CENTERS FOR MEDICARE AND MEDICAID SERVICES
Decision of the Administrator

In the case of:	**Claim for:**
AnMed Health	**Reporting Period: Discharges on or after August 25, 2017**
Provider	
vs.	
Palmetto GBA c/o National Government Services, Inc.	**Review of: PRRB Dec. No. 2020-D22**
Medicare Contractor	**Dated: Sept. 4, 2020**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision of the Provider Reimbursement Review Board (Board). The review is during the 60-day period in §1878(f)(1) of the Social Security Act (Act), as amended (42 U.S.C. § 1395oo (f)). The parties were notified of the Administrator's intention to review the Board's decision. The Provider submitted comments, requesting that the Administrator uphold the Board's decision. The Medicare Administrative Contractor (MAC) submitted comments, requesting that the Administrator reverse the Board's decision. Accordingly, this case is now before the Administrator for final agency review.

BACKGROUND

The Provider is an acute care hospital located in Anderson, South Carolina, and is considered an urban hospital. The Provider operates two campuses: one campus is located at 800 North Fant Street, and houses a 461-bed acute care hospital, the other campus is located at 2000 E. Greenville Street, and houses the 72-bed "Women's and Children's Hospital." The North Campus is considered a "remote location" under 42 C.F.R. § 413.65(a)(2).

The Provider filed a request with the MAC for SCH designation on December 21, 2016. The MAC reviewed this request and determined that the Provider did not qualify for SCH designation as it did not meet the distance requirement set forth in 42 C.F.R. § 412.92(a). The MAC used the locations of both the Provider's Main Campus and North Campus in evaluating the distance criteria of "between 25 and 35 miles from other like hospitals." The MAC found that the North Campus was less than 25 miles from two other "like" hospitals. Thus, the request for SCH designation was denied.

ISSUE AND BOARD DECISION

The issue was whether the Provider's request for sole community hospital (SCH) designation by CMS and the MAC was proper.

The Board held that CMS and the MAC improperly denied the Provider's request for SCH designation, and that the Provider should be approved for an SCH designation effective for discharges on or after August 25, 2017.

The Board stated that the MAC denied the Provider's application for SCH designation based on its determination that the Provider's North Campus is a "remote location" as defined in 42 C.F.R. § 413.65(a)(2), and that this location does not meet the distance requirements in 42 C.F.R. § 412.92(a)(1), as it is not located 25 miles or more from other like hospitals.

The Board found that a plain reading of 42 C.F.R. § 412.92 confirms that the term "the hospital" as used therein necessarily encompasses both the Provider's Main Campus and the Provider's North Campus; and that the distance requirement should only have been measured from the Main Campus where the "front entrance of the hospital" is located. The Board found that while the MAC pointed out that CMS stated in the FY 2019 IPPS Final Rule that it was clarifying its longstanding policy to measure from both the main and remote location for distance calculations, there is no support for this. The Board found that the regulation at 42 C.F.R. § 412.92(c)(1) as it existed in 2017 was very specific in determining mileage by measuring up to "*the* front entrance of *the* hospital" and does not mention remote locations or multiple front entrances (emphasis by Board). The Board found that absent evidence to the contrary, the plain meaning of the regulation references a single entrance of a single building, as does the singular use of "the hospital" in the phrase "The hospital is located between 25 and 35 miles from other like hospitals."[1]

The Board pointed out that in the FY 2002 IPPS rulemakings (both the proposed and final rules), in discussing how mileage is to be calculated from an SCH to a like hospital, CMS states the mileage calculation is to include the "paved surfaces up to the front entrance of the hospital", and notes that this definition provides consistency with the Medicare Geographic Classification Review Board (MBCRB) definition of mileage. Based on this, the Board argued, the regulation at §412.92(c)(1) must be interpreted consistent with the then-existing MGCRB definition of "miles" where distance from the hospital is measured based on paved surfaces from the front door of the "main" hospital.

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[11] The Board also pointed out in a footnote that the Provider Reimbursement Manual (PRM) 15-1 § 2810 (Rev. 479) addresses the requirements for a hospital to be designated as an SCH and describes in great detail the information and documentation that must be included in an application. These provisions do not require information on a hospital's remote location, and do not require distance measurements from remote locations to other like hospitals.

The Board noted that in the FY 2008 IPPS Final Rule, where CMS formally adopted a rule for Critical Access Hospitals (CAHs) measuring distance from both a main campus and a remote location, CMS specifically noted that CAHs were different, and that this distance-based requirement did not apply to other rural entities. Thus, the Board found that based on CMS' own comments, the new requirement to use a CAH's remote location when measuring distance to other hospital was not meant to apply to SCHs.

Finally, the Board averred that CMS itself noted that there was nothing in the regulation regarding multicampus hospitals, stating in the preamble to the FY 2019 IPPS Final Rule that:

> [T]he regulations at § 412.92 for sole community hospitals (SCHS)…do not directly address multicampus hospitals. Thus, in the FY 2019 proposed rule, we proposed to codify in these regulations the policies for multicampus hospitals that we have developed in response to recent questions regarding CMS' treatment of multicampus hospitals for purposes other than geographic reclassification under the MGCRB.[2]

The Board found that in this preamble discussion, the Secretary conceded that the existing regulations did not contain a policy for multicampus hospitals, and also found that the Secretary's prior multicampus policy was initially developed and applied in the context of MGCRB reclassification, and that that application of such policies to the requirements of § 412.92(a) was new, and developed in response to "recent questions" regarding CMS treatment of multicampus hospitals. Thus, the Board concluded, the multicampus policies published in the FY 2019 IPPS Final Rule were not in place at the time of the Provider's SCH application. Additionally, the Board found, the policy was not a "clarification" of a long-standing policy, but rather, a change in policy, and thus, cannot be applied retroactively to the Provider's 2017 application.[3]

The Board pointed to the Supreme Court's recent decision in *Azar v. Allina Health Services*[4] in support of its conclusion that the policy underlying the revisions to 42 C.F.R. § 412.92 were a substantive policy change and thus cannot be applied retroactively. Additionally, the Board noted, applying the concepts of Allina casts further doubt on the Secretary's claim that considering remote locations in the measurement of miles from a like hospital for purposes of the § 412.92(a) requirements for SCH designations was policy prior to the FY 2019 IPPS Final Rule. The Board looked to 42 C.F.R. § 412.92(b) as it existed prior to the FY 2019 IPPS Final Rule. First, the Board noted, § 412.92(b)(3)(ii) (2017) listed five specific events that, if any of them occurred, a hospital's SCH classification would be affected and the SCH must communicate that event to its Medicare contractor within 30 days. Second, the Board noted, § 412.92(b)(3)(iii) (2017) included a

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[2] 83 Fed. Reg. 41,144, 41,369-70 (Aug. 17, 2018).

[3] The Board noted that the MAC did not produce any written CMS policy statements issued prior to the FY 2019 IPPS Final Rule that provided notice of CMS' policy regarding multicampus hospitals as it related to SCH designations.

[4] 139 S. Ct. 1804 (2019).

catchall reporting requirement for any changes beyond those listed in (b)(3)(ii) that would affect a sole community hospital's classification. The Board argued that if opening a remote location affected a hospital's continued status as an SCH in 2017, then CMS would (and should) have either listed it as an event that required reporting, or clearly stated that requirement elsewhere so that SCHs would have clear and proper notice of the requirement.

Thus, the Board concluded that, at the time of the Provider's SCH determination in 2017, CMS did not have a "longstanding" policy with regard to the application of the distance requirements to remote locations and the § 412.92(a) requirements for SCH designation cannot be construed to include such a policy. As such, the Board found that the MAC improperly denied the Provider's request for as SCH designation based on the MAC's determination that the Provider's North Campus was less than 25 miles from a like hospital. The Board concluded that the Provider satisfied the regulation at 42 C.F.R. § 412.92(a)(1) (2017) because the "front entrance to the hospital" can only mean the front entrance of the Provider's main campus, and this entrance meets the § 412.92(a)(1) requirement that it be located "between 25 and 35 miles from other like hospitals."

SUMMARY OF COMMENTS

The Provider submitted comments, requesting that the Administrator uphold the Board's decision.[5] The Provider noted that the Board's decision is principally based on the definition of "miles" at 42 C.F.R. § 412.92(c)(1). The Provider stated that the Board correctly held that the plain language of the regulation dictates that the mileage criteria applicable to SCHs requires measurement from only one point—the front entrance of the hospital. The Provider argued that the Board's reasoning follows a long line of decisions that require a reviewing court or administrative body to follow the plain meaning of a regulation's text, and that deference is only owed to an agency's interpretation when a regulation is ambiguous.[6] In this case, the Provider claimed, the language of the regulation is not ambiguous. Rather, the regulation in effect at the time the Provider applied for SCH status plainly stated that the distance measurement should be taken from the front entrance of the hospital. The Provider pointed out that CMS made corroborating statements as to the fact that the distance should be measured from the front entrance of the hospital only.[7]

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[5] The Provider also commented that the Administrator should uphold the Board's ruling to exclude MAC's Exhibits C-10 through C-14, which was based on the Board's finding that timing of the submission was late.

[6] *Citing Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000).

[7] 66 Fed. Reg. 39,828, 39,874 (Aug. 1, 2001) ("Under §412.92(c)(1), we define mileage. We believe that mileage should continue to be measured by the shortest route over improved roads maintained by any local, State, or Federal government entity for public use. We consider improved roads to include the paved surface up to the front entrance of the hospital because this portion of the distance is utilized by the public to access the hospital. This definition provides consistency with the interpretation of the MGCRB when considering hospital reclassification applications."); 72 Fed. Reg. 66,580, 66,880-81 (The Provider pointed out that the regulation change to address off-campus requirements for all Critical Access Hospitals (CAHs) applied only to newly created or acquired off-campus

The Provider pointed out that the Supreme Court's recent ruling in *Azar v. Allina Health Services* is controlling in this case.[8] In *Allina*, the Supreme Court held that CMS must promulgated regulations that establish or change a "substantive legal standard" through notice and comment rulemaking. The Provider argued that in the FY 2019 IPPS Final Rule, CMS asserted that its new regulation measuring distance from remote locations of SCHS was merely a codification of its "existing" policy. However, the Provider noted, the contents of the rule, not its label, dictate whether this regulation established a new substantive legal standard. The Provider argued that CMS clearly adopted a new "substantive legal standard" and was not merely codifying existing policy. Thus, the change to the regulation cannot be applied retroactively. CMS explicitly acknowledged in the preamble to the Final Rule that its policy on measuring distance for remote locations of SCHs was "adopted in response to recent questions". Thus, the Administrator should uphold the Board's decision that the MAC should only have measured the distance up to the front entrance of the Main Campus location for purposes of meeting the SCH distance criteria.

The MAC submitted comments, requesting that the Administrator reverse the Board's decision and confirm the denial of SCH designation for the Provider. The MAC noted that its utilization of the Provider's North Campus location in measuring distance was proper, as inpatient services are provided at that location. The MAC pointed out that the purpose of the distance measurement is to ensure that the Provider is the sole provider of inpatient services within a given geographic area. The MAC stated that the Board's ruling does not give this purpose the proper weight or consideration.

The MAC argued that the FY 2019 IPPS Final Rule clarified the regulations and specifically required the inclusion of each facility that offers inpatient services when calculating the distance requirement. The MAC stated that while the SCH regulations for FY 2017 do not mention whether each location must meet the distance requirement, it is implied if the remote location offers inpatient services. The MAC argued that because the purpose of the distance measurement is to assure that a provider is the sole source of those services in a given geographical area, and that "sole" means "only". Otherwise, the MAC noted, a provider could have multiple remote locations that offer inpatient services within a given geographical area. This would allow a provider to circumvent the purpose of the distance requirement. Thus, the MAC averred, it was proper to measure the distance from each of the Provider's two locations.

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provider-based locations, thus grandfathering in existing off-campus provider-based locations. CMS also did not choose to apply this regulation change to SCHs.); "CMS, Sate Operations Manual, Appendix W- Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs", available online at www.cms.gov/Regulations-and-Guidance/Guidance/transmittals/downloads/R49SOMA.pdf (Transmittal amending State Operations Manual to incorporate change adopting new mileage criteria for CAHs. The Provider pointed out that there was no corresponding change made for SHCs.).

[8] 139 S. Ct. 1804 (2019).

DISCUSSION

The entire record, which was furnished by the Board, has been examined, including all correspondence, position papers, and exhibits.[9] The Administrator has reviewed the Board's decision. All comments were received timely and are included in the record and have been considered.

The operating costs of inpatient hospital services are reimbursed by Medicare primarily through the Inpatient Prospective Payment System (IPPS). The IPPS provides Medicare payment for hospital inpatient operating and capital related costs at predetermined, specific rates for each hospital discharge. The IPPS also allows special treatment for facilities that qualify as an SCH. The main statutory provisions governing SCHs are located in § 1886(d)(5)(D)(iii) of the Social Security Act (Act). A SCH is defined as any hospital:

> (I) that the Secretary determines is located more than 35 road miles from another hospital,
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> (II) that, *by reason of factors such* as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, *or absence of other like hospitals (as determined by the Secretary),* is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A of this subchapter, or
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> (III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1395i–4(i)(1) of this title as in effect on September 30, 1997.

The regulation at 42 C.F.R. § 412.92(a)(1) (2017) details the criteria that a hospital must meet in order to obtain SCH status:

> § 412.92 Special treatment: Sole community hospitals.
>
> (a) *Criteria for classification as a sole community hospital*. CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, *or it is located in a rural area (as defined in §412.64) and meets one of the following conditions*:
>
> (1) *The hospital is located between 25 and 35 miles from other like hospitals* and meets one of the following criteria:

[9] Exhibits C-10 through C-14 were not considered, per the Board's evidentiary ruling, and is not considered here only because of the procedural lateness of the submission.

> (i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;
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> (ii) The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or
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> (iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.
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> (2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.
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> (3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

The terms "miles," "like hospital", and "service area" are defined in the regulation under subsection (c):

> (c) *Terminology*. As used in this section—
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> (1) The term *miles* means the shortest distance in miles measured over improved roads. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road includes the paved surface up to the front entrance of the hospital.
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> (2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

> (3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital.

Relevant to this case, the regulation at 42 C.F.R. § 413.65, "Requirements for a determination that a facility or an organization has provider-based status" at paragraph (a)(2), defines the following terms:

> *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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> *Provider-based entity* means a provider of health care services, or an RHC as defined in §405.2401(b) of this chapter, 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, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.
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> *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.
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> *Remote location of a hospital* means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

In this case, the Provider is an acute care hospital located in Anderson, South Carolina, and is considered an urban hospital, The Provider filed a request with the MAC for SCH designation on December 21, 2016 and concurrently requested reclassification under 42 CFR 412.103 for rural designation if SCH status would be granted. The Provider operates two campuses. The AnMed Health Medical Center Campus is located at 800 North Fant Street, and houses a 461-bed acute care hospital. The AnMed Health North Campus, where the AnMed Health Women's and Children's Hospital Campus is located at 2000 E. Greenville Street, and houses a 72-bed Women's and Children's Hospital. The North Campus is considered a "remote location of a hospital" under 42 C.F.R. § 413.65(a)(2). The MAC in denying the request stated that:

> As AnMed Health provides inpatient services on two campuses (800 North Fant St. and 2000 E.Greenville St.), both hospital locations were evaluated for the distance criteria of "between 25 and 35miles from other like hospitals." It was found that the 2000 E Greenville St. location is less than 25 miles from two other hospitals (Baptist Easley Hospital and Greenville Memorial Hospital). As a result, the distance requirement is not met.[10]

The record shows that the North Campus opened in 2005. The services listed as provided in this 72-bed facility included: adult surgery, inpatient pediatric care[11], maternity services, joint replacement surgery.[12] The listing of services shows an admitting office for the North Campus "Women's and Children's Hospital." [13] AnMed presents the two campuses as follows:

> Med Health has grown from an inpatient community hospital to a multidisciplinary system with nearly 60 locations. While we have offices around the Upstate and northeast Georgia, many of our services are located on two campuses along East Greenville Street in Anderson.
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> The AnMed Health Medical Center Campus is at the corner of East Greenville and North Fant Streets in downtown Anderson. This location has been home

[10] Exhibit C-2. The MAC did not challenge any other criteria as not met.

[11] The Provider refers to the remote location of the hospital as a "women's and children's hospital", but it does not appear that the reference to a "children's hospital" is in the context of 42 CFR § 412.23. ("42 C.F.R. § 412.23 Excluded hospitals: Classifications. Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in § 412.1(a)(. 1):… (d) *Children's hospitals.* A children's hospital must - (1) Have a provider agreement under part 489 of this chapter to participate as a hospital; and (2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.")

[12] *See, e.g.,* Exhibit I-7 for excerpts from the Provider's website and other internet cites regarding the provided services provided at the North Campus.

[13] https://anmedhealth.org/locations/north-campus

> to AnMed Health's acute, inpatient services since the original Anderson County Hospital opened in 1906. The Medical Center Campus includes AnMed Health Medical Center, AnMed Health Heart and Vascular Center, most of the system's support and professional staff, and a number of doctors' offices along North Fant Street.
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> The AnMed Health North Campus is two miles up the road at the corner of East Greenville Street and East Reed Road in Anderson. The North Campus is home to AnMed Health Women's and Children's Hospital, where thousands of babies are born each year. The North Campus is also where you will find most of our outpatient and diagnostic services. The North Campus includes AnMed Health Cancer Center, AnMed Health Rehabilitation Hospital and more than 30 doctors' offices.[14]

Applying the law to the facts of this case, the Secretary has properly determined that, where a hospital has more than one location providing inpatient hospital services, each location of the hospital must meet the relevant SCH criteria for designation. Such a reading is consistent with the plain language of the statute at § 1886(d)(5) of the Act, which defines a SCH, as a hospital, that by reason of the absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under Part A. In particular, as codified in the regulation at 42 C.F.R. § 412.92, in determining that the hospital is located less than 25 miles from other like hospitals and, therefore, does not meet the criteria to be between 25 and 35 miles from other like hospitals, the Secretary's delegatee determines the mileage from the front entrance of the "hospital' to the like hospital(s). In this case, the Hospital is comprised of two locations and therefore the mileage to the like hospital(s) was determined from the front entrance of the Medical Center campus and the front entrance of the Women's and Children's Hospital as both locations provide IPPS services. The "Hospital" as defined by the Act[15], is comprised of two campuses that are providing IPPS services and the "Hospital" must accordingly, meet the mileage rule for both campuses in order to qualify as an SCH.

The Provider argued that the MAC's application of the rule to both locations was an incorrect reading of the statute and regulation, and should have been only to the "main" campus. The Provider also argued that the north campus, which comprised the remote location at 2000 E Greenville St., does not present as a "hospital" as it does not operate an Emergency Room and serves only a small subset of individuals. Without an emergency

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[14] https://anmedhealth.org/locations

[15] Section 1861(e) of the Act defines a "hospital". The definition does not distinguish or recognize separate identities for multicampus hospital locations. Consequently, the SCH rules at § 1886(d)(5)(D)(iii) of the Social Security Act defines an SCH, qualified based on mileage, as any "hospital" "that the Secretary determines is located more than 35 road miles from another hospital." The Secretary's delegated official has determined that the hospital in this case with a remote location within the mileage criteria set forth in the rule, cannot meet this criterion.

room, the Provider stated that the location cannot be certified by the State as a distinct acute- care hospital and cannot be licensed by Medicare as a distinct acute care hospital. Only by being a remote location of the main hospital (800 North Fant St.) is the remote location able to provide inpatient hospital services. The Provider maintained that the remote location is not a "hospital furnishing short- term, acute care", rather it is a remote location of a hospital and it does not meet the definition of a hospital under § 1886(d)(1)(B) of the Social Security Act or the definition of a "like" hospital under 42 C.F.R. § 412.92(c)(2). The Provider contends that the location should be excluded as a starting point for any measurement within the context of determining SCH status.

While the Provider argues the remote location is, in essence, less than a hospital, the CMS' establishment under §413.65 of provider-based status, including remote locations of hospitals, as defined in paragraph (a)(2), recognizes that a "Hospital" includes a location that will not independently meet the condition of participation, but is still the site of IPPS services for the Hospital, for which payment may be made. Both the main location and remote location are the "Hospital" and provide the IPPS services under the one provider agreement. Consequently, regardless of whether the remote location could meet the independent conditions of participation, it is one of the two locations for IPPS services. To determine whether the Hospital "is the sole source of *inpatient hospital services* reasonably available to individuals in a geographic area who are entitled to benefits under Part A" the mileage from both sites of inpatient services of the "Hospital" to "like" hospitals must be determined.

The Provider and the Board argued that the foregoing is "new policy" or a change in policy, which must be promulgated pursuant to notice and comment rulemaking, prospectively. However, the policy applied in this case is consistent with the plain statutory and regulatory language and is not a new or change in policy. CMS responded to similar comments in 2018, after receiving an increasing number of inquiries regarding the treatment of multicampus hospitals as the number of multicampus hospitals grew. CMS codified its policies regarding multicampus hospitals in the FY 2019 IPPS Final Rule.[16] CMS explained that to qualify for SCH status, "it would be insufficient for only the main campus, and not the remote location, to meet the distance criteria" contained in 42 § 412.92(a). Thus, relevant to the Provider in this case, CMS restated the policy expressed in the denial letter, that both the main campus and its remote location must be located between 25 and 35 miles from other like hospitals.

As CMS explained in the final rule, it was not promulgating a rule retroactively, as these were longstanding policies and were not changes to existing policy. Requiring both the main campus and remote location to meet the criteria of 42 § 412.92(a) is necessary to show that the hospital is indeed the sole source of inpatient hospital services reasonably available to individuals in a geographic area as required by the statute.

[16] 83 Fed. Reg., 41,144, 41,369-74 (Aug. 17, 2018). *See also* FY 2019 Proposed Rule, 83 Fed. Reg. 20,164, 20.358-60 (May 7, 2018)

In addition, CMS explained the operational origins of the policy, which reflected the legal status of a multicampus hospital, that have existed from the start of the growth of these healthcare arrangements under IPPS that: "[E]ach remote location of a hospital is included on the main campus's cost report and shares the same provider number. That is, the main campus and remote location(s) would share the same status or rural reclassification because the hospital is a single entity with one provider agreement. Second, it would not be administratively feasible for CMS and the MACs to track every hospital with remote locations within the same CBSA and to assign different statuses or rural reclassifications exclusively to the main campus or to its remote location."[17]

In addition, the Provider's request for SCH status in 2010 was denied for this same reason. In its denial of the Provider's 2010 request, the Medicare contractor found:

> The provider states that it meets the SCH criteria under 42 CFR Section 412.92(a)(1)(i). Part of those criteria requires the hospital to be located between 25 and 35 miles from other "like hospitals". The North Campus facility, Women's and Children Hospital, does not meet this requirement per documentation provided.[18]

Thus, this policy set forth in this SCH determination was not a "new" policy, and the Provider was, in fact, had personal notice of the fact that it was not eligible to be designated as an SCH as early as 2010, because its North Campus location did not meet the distance requirements of 42 C.F.R. § 412.92(a).[19] CMS also responded in the final rule to similar arguments that:

> In response to the commenters' questions regarding the effective date of the policies discussed in the proposed rule, we reiterate that we proposed to codify in the regulations our existing policies for multicampus hospitals, and thus these policies have been and continue to be in effect. Consequently, there is no need to "grandfather in" multicampus hospitals with existing special statuses or reclassifications. Similarly, we disagree that we are promulgating a rule retroactively because these policies are CMS' longstanding policies. *We note that the commenter's assertion that these*

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[17] 83 Fed. Reg. 41,369.

[18] *See* MAC Exhibit C-16. Letter dated December 21, 2010 from Dale K. Kendrick, Associate Regional Administrator, Division of Financial Management & Fee-for-Service Operation denying AnMed Health's request for Sole Community Hospital Classification.

[19] The description of the policy, as longstanding, must also be viewed in the context of the shorter timeframe within which multicampus hospitals have been established and grown as a healthcare model under Medicare rules giving rise to these issues. In addition, neither the Provider, nor commenters, to the 2019 IPPS rule submitted evidence of a contrary application by CMS of the SCH rules to multicampus hospitals.

> *proposed codifications are a change in longstanding CMS policy were not accompanied by examples of CMS treating multicampus facilities as distinct entities.*[20]

The Provider also references a 2002 preamble describing that mileage for the SCH criteria should be a measure to include "paved surfaces up to the front entrance of the hospital." The Board concluded that the mileage for SCH status at 42 CFR § 412.92(c)(1) must be interpreted consistent with "then-existing" MGCRB definition of "miles" where distance from the hospital is measured based on paved surfaces from the front door of the "main hospital" although the Board recognized that the MGCRB rules were not incorporated by reference in the regulation. While the Board relied on the fact there is no reference to mileage to the plural hospitals or campuses. However, there is no reference to the "main hospital" in the discussion of the SCH mileage provision[21] or in the text of the regulation. Measuring to the entrance of the hospital is not inconsistent with the calculation completed in this case where mileage was calculated to the front entrance of the hospital via paved roads to its two locations that comprise "the" Hospital. The fact that the reference in the regulation and statute is to a singular "hospital" does not negate this reading as there always only one Hospital, under Medicare rules, being evaluated even if the Hospital has more than one location or campuses operating under that provider agreement.

The Provider also pointed out, as significant, the CMS response to a 2008 preamble discussing CAH requirements. The Provider incorrectly states that CMS specifically suggested that distance rules would not apply to the remote location of SCH applicants and that, to the extent CMS was applying such a rule to SCHs, it would have explicitly stated it in this rule. However, CMS made changes specific to CAHs in this rule because of statutory changes and the possible impact on its State's Medicare Rural Hospital Flexibility Program (MRHFP). CMS explained that: "As stated above, CAHs by statute and regulation must comply with the distance requirements. As such, we view this rule as a clarification on the distance requirements of participation for CAHs and their provider-based locations and off-campus distinct part units in light of the change in statute concerning necessary provider designations." Consequently, the rule was promulgated in response to CAH specific statutory changes.[22]

The Board agreed with the Provider that the CMS application of the distance criteria for CAHs specifically excluded SCHs from similar treatment. The Board's conclusion was

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[20] 83 Fed. Reg. 41,372.

[21] As noted by CMS in the foregoing 2018 preamble, the MGCRB rules for reclassification in dealing with the multicampus hospitals are controlled by the statutory provisions regarding the adjustment of wage levels under section 1886(d)(3)(E) of the Act where wages of the multicampus hospital are recognized, and its impact and on reclassification rules under section 1886(d)(10) of the Act, CMS tracks multicampus remote locations located in different CBSAs for wage index purposes only, in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act

[22] 72 Fed. Reg. 42,628, 42,805-42,807 (2007)

based on CMS' response to a combination of comments including one received from an SCH, that stated:

> [I]ts Medicare designation as a sole community hospital has geographic limitations, but that it should not be threatened with loss of its special reimbursement status if it meets community needs by developing provider-based or off-campus services. The commenter questioned why CMS is treating CAHs differently.[23]

The SCH does not refer to concerns about losing its SCH designation (or CAHs losing theirs) due to having a "remote located hospital", but rather due to it developing "provider-based"[24] (a technical term) or "off-campus services" to serve the community. It is not evident from the statement that CMS' response, referring to CAHs' special status compared to other rural entities, was addressing or even suggesting SCH remote location hospitals would be exempt from the distance requirements to retain their status.[25] The CMS response

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[23] CMS response to the combined comments stating that: "We believe the distance requirement is a statutory requirement that reflects the intent of the CAH program to provide hospital-level services in essentially small rural communities. Our proposal reflects this understanding and the special status of CAHs (as opposed to other rural entities) and should not limit access to care." CMS went on to state that: "However, CAHs (including necessary provider CAHs) will still be able to acquire and create new provider-based clinics as long as those provider-based clinics are either RHCs or entities that comply with the distance requirements for a CAH that are allowed under the Act and under the requirements. In addition, all CAHs will be able to establish provider-based entities on their campus."

[24] Regarding the definition of a provider based entity, 42 CFR 413.64, states that "A *provider based entity* means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, 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, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity"

[25] Regarding the special status of CAHs, they are, as CMS noted, statutorily established and receive 101 percent of reasonable costs payment with a significant number having health clinics, psychiatric units, and rehabilitation units. CMS stated that: "We do not know how many of the existing clinics and distinct part units are at off-site locations. However, we are concerned with CAHs creating or acquiring off-campus locations, including distinct part psychiatric and rehabilitation units, that do not comply with the CAH location requirement relative to other facilities. Therefore, when such off-campus facilities are created by a CAH with a necessary provider designation, there is no reason to assume that

recognizes the special statutory basis for CAHs and the unique situation for CAHs where even the CAH's provider-based clinic(s) (other than an RHC) and excluded units are considered part of the CAH and are paid the same as the CAH, that is, 101 percent of reasonable cost and therefore is part of the CAH's distance calculation. In contrast, provider-based/off-site clinics and excluded units are not paid under IPPS and are not involved in the determination of SCH status. The policy treatment of the various off-site entities under the CAH provisions, required due to CAH statutory changes, does not address, nor is relevant to, SCH determinations, and was properly not addressed in this rule.

Therefore, the Administrator reverses the Board's decision. The MAC properly determined that the Provider did not meet the mileage requirements to qualify for designation as an SCH.

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the distance exemption given to the CAH should be extended without qualification to any location for that CAH's off-campus facilities. Accordingly, any CAH off-campus locations must satisfy the current statutory CAH distance requirements, without exception, regardless of whether the main provider CAH is a necessary provider CAH…. Accordingly, any CAH off-campus locations must satisfy the current statutory CAH distance requirements, without exception, regardless of whether the main provider CAH is a necessary provider CAH. Therefore, in the CY 2008 OPPS/ASC proposed rule (72 FR 42807), we proposed to clarify that if a necessary provider CAH, or a CAH that does not have a necessary provider designation, operates a provider-based facility as defined in § 413.65(a)(2), or a psychiatric or rehabilitation distinct part unit as defined in § 485.647 that was created or acquired on or after January 1, 2008, it must comply with the distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain or in areas with only secondary roads)."

DECISION

The decision of the Board is reversed in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: October 29, 2020

/s/
Demetrios L. Kouzoukas
Principal Deputy Administrator
Centers for Medicare & Medicaid Services