such as a hospital, may own and operate another type of facility, such as an outpatient clinic, that is located on or apart from the provider's main building or campus. See 63 Fed. Reg. 47,552, 47,587 (Sept. 8, 1998). Often in this situation, the "main provider" (a hospital in this instance) and subordinate facility share overhead costs and use of revenue-producing assets. Id. When CMS affirmatively determines (based on specific criteria) that the main provider and subordinate facility are integrated, Medicare recognizes the subordinate facility as having a "provider-based" relationship with the main provider. Id. Recognition of the subordinate facility as provider-based enables the main provider to obtain Medicare outpatient PPS payments for services provided in the subordinate facility. Id. at 47,587-47,588; see also ALJ Hearing Transcript (Tr.) at 20-21; Response Br. at 3, n.2. In some instances, a determination that a facility is provider-based results in Medicare payments for covered services that exceed what Medicare would pay for those services if the facility were not classified as provider-based. 63 Fed. Reg. at 47,588. Designating a facility as provider-based may also serve to increase the coinsurance liability of Medicare beneficiaries who receive covered services in that facility. Id.

After implementing the hospital inpatient PPS in 1983, CMS observed that financial and other incentives – including the opportunity to obtain higher Medicare program payment – existed for providers to claim provider-based status for their subordinate facilities.⁴ 63 Fed. Reg. at 47,587. CMS expressed concern that some providers might inappropriately claim provider-based status in order to increase Medicare payments without any commensurate benefit to the Medicare program or its beneficiaries. Id. Accordingly, CMS developed criteria to guide

³ The term "provider" is defined in Medicare law to include hospitals, skilled nursing facilities, home health agencies, and other health care organizations. 42 C.F.R. § 400.202.

⁴ "Before implementation of the hospital inpatient PPS in 1983, there was little incentive for providers to affiliate with one another merely to increase Medicare revenues or to misrepresent themselves as being provider-based, because at that time each provider was paid primarily on a retrospective, cost-based system." 65 Fed. Reg. at 18,504.

its decisions on requests for provider-based status. Id. at 47,589.

Prior to April 2000, those criteria were published in CMS program memoranda. 47 Fed. Reg. 47,589. In a final rule dated April 7, 2000, CMS promulgated regulations, codified in 42 C.F.R. § 413.65, to provide clearer and more comprehensive criteria governing provider-based designations. 65 Fed. Reg. at 18,504. CMS explained that its objective in issuing the regulations was--

to ensure that higher levels of Medicare payment and increases in beneficiary liability for deductibles and 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.

Id. at 18,506.

Section 413.65(d) and 413.65(e) set out the conditions that must be met in order for a facility to be granted "provider-based status."⁵ In essence, these conditions, which apply to all types of facilities for which provider-based status is sought, whether located on or off the main provider's "campus," mandate a substantial legal, financial and operational nexus between the main provider and subordinate facility.

At issue here is the last sentence of section 413.65(d)(1), which states:

If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State *finds that a particular facility or organization is not part of a provider*, CMS will determine that the facility or organization does not have provider-based status.

(Italics added.) Regarding that provision, CMS explained in its September 8, 1998 Notice of Proposed Rulemaking (NPRM):

⁵ The term "provider-based status" means "the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section." 42 C.F.R. § 413.65(a)(2).

We believe it would be inappropriate for a facility or organization to be considered free-standing for State ratesetting purposes, but [to seek] provider-based status under Medicare.

63 Fed. Reg. at 47,590. Responding to public comments on the NPRM, CMS discussed the provision further in the preamble to the April 7, 2000 final rule:

Comment: With regard to the proposed requirement that states that our determination regarding provider-based status will be based on a State health facilities' review commission, one commenter argued that relying on the commission's criteria for purposes of making provider-based determinations is arbitrary and inappropriate. The commenter believes [that] imposing this criterion could disadvantage providers and discourage expansion to off-site locations, thus indirectly leading to shortages of care. Another commenter requested that there be a delay in implementation during which time changes can be made to the commission's definition of what rates it can regulate.

Response: We continue to believe it would be inappropriate for a facility to claim to be separate from the provider for State rate-setting purposes while also claiming to be an integral and subordinate part of the provider for Medicare purposes. To allow this practice would authorize providers to misrepresent their structures and affiliations in whatever way will yield the highest payment. Thus, we did not make changes to reflect this comment.

65 Fed. Reg. at 18,513.

Case Background

The facts recounted in this section are undisputed and are drawn from the ALJ Decision and the evidence of record.

In response to population growth and traffic congestion in its service area, Shady Grove (the "main provider" in this case) sought to open an off-campus emergency department in Germantown, Maryland. When the idea for the Germantown emergency center was conceived, Maryland law did not authorize the creation or licensing of an emergency department located away from a hospital campus. To remove the legal hurdles and help bring Shady Grove's plan to fruition, the Maryland General Assembly enacted

legislation in 2005 to authorize the establishment of "freestanding medical facilities." See Md. Code Ann., Health-Gen. §§ 19-131, 19-3A-01 through 19-3A-05, 19-3A-07. The 2005 legislation defined the term "freestanding medical facility" in part to mean a facility that is "physically separate from a hospital or hospital grounds" but "an administrative part of a hospital or related institution[.]" *Id.* § 19-3A-01. The 2005 legislation also called for the adoption of licensing requirements under which a freestanding medical facility would be obligated to operate full-time, be staffed and equipped to provide "medical treatment for immediately life-threatening medical conditions," and comply with other operational standards and protocols. *Id.* § 19-3A-02. In enacting this legislation, the Maryland General Assembly contemplated that the HSCRC and Shady Grove would work to obtain Medicare provider-based status for the Germantown emergency center.⁶

One month before opening the Germantown emergency center, Shady Grove submitted an application to CMS seeking provider-based status for that facility. P. Ex. 1. Included in the application was a September 15, 2005 letter to Shady Grove from HSCRC's executive director, Robert Murray. *Id.* at 24. Mr. Murray's letter stated in relevant part:

My understanding is that, pursuant to federal law at 42 C.F.R. § 413.65(d)(1), the Centers for Medicare and Medicaid Services (CMS) will not grant a facility provider-based status if a state cost review commission – such as the HSCRC – "finds that a particular facility is not part of a provider." Under Maryland law, the HSCRC's rate-setting authority over hospital outpatient services is limited to those services furnished "at the hospital." Section 19-201(d), Health-General Article, Annotated Code of Maryland. The HSCRC has concluded

⁶ Chapter 549 of the 2005 Laws of Maryland contains the following uncodified language:

On or before October 1, 2005, the Health Services Cost Review Commission and Shady Grove Adventist Hospital shall report . . . to the Senate Finance Committee and the House Health and Government Operations Committee on their progress in obtaining provider-based status from the federal Centers for Medicare and Medicaid Services for the freestanding medical facility pilot project established under § 19-3A-07, as enacted by Section 1 of this Act.

that because the Germantown facility is not physically located at Shady Grove Adventist Hospital or on the hospital's campus, the HSCRC will not regulate the rates paid to the facility. The HSCRC, however, has made no "finding" that the Germantown facility is "not part of" Shady Grove Adventist Hospital, as those terms are used in [the last sentence of 42 C.F.R. § 413.65(d)(1)].

CMS Ex. 2, at 29 (footnote added).

In a later letter dated June 5, 2007, Mr. Murray sought to clarify statements he had made in the September 15, 2005 letter:

Under its enabling legislation, whether the HSCRC asserts rate-setting jurisdiction over outpatient services provided by a hospital depends on whether the services are provided "at the hospital." If the Commission "finds" that the services are provided at the hospital, they are subject to rate regulation; contrariwise if the finding is the opposite. In the case of the Germantown facility, the Commission found that it is not "at the hospital," and, *therefore, the HSCRC does not consider it to be part of Shady Grove Adventist Hospital for purposes of rate regulation by the HSCRC.*

When I indicated in the 2005 letter that the HSCRC "has made no finding that the Germantown facility is not part of Shady Grove Adventist Hospital, as those terms are used in the federal regulation," I was attempting to make the point that while the Commission makes findings as to its jurisdiction over outpatient services in accordance with its own statutory law, *it takes no position on whether the facility is "provider-based" under applicable federal regulation. The HSCRC leaves that determination, or finding, up to CMS.*

CMS Ex. 18, at 1 (italics added).

On November 6, 2006, CMS issued a written determination denying Shady Grove's application for provider-based status for the Germantown emergency center.⁷ P. Ex. 3. In support of the denial, CMS indicated that the limitation contained in the last

⁷ Shady Grove filed a request for reconsideration of CMS's determination. P. Ex. 4. CMS denied the request in a letter dated March 1, 2007 letter. CMS Ex. 4.

sentence of section 413.65(d)(1) was applicable because the HSCRC had found that the Germantown emergency center was "not part of" Shady Grove "for purposes of rate regulation" by the HSCRC. Id.⁸

In the ALJ proceeding, Shady Grove argued that CMS had misinterpreted and misapplied the last sentence of section 413.65(d)(1). It asserted that the HSCRC's finding that it would or could not regulate rates paid for services provided at the Germantown emergency center was not equivalent to a finding that the Germantown emergency center was "not part of" Shady Grove within the meaning of the last sentence section 413.65(d)(1). By interpreting that provision as calling for a finding concerning the scope of HSCRC's rate-setting jurisdiction, said Shady Grove, CMS had given the regulation a meaning inconsistent with its "plain" and "unambiguous" language. Shady Grove asserted that the HSCRC had not, in fact, made the "finding" contemplated by the regulation, relying principally on the September 15, 2005 statement by HSCRC's executive director that the HSCRC "ha[d] made no 'finding' that the Germantown facility is 'not part of' Shady Grove Adventist Hospital, as those terms are used in [the last sentence of 42 C.F.R. § 413.65(d)(1)]." The ALJ largely accepted Shady Grove's argument.

The ALJ Decision

In overturning CMS's determination, the ALJ made several numbered "Findings of Fact" and "Conclusions of Law." The Findings of Fact included the following:

12. CMS determined that, at the time of [Shady Grove's] application [for provider-based status], the Germantown Emergency Center met all requirements at 42 C.F.R. § 413.65 for provider-based status as a remote location of [Shady Grove], except for the requirement contained in the last sentence of 42 C.F.R. § 413.65(d)(1) . . .

* * *

16. The HSCRC determined that its rate-setting authority over outpatient services provided by a hospital is limited to such services provided "at the hospital," citing MD. Code Ann., Health-Gen. § 19-201(d).

⁸ It is undisputed that the Germantown emergency center meets the other regulatory criteria for provider-based status.

17. The HSCRC determined that because the Germantown Emergency Center is not physically located at Shady Grove or on its campus, the HSCRC had no authority under its enabling act to regulate rates paid to the facility.
18. The HSCRC specifically made no finding as to whether or not the Germantown Emergency Center was "part of" Shady Grove within the meaning of [the last sentence of section 413.65(d)(1)].

ALJ Decision at 3-4 (citations to record omitted). Based on these findings, the ALJ concluded that CMS had erred in denying provider-based status for the Germantown emergency center because there had been no finding by a state cost review commission that the Germantown emergency center was "not part of" Shady Grove. Id. at 4-5 (Conclusions of Law ¶¶ 1-6), 10.

The Parties' Contentions on Appeal

CMS contends that the ALJ erred in his interpretation of the last sentence of section 413.65(d)(1). CMS Br. at 6, 8. CMS interprets that provision as requiring it to deny provider-based status to a facility if a state cost review commission finds that the facility is "not part of" a provider *for state rate-setting purposes*. Id. at 6, 10. CMS contends that the ALJ should have applied this reasonable and longstanding interpretation of the last sentence of section 413.65(d)(1). Id. at 6. CMS further contends that its decision to deny provider-based status to the Germantown emergency center was correct based on its interpretation of the last sentence of section 413.65(d)(1) because the HSCRC expressly found that the Germantown emergency center was not considered "part of" Shady Grove "for purposes of rate regulation by the HSCRC." CMS Ex. 18, at 1.

Shady Grove responds that CMS's interpretation of the applicable regulation ignores or conflicts with the regulation's "plain" and "unambiguous" language and with its stated purpose. Response Br. at 24-25, 33-34. Shady Grove further contends that CMS's interpretation (1) is inconsistent with certain legislatively-recognized objectives of the Medicare program relating to payment for hospital services (id. at 26-27); (2) is "arbitrary and capricious" (id. at 34-35); and (3) creates "significant constitutional implications based on denial of equal protection" (id. at 35-36). Shady Grove argues that the record "indisputably" shows that the HSCRC made no finding about whether or not the Germantown emergency center was "part of" Shady Grove

for purposes of the last sentence of section 413.65(d)(1). Id.
at 19-20.

Standard of Review

The Board reviews a disputed factual finding to determine whether it is supported by substantial evidence, and a disputed legal conclusion to determine whether it is erroneous. *Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* (at <http://www.hhs.gov/dab/guidelines/prov.html>); South Valley Health Care Center, DAB No. 1691, at 2 (1999), aff'd, South Valley Health Care Center v. HCFA, 223 F.3d 1221 (10th Cir. 2000).

Discussion

The last sentence of section 413.65(d)(1) obligates CMS to deny provider-based status when the following two circumstances exist: (1) there is a "cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers" in the state; and (2) the cost review commission finds that the facility or organization for which provider-based status is sought is "not part of" a hospital or other provider. We discuss each element in turn.

A. *HSCRC is a cost review commission as defined in 42 C.F.R. § 413.65(d)(1).*

The ALJ found that the first circumstance did not exist "as a matter of fact" because the HSCRC determined that it lacked authority to establish payment rates for services provided at the Germantown emergency center. ALJ Decision at 10. The ALJ reasoned that the applicable regulation describes a cost review commission as an entity authorized to regulate rates charged by "hospitals" or other "providers." The Germantown emergency center, he concluded, is neither a hospital nor a provider under state law,⁹ according to the HSCRC's decision that the center was not subject to its jurisdiction. The ALJ then in effect concluded that the HSCRC was not a cost review commission under section 413.65(d)(1) because it did not regulate rates for services provided at the specific facility seeking provider-based status.

⁹ The HSCRC relied on Maryland law to determine that the Germantown emergency center was a "freestanding medical facility," not a hospital or other type of provider under the HSCRC's jurisdiction. See Md. Code Ann., Health-Gen. § 19-3A-01 et seq.; Tr. at 54.

This finding rests on a misreading of the regulation's description of a cost review commission. Section 413.65(d)(1) does not require that a cost review commission regulate rates at every health care facility in the state, nor does it state that a cost review commission must regulate rates charged by the specific facility seeking provider-based status. The regulation rather refers to a cost review commission that has "authority to regulate *rates charged by hospitals and other providers*" (italics added). The terms "hospital" and "provider" are defined in the Medicare statute and regulations as including many – but not all – types of health care facilities or organizations. See Act § 1861(e); 42 C.F.R. § 400.202.

Thus, for CMS to invoke the regulation, a state cost review commission need only have authority to regulate rates "charged by hospitals or other providers." The record and Maryland law clearly show that the HSCRC satisfies the federal regulation's plain words, since it is a body with authority to regulate the rates charged by hospitals in Maryland. CMS Ex. 5-11, 14-16, 18-19; Md. Code Ann., Health-Gen. § 19-201 et seq.

B. *The HSCRC made the finding required by 42 C.F.R. § 413.65(d)(1) that the Germantown emergency center is "not part of" Shady Grove.*

1. The applicable regulation requires only a finding that the facility is not part of a hospital for state rate-setting purposes.

Because we conclude that the HSCRC is a cost review commission with the requisite authority, the dispute in this case centers on whether the HSCRC found that the Germantown emergency center was "not part of" of Shady Grove. The ALJ found that the HSCRC had made no such finding based on his reading of the regulatory requirement. The ALJ applied his interpretation of the regulation to his review of the contents of the September 15, 2005 and June 5, 2007 letters from HSCRC's executive director, Mr. Murray, and concluded that nothing in the letters met the regulatory requirement. ALJ Decision at 5 (¶ 18), 10. The ALJ further opined that any finding by the HSCRC that the Germantown emergency center was not part of Shady Grove would be contrary to Maryland law, which requires that a "freestanding medical facility" be "an administrative part of a hospital or related institution[.]" Id. at 10-11 (relying on Md. Code Ann., Health-Gen. § 19-3A-01(3)).

The ALJ found, as a factual matter, that the "HSCRC specifically made no finding as to whether or not the Germantown Emergency

Center was 'part of' Shady Grove *within the meaning of the federal regulation.*" ALJ Decision at 4 (italics and emphasis added). It is true that HSCRC did not purport to find whether or not the Germantown emergency center was 'part of' Shady Grove within the meaning of the federal regulation's criteria for determining whether a facility is "part of" another provider, leaving that issue to CMS. The problem with the ALJ's finding is that it again rests on a misreading of what kind of finding the regulation requires from a state cost review commission to trigger denial of provider-based status. We disagree with the ALJ that the federal regulation contemplates a state cost review commission making findings about whether facilities were part of hospitals under federal provider-based criteria.

For the following reasons, we find instead that the applicable regulation refers to a finding by the HSCRC that a facility is not part of a hospital or other provider *for state rate-setting purposes*. First, the context of the finding within the language of the regulation makes this reading logical. The entity that makes the required finding is, in the regulation's words, a "cost review commission . . . *that has authority to regulate the rates charged by hospitals or other providers*" (italics added). Because the regulation expressly identifies the function and authority of a cost review commission – to regulate rates under a state waiver – we find it appropriate to infer that the "finding" contemplated by the regulation relates to the commission's authority to make decisions about whether facilities are or are not part of a regulated hospital or provider for its own rate-setting purposes. Because a cost review commission establishes hospital or provider payment rules that effectively supplant Medicare payment rules in a state that operates under a section 1814(b)(3) waiver, it makes sense that the "finding" called for in the last sentence of section 413.65(d)(1) would be one that concerns a facility's status under the *commission's* payment or rate-setting scheme. We conclude that nothing indicates that the state cost review commission's finding referred to in the regulation was to be about whether a facility is part of a provider under the federal definition of "provider-based" facilities.

Contrary to the ALJ's view that the HSCRC could not be the entity referred to by the regulation once it determined it lacked jurisdiction over the Germantown emergency center, the regulation instead defers to state entities precisely in the area of their assessments of their own jurisdiction. In other words, the clear meaning of the regulatory language read in context is that, once a state undertakes to set rates for hospital services under a state Medicare waiver, CMS will defer to the state's own decision

about whether a facility can qualify as part of a hospital eligible to receive reimbursement as provider-based, even if the state does not treat as provider-based a facility that might otherwise have qualified under normal Medicare principles.

The regulatory history supports our interpretation. Section 413.65(d)(1) is part of a set of regulations that govern when Medicare will recognize a facility to be "provider-based" - that is, an "integral and subordinate part of" of a hospital or other provider - *for purposes of determining the appropriate Medicare payment for services furnished by the facility.* 65 Fed. Reg. 18,506 (italics added). The preamble emphasizes that this recognition is intended to be "limited to situations where" a facility "clearly and unequivocally" meets all the relevant criteria. *Id.* One of the relevant criteria that must be clearly and unequivocally met is that no finding have been made by a state rate-setting commission that the facility is not part of a hospital.

Not only is our interpretation consistent with the regulatory language and history, it is consistent with CMS's stated reason for this particular limitation. In the preambles to the September 8, 1998 NPRM and April 7, 2000 final rule, CMS indicated that it intended to deny provider-based status for any facility that was or claimed to be "freestanding for State ratesetting purposes" while seeking provider-based status under federal Medicare payment rules. 63 Fed. Reg. at 47,590; 65 Fed. Reg. at 18,513. In other words, CMS indicated that if a state cost review commission recognized a facility or organization as "freestanding" - that is, not part of a hospital (or other provider) - in determining the amount of payment to be made under the state's hospital rate-setting system, then that facility will not be treated as provider-based under Medicare hospital payment rules, even if the facility otherwise qualified for that status.

At oral argument, Shady Grove claimed that it lacked notice of this interpretation prior to the events leading to this litigation. We reject that claim. In our view, Shady Grove had constructive notice of the interpretation no later than April 7, 2000, when CMS issued its final rule on section 413.65. The preambles to the NPRM and the final rule indicate that a denial of provider-based status under the last sentence of section 413.65 would occur when the facility seeking provider-based status is found to be separate or freestanding for state rate-setting purposes even if otherwise **part of** a provider under federal criteria. The juxtaposition of these circumstances - "separate" for state rate-setting purposes but an "integral and subordinate part of" the provider for Medicare purposes - was

sufficient to notify the public that the finding in section 413.65(d)(1) which triggers the denial of provider-based status is a finding that the facility or organization is not part of a provider for state rate-setting purposes.¹⁰ Our conclusion that the public received adequate notice is bolstered by the fact that, according to the final rule's preamble, one of the commenters to the NPRM, presumably a Maryland organization (since, at that time as well, Maryland had the only section 1814(b)(3) waiver), asked CMS to delay implementation of the regulation so that changes could be made to the "commission's definition of what rates it can regulate." 65 Fed. Reg. at 18,513. This comment reflects some public understanding or awareness that the required finding relates to the cost review commission's rate-setting purposes.

Shady Grove also contends that our interpretation of the last sentence of section 413.65(d)(2) is unreasonable on several grounds. At oral argument, Shady Grove suggested that the practical effect of our interpretation, which is to require that all provider-based facilities in Maryland be subject to rate regulation by the HSCRC, is inconsistent with the regulation's purpose (as stated in the preambles to the proposed and final rules). We disagree. CMS's stated purpose in promulgating the last sentence of section 413.65(d)(1) was to foreclose the possibility that a hospital in Maryland (or other section 1814(b)(3) waiver state) would evade the rates for hospital services set by the HSCRC under its section 1814(b)(3) waiver in order to claim payment as hospital services under the federal PPS rates by seeking federal provider-based status. The last sentence of section 413.65(d)(1) clearly advances that purpose by denying a facility provider-based status - and thus Medicare outpatient PPS payments for that facility's services - when the facility is not recognized as part of the hospital under the HSCRC's payment scheme. So, for example, if an off-campus facility is found to be not part of a hospital for state rate-setting purposes, then it will not be recognized as provider-based for federal regulatory purposes (and thus will be ineligible to receive Medicare PPS payments for the facility's services). If the facility is part of the hospital under the state hospital payment scheme, then it will be subject to rates

¹⁰ Even if Shady Grove had not received notice of what we determine to be the correct interpretation, and even were we persuaded the regulation was ambiguous, we would hold that the ALJ should have deferred to CMS's interpretation here because Shady Grove failed to establish that it detrimentally relied on a reasonable alternative interpretation. See Alaska Dept. of Health and Social Services, DAB No. 1919, at 14 (2004).

established by the HSCRC for hospital services. Under either scenario, there is no opportunity or incentive for the hospital to structure or represent itself so as to remove itself from the state rate-setting system for hospital rates but still claim hospital rates under Medicare PPS where that would maximize its total reimbursement.

2. The correct interpretation of 42 C.F.R. § 413.65(d)(1) does not conflict with Board precedent.

Shady Grove next contends that our interpretation conflicts with a holding in Johns Hopkins Health Systems, DAB CR598, aff'd, DAB No. 1712 (1999). Response Br. at 9-10, 25. In that case, the issue before the ALJ was whether CMS had improperly denied provider-based status to an off-campus outpatient oncology center owned by the Johns Hopkins Hospital, located in Baltimore, Maryland. CMS's denial, which predated the promulgation of section 413.65, was based on CMS Program Memorandum (PM) A-96-7, which specified eight criteria that had to be met before a facility or organization could "be designated as part of a provider for payment purposes." See Johns Hopkins Health Systems, DAB No. 1712, at 3. In support of its determination, CMS argued that the oncology center was not part of the hospital because the rates charged for services provided by the oncology center were not regulated by the HSCRC. Johns Hopkins Health Systems, DAB CR598. The ALJ rejected that contention, stating, among other things, that the scope of the HSCRC's authority to regulate rates charged by the oncology center was "irrelevant to the issue of whether the oncology center met the criteria for a provider-based designation" under PM A-96-7. Id.

Shady Grove suggests that because the ALJ in Johns Hopkins rejected CMS's contention that the absence of HSCRC rate regulation meant that the oncology center was "not part of" the hospital (and thus not eligible for provider-based status under the pre-regulatory CMS guidelines), the Board in this case should hold, by analogy, that the HSCRC's disclaimer of authority over the Germantown emergency center is not, in effect, a finding that the center is "not part of" Shady Grove within the meaning of section 413.65(d)(1). See Response Br. at 25. This analogy does not hold. In Johns Hopkins, the argument that the oncology center was "not part of" the hospital rested on specific criteria set by federal guidelines. The HSCRC's views on the status of the oncology center were not included among those criteria. However, the regulation now in force adds a criterion for federal provider-based status that a facility not be subject to a state cost review commission's finding that it is not part of a hospital for state rate-setting purposes. Thus, we see no valid

grounds to reject our interpretation based on the holding in Johns Hopkins.

3. Our conclusion that the regulation requires a finding that the Germantown emergency center is not part of Shady Grove for state rate-setting purposes is neither unfair nor arbitrary or capricious.

Shady Grove further contends that our interpretation undercuts certain Medicare program objectives. Response Br. at 26. Shady Grove asserts that when Congress established Medicare, it intended "to expand access to high-quality healthcare, especially emergency care, and to ensure that providers of such services – particularly emergency hospital services – would be paid as closely as practicable the costs (both direct and indirect) of services rendered to beneficiaries of the program." Id. According to Shady Grove, our interpretation of the last sentence of section 413.65(d)(1) "would unfairly deprive the Hospital of reimbursement to which it otherwise is entitled for costs incurred at its Off-Campus ED, which clearly would be contrary to Congressional intent to reimburse hospitals fully for costs incurred in providing services." Id. at 27.

We disagree. The perceived unfairness described by Shady Grove is less the result of an interpretation of the applicable regulation than of Maryland's decision to opt out of Medicare's hospital payment system and accept Medicare payment for hospital services based on rates established by the HSCRC. Under that waiver, Maryland is free to establish outpatient hospital service rates applicable to off-campus emergency departments, and Shady Grove assures us that those rates would be comparable to or more generous than Medicare PPS rates. Response Br. at 28 (stating that the "Hospital would be much better off financially if services provided at the Off-Campus ED were subject to the HSCRC rate-setting regimen"). See Response Br. at 28. Essentially, by means of the waiver, CMS has deferred to Maryland to make choices about how to compensate hospitals fairly, without exceeding total benchmarks. Act § 1814(b)(3); CMS Ex. 11. For hospitals in Maryland to seek reimbursement under Medicare outpatient PPS outside the waiver would undercut the central point of transferring hospital rate-setting authority to the HSCRC. For these reasons, we do not agree that our interpretation deprives Shady Grove of adequate reimbursement for off-campus emergency services.

Shady Grove next asserts that our interpretation is "arbitrary and capricious" because it "effectively prohibit[s] off-campus

provider-based facilities in Maryland, while permitting them in every other State in the nation," and because there is no rational basis for the distinction. Response Br. at 33-34. In a related argument, Shady Grove contends that our interpretation operates to deny it equal protection of the law, asserting that it is "seeking only the treatment that it would receive if it were located in any other state: reimbursement under the outpatient prospective payment system for emergency services." Id. at 35-36.

The problem with these contentions is that hospitals in Maryland, unlike hospitals in other states, receive Medicare payment pursuant to a waiver of Medicare payment rules and based on rates established by the HSCRC. The regulation draws a reasonable distinction based on that fact, in effect prohibiting Medicare payment to a Maryland hospital for off-campus emergency services unless the rates for those services are set by the HSCRC along with all other Medicare rates for hospitals in Maryland. Given that Maryland's Medicare waiver encompasses outpatient hospital services that elsewhere would be paid for under the federal outpatient PPS, CMS may rationally insist that a provider-based facility be subject to state rate-setting as a condition of receiving payment for outpatient hospital services under the state's Medicare waiver. The state sets hospital services rates and allocates them between outpatient and inpatient services in a manner designed to ensure that the total outlay does not produce an excessive rate of growth in Medicare payments to the state's hospitals compared to the national system. See Act § 1814(b)(3); CMS Ex. 11. To remove certain outpatient services from the outlay under the waiver by treating a facility as non-provider-based for state rates while the facility nevertheless receives hospital services payments as provider-based from Medicare outpatient PPS outside the waiver would potentially distort assessment of the state's compliance with the statutory prerequisites to continue operating a waiver program.

As for any equal protection claim, Shady Grove can hardly claim that it is "similarly situated" with hospitals in states that do not receive Medicare payment under a section 1814(b)(3) waiver. Cleburne v. Cleburne Living Center, Inc., 473 U.S. 432, 439 (1985) (The Equal Protection Clause of the Fourteenth Amendment "is essentially a direction that all persons similarly situated should be treated alike.").

4. HSCRC's statements constitute the "finding" contemplated by the last sentence of 42 C.F.R. § 413.65(d)(1).

Applying the correct interpretation of section 413.65(d)(1), we conclude that the HSCRC did in fact make a "finding" that the Germantown emergency center was "not part of" Shady Grove for purposes of state rate-setting. In his September 15, 2005 and June 5, 2007 letters, the HSCRC's executive director, Mr. Murray, effectively tries to draw a careful distinction between acknowledging HSCRC's conclusion that the Germantown emergency center is not part of Shady Grove for purposes of resolving its own rate-setting jurisdiction, while denying that this conclusion includes an opinion about the center's status under the federal regulation.

Thus, Mr. Murray indicated that the HSCRC had made a finding about its "jurisdiction" over the "outpatient" services provided at the Germantown emergency center. CMS Ex. 2, at 29; CMS Ex. 18. Mr. Murray further indicated that the HSCRC's jurisdiction over outpatient services was limited to outpatient services provided "at the hospital," citing a state statute which defines the scope of "hospital services" whose rates are subject to HSCRC regulation.¹¹ *Id.* According to Mr. Murray:

In the case of the Germantown facility, the Commission found that it is not "at the hospital," and, therefore, ***the HSCRC does not consider it to be part of Shady Grove Adventist Hospital for purposes of rate regulation by the HSCRC.***

CMS Ex. 18 (italics and emphasis added). This statement clearly indicates that the HSCRC viewed its finding that Shady Grove and the Germantown emergency center were physically separate as equivalent to a finding that the Germantown emergency center was "not part of" Shady Grove for state rate-setting purposes. For that reason, we conclude that Mr. Murray's statements effectively convey an HSCRC finding that the Germantown emergency center was

¹¹ As indicated above, a state statute prescribes the categories of "hospital services" over which the HSCRC has jurisdiction to include "emergency services." The statute does not expressly restrict emergency services to those provided at the hospital, as it does with outpatient services. Neither party has explained why services provided at the Germantown emergency center do not constitute "emergency services" under Maryland law.

not part of Shady Grove within the meaning of the last sentence of section 413.65(d)(1).¹²

We are aware, of course, that Mr. Murray stated in his September 15, 2005 letter that the HSCRC had not made the finding contemplated by section 413.65(d)(1). However, in seeking to clarify that assertion, Mr. Murray suggested in his June 5, 2007 letter that he understood the regulation to require an HSCRC finding about whether or not the Germantown emergency center was *provider-based under federal law*. CMS Ex. 18, at 1 (stating that the HSCRC had taken "no position" about whether the Germantown emergency center was provider-based under applicable regulations). Mr. Murray was mistaken in his understanding of the federal regulation for the reasons we explained above. As discussed, the finding required by section 413.65(d)(1) is, in essence, a finding about the scope of the HSCRC's rate-setting jurisdiction, not a finding about whether a facility was provider-based under federal law. The latter finding does not lie within the purview of the HSCRC but with the federal regulators.

In any event, Mr. Murray's subjective understanding of what the regulation required is irrelevant. What is relevant is what Mr. Murray actually said, and what he said, in effect, was that the HSCRC had found that the Germantown emergency center was not part of Shady Grove for state rate-setting purposes. Based on that finding by the HSCRC, we are compelled to conclude that CMS's denial of provider-based status for the Germantown emergency center was legally proper under the last sentence of section 413.65(d)(1).

Conclusion

Based on our analysis of the law and discussion of the evidence of record set out above, we strike Finding of Fact 18 in section II.A of the ALJ Decision. We also strike Conclusions of Law 3-6

¹² Shady Grove contends (and the ALJ agreed) that the HSCRC could not have found the Germantown emergency center to be "not part of" Shady Grove because under Maryland law, a "freestanding medical facility" must be an "administrative part of a hospital." Response Br. at 21-22, citing Md. Code Ann., Health-Gen. § 19-3A-01. This contention is meritless because it is irrelevant that the Germantown emergency center was "administratively" part of the hospital. The applicable regulation requires a finding that the center was not part of Shady Grove *for state rate-setting purposes*, not a finding that the center was not part of Shady Grove for administrative or other purposes.

