UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANMED HEALTH, *Plaintiff*, v. XAVIER BECERRA,[1] *Defendant.*	Civil Action No. 20-3826 (RDM)

MEMORANDUM OPINION

Plaintiff AnMed Health ("AnMed") operates a hospital with two campuses—the main North Fant Street Campus and the remote North Campus—less than 3 miles apart from one another in Anderson, South Carolina. In 2016, AnMed applied for classification as a sole community hospital under the Medicare program. *See* 42 C.F.R. § 412.92. If approved, AnMed would be reimbursed at a higher rate for services provided to Medicare beneficiaries at both of its campuses. To qualify as a sole community hospital under the relevant portion of the governing regulations, AnMed was required to show that it was located more than 25 miles "from other like hospitals." *Id.* § 412.92(a)(1).

The Centers for Medicare and Medicaid Services ("CMS") rejected AnMed's application for failure to satisfy the distance requirement because the hospital's remote North Campus was located less than 25 miles (*i.e.*, 23.8 miles) from a like hospital. AnMed appealed, arguing that the Medicare statute and governing regulations required that AnMed satisfy the distance requirement only as to its main North Fant Street Campus, which was located more than 25 miles

[1] Xavier Becerra is substituted for his predecessor, Alex M. Azar II, as the Secretary of Health and Human Services. Fed. R. Civ. P. 25(d).

from a like hospital. On appeal, the Provider Reimbursement Review Board (the "Board") agreed with AnMed and held that its application should have been approved. The Secretary of the Department of Health and Human Services (the "Secretary"), however, acting through the Principal Deputy Administrator of CMS, reviewed the Board's decision and reversed.

AnMed brings this action pursuant to the Medicare statute, 42 U.S.C. § 1395oo(f), challenging the Secretary's decision, which it contends (1) was not dictated by the Medicare statute; (2) is contrary to the plain language of the then-applicable regulations and to the Secretary's own interpretation of those regulations; and (3) impermissibly gives retroactive effect to a regulation adopted after the relevant reporting period. The parties' cross-motions for summary judgment are now before the Court.

For the reasons explained below, the Court will **DENY** AnMed's motion for summary judgment and will **GRANT** the Secretary's cross-motion.

I. BACKGROUND

A. Statutory and Regulatory Background

1. *Sole Community Provider Rule*

Established in 1965, the Medicare program "provides health insurance for the elderly and disabled and reimburses qualifying hospitals for services provided to eligible patients." *Cath. Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 915–16 (D.C. Cir. 2013). In 1972, Congress authorized the Secretary of Health, Education, and Welfare to set prospective limits on costs that hospitals could recover for services provided to Medicare beneficiaries. Social Security Amendments of 1972, Pub. L. No. 92-603, § 223, 86 Stat. 1329, 1393–94 (1972). The statute did not give special consideration to hospitals that were the sole providers of Medicare services in their communities. The congressional committees that reported the legislation,

however, indicated that they "expect[ed] that the provision [would] not be applicable where there is only one hospital in a community" because "additional charges could be imposed on beneficiaries who have no real opportunity to use a less expensive, non-luxury institution, and where the provision would be difficult to apply because competitive cost data for the area are lacking." S. Rep. No. 92-1230, at 188 (1972); H.R. Rep. No. 92-231, at 84 (1971) (same). In light of these concerns, the Secretary of Health, Education, and Welfare promulgated regulations exempting "sole community provider[s]" from Medicare reimbursement limits "where a provider[,] by reason of factors such as isolated location or absence of other providers of the same type, is the sole source of such care reasonably available to beneficiaries." 20 C.F.R. § 405.460(f)(4) (1975).

The "sole community provider" designation remained purely regulatory until 1983, when Congress overhauled the Medicare provider reimbursement process by establishing the Inpatient Prospective Payment System ("IPPS"). Under the IPPS, hospitals now receive fixed payments for inpatient services at prospective rates set by the Secretary (by this time, Congress had created the Department of Health and Human Services). *See generally* Social Security Amendments of 1983, Pub. L. No. 98–21, tit. VI, §§ 601–07, 97 Stat. 149, 158 (1983). Congress adopted this system "to improve the medicare system's ability to act as a prudent purchaser of services, and to provide predictability regarding payment amounts for both the Government and hospitals." H.R. Rep. No. 98-25, at 132 (1983). Most importantly, the system was adopted "to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost/effective hospital practices." *Id.* At the same time, however, Congress remained concerned about communities with only one hospital, and it therefore established a separate and more generous reimbursement formula for "sole community hospital[s]," which are statutorily

defined as "hospital[s] that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals (as determined by the Secretary), [are] the sole source of inpatient hospital services reasonably available to individuals in a geographical area who are entitled to benefits under [Medicare] part A." Pub L. No. 98–21 § 601(e), 97 Stat. 158.

Congress has amended the statutory definition of a "sole community hospital" or ("SCH") several times since it first appeared in 1983. Under the current definition, which is applicable to the events at issue in this case, an SCH is 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, 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.

42 U.S.C. § 1395ww(d)(5)(D)(iii).

CMS, which administers the Medicare program on behalf of the Secretary, has promulgated regulations implementing this provision. *See* 42 C.F.R. § 412.92. Under those regulations, "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 . . . and meets one of [several alternative] conditions." *Id.* § 412.92(a) (emphasis added). As relevant here, those alternative conditions include that "[t]he hospital is located between 25 and 35 miles from other like hospitals and" the hospital satisfies one of three additional criteria, *id.* § 412.92(a)(1)(i)-(iii),

which are not at issue for present purposes.[2] The SCH regulations define "miles" to mean "the shortest distance in miles measured over improved roads." *Id.* § 412.92(c)(1). An "improved road," in turn, is defined to include (1) "any road that is maintained by a local, State, or Federal government entity and [that] is available for use by the general public" and (2) "the paved surface up to the front entrance of the hospital." *Id.*

The regulations define a "like hospital" to mean:

> 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.

Id. § 412.92(c)(2). Under this rule, CMS uses "inpatient days as the unit of measurement for determining" whether hospitals provide "overlapping services," and a hospital is an "other like

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[2] Those criteria include the following:

> (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 MAC 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.

42 C.F.R. § 412.92(a)(1).

hospital" if "the total acute inpatient days of the nearby hospital is greater than 8 percent of the total inpatient days reported by the SCH applicant hospital." Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates, 67 Fed. Reg. 49,982, 50,054–55 (Aug. 1, 2002).

To apply for classification as an SCH, a hospital must submit a request to its Medicare Administrative Contractor ("MAC"), a private contractor that processes reimbursement claims on behalf of CMS. 42 C.F.R. § 412.92(b)(1)(i); *see also* 42 U.S.C. § 1395h. The MAC then reviews the hospital's request and sends it, with a recommendation, to CMS. 42 C.F.R. § 412.92(b)(1)(iv). CMS, in turn, reviews the request and the MAC's recommendation and "forward[s] its approval or disapproval to the MAC." *Id.* § 412.92(b)(1)(v). If the hospital is dissatisfied with CMS's determination, it may file an appeal with the Provider Reimbursement Review Board, an administrative tribunal "composed of five members appointed by the Secretary," which has "the power to affirm, modify, or reverse a final determination." 42 U.S.C. § 1395oo(a), (d), (h); *see also* 42 C.F.R. § 412.92(b)(2)(ii). The Board's decision is "final unless the Secretary, on his own motion, and within 60 days after the [hospital] is notified of the Board's decision, reverses, affirms, or modifies the Board's decision." § 1395oo(f)(1). The provider may seek judicial review "within 60 days of the date on which notice of any final decision by the Board or any reversal, affirmance, or modification by the Secretary is received." *Id*.

2. *Provider-Based Status*

Since the beginning of the Medicare program, some hospitals have owned, operated, and financially and clinically administered subordinate medical facilities—including off-campus

facilities—under the umbrella of a single entity.[3] Prior to the creation of the IPPS in 1983, "there was little incentive for providers to affiliate with one another merely to increase Medicare revenues . . . because at that time each provider was paid primarily on a retrospective, cost-based system." 65 Fed. Reg. at 18,504. The creation of the IPPS, however, generated "financial and organizational incentives" for hospitals to acquire additional facilities and to bill Medicare as a single unit. *Id.* In the fifteen years following the IPPS's creation, the number of affiliated facilities claiming a Medicare status as a single hospital skyrocketed. *See* Medicare Program; Prospective Payment Systems for Hospital Outpatient Services, 63 Fed. Reg. 47,552, 47,587 (proposed Sept. 8, 1998). In response, CMS adopted requirements that main hospitals and their subordinate facilities must satisfy to obtain "provider-based" status for the subordinate facility—that is, to enable the subordinate facility to be viewed as "part of the hospital" for, among other things, billing purposes. 81 Fed. Reg. at 45,682; *see also* 42 C.F.R. § 413.65.

Current Medicare regulations set detailed conditions for obtaining "provider-based status," including when the main hospital seeks to treat "remote locations" as part of the "the hospital." 42 C.F.R. § 413.65(a)(1)(i). Under these regulations, a "provider-based status" arises when a "main provider" "creates, or acquires ownership of, another entity to deliver additional health care services under [the main provider's] name, ownership, and financial and administrative control." *Id.* § 413.65(a)(2). "[W]hether located on or off the campus of a potential main provider," CMS will grant a "facility or organization" "provider-based status"

[3] *See* Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,504 (Apr. 7, 2000) (to be codified at 42 C.F.R. pts. 409, 410, 411, 412, 413, 419, 424, 489, 498, 1003); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 45,604, 45,682 (proposed July 14, 2016) (to be codified at 42 C.F.R. pts. 416, 419, 482, 486, 488, 495).

only if both the main and affiliated facility (here, a "remote location") satisfy certain requirements. *Id.* § 413.65(d).

First, if permitted by state law, the main and remote locations must operate under the same license. *Id.* § 413.65(d)(1). Second, the "clinical services" of the main and remote locations must be "integrated as evidenced by the following:" (1) the professional staff at the remote location have "clinical privileges" at the main facility; (2) the main provider "maintains the same monitoring and oversight of the [remote facility] as it does for any other department of the provider;" (3) "[t]he medical director of the [remote facility] maintains a reporting relationship with the chief medical officer . . . of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer . . . of the main provider" and is "under the same type of supervision and accountability as any other director . . . of the main provider;" (4) "[m]edical staff committees . . . at the main provider are responsible for medical activities" at the remote facility; (5) "[m]edical records for patients treated in the [remote] facility are integrated into a unified retrieval system . . . of the main provider;" and (6) "[i]npatient and outpatient services" in the two facilities are integrated, so that "patients treated at the [remote] facility . . . who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department . . . of the main provider." *Id.* § 413.65(d)(2). Third, "[t]he financial operations of the" two facilities must be "fully integrated," and, fourth, the remote facility must be "held out to the public and other payers as part of the main provider," so that patients who enter the remote facility "are aware that they are entering the main provider and are billed accordingly." *Id.* § 413.65(d)(3)–(4).

Off-campus facilities or organizations, moreover, must meet additional requirements. *Id.* § 413.65(e). They must, for example, demonstrate that "[t]he facility or organization seeking provider-based status is operated under the ownership and control of the main provider." *Id.* § 413.65(e)(1). They must also meet location-based criteria: To qualify for provider-based status, an off-campus facility must be in the same state or an adjacent state as the main provider, *id.* § 413.65(e)(3)(vii), and must either be within 35 miles of the main provider, *id.* § 413.65(e)(3)(i), or "meet other specified location requirements designed to ensure that the campuses serve the same patient populations," *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1168 n.6 (D.C. Cir. 2015) (citing 42 C.F.R. § 413.65(e)(3)(ii)-(vi)).

As noted above, one type of facility that may obtain provider-based status is a "remote location of a hospital." 42 C.F.R. § 413.65. Under CMS regulations, a remote location of a hospital is defined, in relevant part, as:

> [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.

Id. § 413.65(a)(2). Like other provider-based facilities, remote locations of hospitals operate under the main provider's Medicare provider agreement, using the main provider's Medicare provider number, through which the remote location may bill for services provided to Medicare beneficiaries. *See id.* The main provider and the remote location "operate[] as a single institution with integrated finances, administration, and organization." *Anna Jacques Hosp.*, 797

F.3d at 1158. The combined hospital, known as a "multi-campus hospital," submits a combined Medicare cost report to the Secretary each year. *See id.* at 1158–59.

3. *2018 Sole Community Hospital Regulation*

Although not applicable here, in May 2018, CMS proposed an amendment to the SCH regulations regarding "the treatment of multicampus hospitals" that apply for SCH status. *See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates, 83 Fed Reg. 20,164, 20,358 (proposed May 7, 2018). According to the Notice of Proposed Rulemaking, CMS had "received an increasing number of inquiries regarding the treatment of multicampus hospitals as the number of multicampus hospitals has grown in recent years." *Id.* Recognizing that "the regulations at § 412.92 for sole community hospitals (SCHs) . . . do not directly address multicampus hospitals," CMS "propo[sed] to codify . . . the policies for multicampus hospitals that [it had] developed in response to recent questions." *Id.* Specifically, CMS proposed adopting the following language as one of the "[c]riteria for classification" under 42 C.F.R. § 412.92(a):

> For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (a)(1)(i) and (ii) of this section are met. *For the mileage and rural location criteria in paragraph (a) of this section and the mileage, accessibility, and travel time criteria specified in paragraphs (a)(1) through (3) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements*.

83 Fed. Reg. at 20,566 (emphasis added). In other words, CMS proposed that "a main campus of a hospital cannot obtain [SCH status] independently or separately from its remote location(s), and vice versa." *Id.* at 20,358.

CMS provided two reasons for proposing this regulatory text. First, "each remote location of a hospital is included on the main campus's cost report and shares the same [Medicare] provider number." *Id.* Put differently, "the main campus and remote location(s) would share the same status . . . because the hospital is a single entity with one provider agreement." *Id.* Second, it would not be "administratively feasible" for CMS to track every hospital with remote locations and to "assign different statuses . . . exclusively to the main campus or to its remote location." *Id.* Nor would such separation be appropriate because consideration of both the main and remote campus "is necessary to show that the hospital is indeed the sole source of inpatient hospital services reasonably available to individuals in a geographic area." *Id.* at 20,359.

After providing an opportunity for public comment, CMS approved the file rule on August 17, 2018, and the rule took effect on October 1, 2018. *See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates, 83 Fed. Reg. 41,144 (Aug. 17, 2018). All agree that the new rule does not itself apply retroactively, although the Secretary posits that it clarifies what was, in any event, prior existing policy. *See id.* at 41,371–72.

B. Factual Background

AnMed Health is an acute-care hospital with two locations in Anderson, South Carolina. The main campus, located at 800 North Fant Street, is a "full-service hospital" with 461 beds and

an emergency department. Administrative Record ("AR") 8, 75–76; *see also* AR 76 ("The Fant Street campus . . . do[es] basically everything but transplants."). AnMed describes the North Fant Street Campus as "home to AnMed Health's acute, inpatient services" and states that it "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." AR 17–18.

AnMed's remote location, known as the AnMed Health Women's and Children's Hospital or the North Campus, is located 2.61 miles north of the main campus at 2000 East Greenville Street. AR 76, 162. The North Campus is a 72-bed facility that lists the following services: "adult surgery, inpatient pediatric care, maternity services, [and] joint replacement surgery." AR 17. The North Campus does not have an emergency department; when a patient at the North Campus requires emergency services, the patient is transferred to the main campus. AR 76. According to AnMed's website, "[t]he North Campus includes AnMed Health Cancer Center, AnMed Health Rehabilitation Hospital and more than 30 doctors' offices." AR 18.

In 2010, AnMed applied for classification as an SCH and sought to establish that it satisfied the regulatory criteria for a hospital that is "located between 25 and 35 miles from other like hospitals." AR 199–202 (citing 42 C.F.R. § 412.92(a)(1)(i)). In a letter to CMS, the MAC assigned to AnMed's region identified "[t]he item of concern" regarding AnMed's application: "the location from which the mileage requirement is determined [when] there are two hospital campuses with inpatient services." AR 201. According to data obtained from Google Maps, the main North Fant Street Campus was located more than 25 miles away from "other like

hospitals," but the remote North Campus was not.[4] AR 200–01. The MAC thus determined that if the distance to "other like hospitals" was measured from the main campus only—as AnMed proposed in its application—"then AnMed Health is between 25 and 35 miles from other like hospitals." AR 200. But, if the distance to other like hospitals was "determined from the North Campus," then "the hospital is less than 25 miles from two hospitals." *Id.* Ultimately, the MAC concluded that the distance to other like hospitals should be measured from both campuses and recommended to CMS that "the SCH criteria is not met." AR 201. On December 21, 2010, CMS issued a denial letter to AnMed, explaining that AnMed "does not meet federal requirements found in 42 CFR 412.92 to be classified as a[n] . . . SCH[]" because "[t]he North Campus facility, Women's & Children Hospital, does not meet [the distance] requirement per documentation provided." AR 198. AnMed did not appeal that determination.

On December 21, 2016, AnMed again applied for SCH classification. AR 280–354. The hospital argued that it satisfied the mileage requirement based on CMS's regulatory definition of "miles." AR 281 (citing 42 C.F.R. § 412.92(c)(1)). AnMed maintained that the regulatory definition of "miles" does not merely require CMS to measure the "shortest distance . . . over improved roads . . . maintained by a local, State, or Federal government entity" and the "paved surface" leading up to the hospital, but also specifies the end point for the measurement: "the front entrance of the hospital." *Id.* (citing 42 C.F.R. § 412.92(c)(1)). According to AnMed, "the front entrance of the hospital" refers—in its case—to "[t]he front entrance of AnMed Health [at] 800 North Fant Street, Anderson SC 29621." *Id.* AnMed then identified seven like hospitals

[4] The MAC concluded that the North Campus was 23.8 miles from Palmetto Easley hospital in Easley, South Carolina, and 24.4 miles from Greenville Hospital Center in Greenville, South Carolina. AR 201. The record contains immaterial variations of these calculations, however. *See, e.g.*, AR 45 (stating that the hospitals were 23.3 and 24.9 miles from the North Campus, respectively).

within a 35-mile radius of the main campus, AR 282, and submitted printouts from Google Maps showing that each of those seven hospitals was located more than 25 miles from the front entrance of the North Fant Street Campus, AR 319–39. AnMed Health did not submit evidence regarding the distances between the seven other hospitals and AnMed's North Campus.

On July 25, 2017, CMS again denied AnMed Health's application for SCH classification on the ground that "AnMed Health does not meet [the] distance requirement in 42 CFR 412.92(a)" because "the [North Campus] is less than 25 miles from two other hospitals." AR 355. On August 11, 2017, AnMed requested reconsideration of that determination, arguing that the decision to measure the distance to other like hospitals from *both* of AnMed's locations was inconsistent with the governing regulations. AR 356–358. CMS denied AnMed's reconsideration request, AR 359, and AnMed timely filed an appeal and request for hearing before the Board. AR 361–75. For purpose of that appeal, AnMed and the MAC stipulated that the "sole justification" for denying AnMed's request was that AnMed's remote location was less than 25 miles from other "like hospitals" under 42 C.F.R. § 412.92(a)(1). AR 116.

On September 4, 2020, the Board issued its decision, concluding that CMS erred in applying the SCH distance requirement to both of AnMed's campuses. AR 40. The Board acknowledged that the term "the hospital," as used in the SCH regulations, "necessarily encompasses" both the main North Fant Street Campus and the remote North Campus. AR 45–46. But it nonetheless concluded that CMS should have measured the distance necessary to qualify for SCH status from the main campus alone. That conclusion was dictated, in the Board's view, by the regulatory definition of "miles," which "is very specific" that mileage must be "determin[ed] . . . by measuring 'paved surface up to *the* front entrance of *the* hospital[,]' and [the regulation] makes no mention of remote locations or multiple front entrances." AR 46

(quoting 42 C.F.R. § 412.92(c)(1) (emphasis added)). The Board continued that if required to identify a single "front entrance of the hospital," that entrance must be located on the main (and not the remote) campus. AR 46.

The Board also considered the regulatory history of § 412.92(c)(1) and commentary relating to another rule, which addressed Critical Access Hospitals ("CAHs"). First, the Board observed that, when the definition of the term "miles" was added to the SCH regulations, the preambles to both the proposed and final rules explained that the new definition was "'consistent with *the* [*Medicare Geographic Classification Review Board* ("*MGCRB*")] *definition of mileage*.'" AR 46 (quoting FY 2002 IPPS Proposed Rule 66 Fed. Reg. 22,645, 22,648 (proposed May 4, 2001); FY 2002 IPPS Final Rule, 66 Fed. Reg. 39,828, 39,874–75 (Aug. 1, 2001). This mattered because, according to the Board, the "then-existing MGCRB definition of 'miles'" measured the "distance from the hospital . . . based on paved surfaces from the front door of the main hospital." AR 46.[5]

Second, the Board cited a 2007 rulemaking relating to Critical Access Hospitals, concluding that, in that rulemaking, "the Secretary made clear that the then-existing § 412.92(a) requirements for SCH designation did *not* address multicampuses." AR 47. In the CAH rulemaking, CMS adopted a requirement that hospitals measure distances from both their main campuses and any remote locations when seeking classification as CAHs.[6] *See* CY 2008 OPPS

[5] IPPS reimbursement rates are adjusted according to "wage index[es]" that reflect regional variations in hospital wage costs. *See Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 401 (D.C. Cir. 2005). The MGCRB "reviews applications from hospitals seeking geographic redesignation to a nearby area in order to use that area's (higher) wage index." *Id.* at 402 (citing 42 U.S.C. § 1395ww(d)(1) and 42 C.F.R. §§ 412.230–.235).

[6] CAHs are hospitals that provide certain emergency services in rural areas and are located "more than a 35-mile drive . . . from a hospital, or another facility described" in the CAH subsection. 42 U.S.C. § 1395i-4(c)(2)(B)(i)(I). As with SCHs, Congress has authorized more

Proposed Rule, 72 Fed. Reg. 42,628, 42,807 (proposed Aug. 2, 2007); *see also* 42 C.F.R. § 485.610(e)(2) (2008). According to the Board, a Medicare provider operating an SCH commented on the CAH proposed rule, "express[ing] concerns regarding the loss of ***its*** special reimbursement status" and "question[ing] why CMS was treating CAHs *differently*." AR 47. The Secretary responded that the new distance-based requirement for CAHs was "a statutory requirement that reflect[ed] . . . ***the special status of CAHs (as opposed to other rural entities)*** and should not limit access to care." *Id.* (quoting CY 2008 OPPS Interim Final Rule, 72 Fed. Reg. 66,580, 66,880–81 (Nov. 27, 2007)). In the Board's view, this response signaled that the 2007 distance-based requirement for CAHs "was *not* intended to apply to SCHs." *Id.*

Finally, the Board addressed the preamble to the FY 2019 IPPS rule, which added a new provision to the SCH regulations specifying that, "[f]or a hospital with a main campus and one or more remote locations under a single provider agreement . . . that meets the provider-based criteria at § 413.65[,] . . . the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy" the mileage requirement. *See* 42 C.F.R. § 412.92(a)(4). Although the preamble explained that the new provision was added to clarify existing policy, the Board seized on the agency's observations (1) that it had "'received an increasing number of inquiries regarding the treatment of multicampus hospitals as the number of [such] hospitals has grown in recent years,'" and (2) that the then-existing regulations did "'not directly address multicampus hospitals.'" AR 47 (quoting 83 Fed. Reg. at 41,369–70). In the Board's view, these observations show that the multicampus rule was not "in place at the time of AnMed's SCH application and that the FY 2019 IPPS rule was not a clarification of long-standing policy

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generous reimbursement rates for these hospitals out of concern for rural access to health care. *See St. Helena Clear Lake Hosp. v. Becerra*, 30 F.4th 301, 302 (D.C. Cir. 2022).

as it relates to § 412.92(a) requirements for SCH designation." AR 47–48 (quoting 83 Fed. Reg. at 41,369–70). This mattered, according to the Board, because if the policy adopted in the FY 2019 IPPS rule was, in fact, a new "substantive policy," the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), makes clear that the rule may not be applied retroactively to reporting periods preceding the notice-and-comment rulemaking. AR 48–50.

On October 30, 2020, the Secretary, acting through the Principal Deputy CMS Administrator, reversed the Board's decision. AR 7. The Secretary first concluded that CMS's determination was "consistent with the plain language of the statute [42 U.S.C. § 1395ww(d)(5)(D)(iii)], 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 [Medicare] Part A." AR 18. Most importantly, the statutory definition of a "hospital" "does not distinguish or recognize separate identities for multicampus hospital locations," AR 18 n.15 (citing 42 U.S.C. § 1395x(e)), and, "[i]n this case, the Hospital is comprised of two locations"—the main North Fant Street Campus and the remote North Campus, AR 18. As a result, "[t]he 'Hospital' must . . . meet the mileage rule for both campuses in order to qualify as an SCH." AR 18.

The Secretary was unpersuaded by AnMed's contention that its North Campus was not a "hospital" for purposes of determining SCH status because "it does not operate an Emergency Room and serves only a small subset of individuals" and "is not a 'hospital furnishing short-term, acute care.'" AR 18–19. That argument failed, according to the Secretary, because CMS's provider-based status regulation, 42 C.F.R. § 413.65(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." AR 19. As the Secretary explained, under the governing regulations, "[b]oth the main location and remote location are the 'Hospital' and provide the IPPS services under the one provider agreement." *Id.*

The Secretary also disagreed with AnMed's contention and the Board's conclusion that the SCH regulations (as of the date that AnMed applied for SCH classification in 2016) required CMS to measure the distance to other like hospitals from the front entrance of the main campus and not from the remote campus. The Secretary explained: "[T]here is no reference to the 'main hospital' . . . in the text of" § 412.92(c)(1), and the fact that the regulation refers—in the singular—to "*the* hospital" is of no moment, since "there [is] always only one Hospital . . . being evaluated[,] even if the Hospital has more than one location or campuses operating under [a single] provider agreement." AR 21 (emphasis added).

In addition, the Secretary rejected AnMed's contention and the Board's conclusion that the FY 2019 IPPS Rule represented a change in CMS policy. AR 19. Unlike the Board, the Secretary credited CMS's statements in the Final Rule that it had "proposed to codify in the regulations [its] existing policies for multicampus hospitals, and thus [that] these policies have been and continue to be in effect." AR 20 (quoting 83 Fed. Reg. at 41,372). Indeed, as the Secretary explained, neither AnMed nor any of the commenters to the FY 2019 IPPS Rule submitted any evidence of a "contrary application by CMS of the SCH rules to multicampus hospitals." AR 20 n.19. AnMed itself, moreover, had been rejected for SCH classification in 2010 "for th[e] same reason" given by CMS in 2016, proving a concrete and apt example of the agency's prior practice. *See* AR 20.

Finally, the Secretary dismissed the Board's reliance on (1) the reference to the MGCRB definition of "miles" in the FY 2002 IPPS Rule amending the SCH regulations to include a

definition of "miles" and (2) the response to the comments submitted to the CAH rule in 2007. AR 21–23. Regarding the reference to the MGCRB's approach to measuring "miles" "when considering hospital reclassification applications," 66 Fed. Reg. at 39,874, the Secretary concluded that the Board read too much into the preamble to the FY 2002 IPPS rulemaking, noting (as the Board did) that the rulemaking said nothing about multiple campus hospitals and noting (as the Board failed to do) that neither the preamble nor the rule said anything about "the 'main hospital.'" AR 21. With respect to CMS's adoption of a distance requirement for CAHs in 2007, the Secretary explained that "[i]t is not evident from [CMS's] statement that CMS'[s] response, referring to CAHs' special status compared to other rural entities, was addressing or even suggesting [that] SCH remote location hospitals would be exempt from the distance requirements to retain their status." AR 22. Noting the differences between the CAH and SCH schemes, the Secretary reasoned that "[t]he policy treatment of the various off-site entities under the CAH provisions, required due to [changes in the CAH statute], does not address, nor is relevant to, SCH determinations." AR 23.

AnMed filed this action on December 28, 2020. Dkt. 1. It claims that the Secretary's decision violates the Medicare regulations that were in effect at the relevant time and is "contrary to the Medicare statute because it applies a regulation retroactively." *Id.* at 3 (Compl. ¶ 7). AnMed asks the Court to "reverse the Secretary's decision and [to] order the Secretary to recalculate AnMed's Medicare payments under the reimbursement methodology applicable to SCHs, effective August 25, 2017." *Id.*; *see also id.* at 21–22 (Prayer for Relief).

AnMed moved for summary judgment on August 16, 2021, Dkt. 16, and the Secretary cross-moved for summary judgment on October 22, 2021, Dkt. 18. For the following reasons,

the Court will **GRANT** the Secretary's cross-motion for summary judgment and will **DENY** AnMed's motion for summary judgment.

II. LEGAL STANDARD

The Court's jurisdiction is premised on the Medicare statute, 42 U.S.C. § 1395oo(f)(1), which authorizes judicial review under the same standards applicable under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706; *Humana, Inc. v. Heckler*, 758 F.2d 696, 698–99 (D.C. Cir. 1985) ("The Medicare Act itself incorporates the standard of review set out in section 706 of the Administrative Procedure Act."); *Flint v. Azar*, 464 F. Supp. 3d 1, 7 (D.D.C. 2020). The Court, accordingly, must consider whether the Secretary "violated the Administrative Procedure Act by taking action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Forsyth Mem'l Hosp., Inc. v. Sebelius*, 639 F.3d 534, 537 (D.C. Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)). This review is "fundamentally deferential." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012). Nonetheless, the APA requires that "an agency's decreed result be within the scope of its lawful authority" and that "the process by which it reaches that result . . . be logical and rational." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998).

III. ANALYSIS

According to AnMed, the Secretary's decision must be set aside for four reasons. First, the decision was "not dictated by the Medicare statute" and was "not required for consistency with the statute." Dkt. 16-1 at 29. Second, the decision "is contrary to the plain reading of the applicable regulation at the time that AnMed submitted its SCH application." *Id.* Third, the decision "is contrary to the Secretary's interpretation of that regulation over many years." *Id.* at

29–30. Finally, the decision constitutes "improper retroactive rulemaking." *Id.* at 30. The Court will consider each argument in turn.

A. The Medicare Statute

AnMed's first contention is not your typical administrative law argument. In a garden-variety administrative law case, the plaintiff or petitioner typically argues that the agency has exceeded its statutory authority or that its application of the statute is unreasonable. Here, in contrast, AnMed starts by arguing that the Secretary has broad authority to implement the SCH provision of the Medicare statute. *See id.* at 31–32. It argues, for example, that Congress delegated to the Secretary authority to determine "whether distance must be measured from remote locations in establishing . . . eligibility" as a SCH or to decide whether a remote location should be treated as part of the hospital for purposes of the SCH program. *Id.* at 32. More succinctly put, AnMed maintains that "the Medicare statute does not address the question at issue in this case" and that "Congress left the Secretary to fill in many of the gaps in the statutory text authorizing SCHs." *Id.* at 38.

To the extent AnMed contends that the Secretary's decision must be set aside because the Secretary mistakenly believed that Congress tied his hands, depriving him of authority to adopt (at least through a rulemaking) AnMed's preferred rule, AnMed misreads the decision. AnMed is correct that the Medicare statute confers broad discretion on the Secretary to implement the SCH program in a manner consistent with the statutory objective of providing an enhanced IPPS rate for "hospital[s] that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals" are "the sole source of inpatient hospital services reasonably available to individuals in a geographic area." § 601(e), 97 Stat. at 158. As the Ninth Circuit observed in *San Bernardino Mountains Community Hospital District v. Secretary of*

Health and Human Services, 63 F.3d 882, 886–87 (9th Cir. 1995), the Medicare statute makes "clear that Congress intended to delegate to the Secretary the task of outlining and defining the criteria for attaining [SCH] status." *See also Clinton Mem'l. Hosp. v. Shalala*, 10 F.3d 854, 857 (D.C. Cir. 1993) (noting the statute's "delegation to the Secretary of primary responsibility for implementing the SCH definition").

The statute provides that a hospital is an SCH if "the Secretary determines [that it] is located more than 35 road miles from another hospital," but it does not specify how the Secretary should "determine" whether a hospital meets the 35-mile requirement. 42 U.S.C. § 1395ww(d)(5)(D)(iii)(I). The statute also provides general guidance as to how the Secretary should determine whether a hospital "is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under [Medicare] part A," by including a nonexclusive list 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)." *Id.* § 1395ww(d)(5)(D)(iii)(II). Beyond that guidance, however, the question of how to measure the distance between a multicampus hospital and other like hospitals is "precisely the type of interstitial question of implementation that the statute leaves in the Secretary's administrative hands." *Anna Jacques Hosp.*, 797 F.3d at 1165.

The Secretary, for his part, agrees that the statute contains a broad delegation of authority to implement the SCH program in a reasonable manner, and, indeed, although not applicable to this case, the Secretary has promulgated a regulation that speaks directly and clearly to the question how to treat "a hospital with a main campus and one or more remote locations under a

single provider agreement." *See* 42 C.F.R. § 412.92(a)(4). More to the point for present purposes, to the extent AnMed contends that the Secretary denied its application for SCH status based on the mistaken belief that the Medicare statute admits of no discretion in this regard, it misreads the decision; the decision does not conclude that the Secretary is without discretion to exclude remote campuses when measuring the distance between "the hospital" and "other like hospitals," 42 C.F.R. § 412.92(a)–(b). Rather, the Secretary construed CMS's then-existing regulation and concluded, based on the law as it then stood, (1) that a qualifying "hospital" must be more than "25 miles . . . from other like hospitals;" (2) that (in the absence of any rule to the contrary) the term "hospital," as used in the SCH regulations, should be given the meaning generally assigned to that term in the statute and regulations, AR 18; (3) that the statutory definition of a "hospital" "does not distinguish or recognize separate identities for multicampus hospital locations," AR 18 n.15; and (4) that the regulations governing "provider-based status" "recognize[] 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," AR 19.

That syllogism is consistent with the D.C. Circuit's observation that various provisions of the Medicare statute "make clear that a 'hospital' can encompass institutes with multiple campuses and facilities." *Anna Jacques Hosp.*, 797 F.3d at 1165. The Secretary's reasoning, moreover, does not imply that CMS is without authority to depart from the default rule and to promulgate a rule that measures distance for purposes of the SCH program from only a portion of the hospital. But that step, unlike what the Secretary did here, would have required looking beyond the text of the then-existing rules and exercising prospective, policymaking authority. To the extent that AnMed maintains that the Secretary misconstrued the statute, the Court is unpersuaded.

Although AnMed does not develop the challenge in any detail, it also at least alludes to a *Chevron* Step Two argument, suggesting that the Secretary's decision is at odds with the purpose of the SCH program. At *Chevron* Step Two, the Court must determine "whether the Secretary has provided a reasonable rationale for his policy choice." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232 (D.C. Cir. 1994). That inquiry is "concededly narrow," *New Lifecare Hospitals of Chester County LLC v. Azar*, 417 F. Supp. 3d 31, 45 (D.D.C. 2019), particularly in the Medicare context, where "heightened deference [must be given] to the Secretary's interpretation of [the] 'complex and highly technical [Medicare] program," *Methodist Hospital*, 38 F.3d at 1229 (quoting *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994)).

Although far from clear, AnMed seems to make two versions of a *Chevron* Step Two argument. It first argues that, to the extent the Secretary believed that he was compelled at *Chevron* Step Two to treat multicampus hospitals, like AnMed, as a single hospital and to measure the distance to any "other like hospital" from both the main and remote campuses, the Secretary erred. Dkt. 16-1 at 36. As AnMed puts it, *Chevron* Step Two comes into play only if "'the governing statute, read as a whole, reveal[s] a clear congressional intent regarding the relevant question or that the text of the statute and reasonable inferences from it give a clear answer.'" *Id.* (quoting *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 891 F.3d 1041, 1047 (D.C. Cir. 2018)). The problem with this version of AnMed's argument is that the Secretary never said that he was compelled, at *Chevron* Step One or Two, to reject AnMed's preferred rule. He merely concluded that the SCH regulations, as written, referred to the distance to "the hospital," and, based on the statute and regulations, that reference was construed to mean the entire hospital, including any remote campus. Notably, AnMed itself concedes that the Secretary

is entitled to *Auer* deference in interpreting the SCH regulations, *see* Dkt. 21 at 8 (citing *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019)), and, here, the Secretary read the term "the hospital" in the SCH regulations to include any remote campuses.

The second version of AnMed's *Chevron* Step Two argument posits that AnMed's remote North Campus "serves only a small subset of patients" and "does not provide most inpatient hospital services needed by women" and "provides very few inpatient services to men." Dkt. 16-1 at 37. AnMed then argues that "Congress likely did not intend that a [remote] facility that is not required [separately] to meet the Medicare Conditions of Participation, does not have an emergency department, and treats only a few specialized conditions to be considered a 'source of inpatient hospital services reasonably available to individuals in a geographic area.'" *Id.* (quoting 42 U.S.C. § 1395ww(d)(5)(D)(iii)(II)). To this, AnMed adds, "the legislative history of the SCH statute suggests that Congress intended for the Secretary to adopt broad criteria for SCH eligibility" and intended to avoid inconsistent, narrow, and restrictive interpretations of the governing qualifications. *Id.* at 37–38.

In pressing this argument, AnMed disregards the Secretary's well-reasoned explanation for his decision. Beyond the textual rationale explained above, the Secretary noted that "the operational origins of [CMS's] policy" reflect "the legal status of a multicampus hospital," including the fact that a "remote location of a hospital is included on the main campus's cost report and shares the same provider number." AR 20. This means that the main and remote campuses "share the same status . . . because the hospital is single entity with one provider agreement." *Id.* As a result, if the hospital qualifies for the enhanced SCH Medicare reimbursement rates, the main and remote campuses both obtain the benefit. And, as the Secretary further explained, "it would not be administratively feasible for CMS and the MACs to

track every hospital with remote locations within the same [area] and to assign different statuses or rural reclassifications exclusively to the main campus or to its remote location." *Id.* (quoting 83 Fed. Reg. at 41,369). In short, because AnMed's remote North Campus would receive the same enhanced SCH rate that its main North Fant Street Campus would receive should AnMed qualify for that benefit, and because any effort to treat the North Campus as distinct for this one reason would pose unreasonable administrative burdens on CMS, the Secretary was unpersuaded by AnMed's policy arguments. That decision, moreover, was eminently reasonable and easily satisfies *Chevron* Step Two.

In the end, it is unclear whether AnMed is pressing these statutory arguments because it believes the Secretary actually misconstrued or misapplied the Medicare statute or whether, as seems more likely, merely to set the stage for its remaining arguments. But, as explained below, those arguments fare no better.

B. The "Miles" Regulation

The principal argument that AnMed raised in the administrative process, which it renews here, focuses on the definition of the term "miles" contained in the SCH regulations. The relevant text provides as follows:

> 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.

42 C.F.R. § 412.92(c)(1). As AnMed reads it, this provision requires CMS to measure distance for purposes of the SCH rule from the front door of the main hospital of a multicampus and to disregard any remote campuses or facilities. The Court is unpersuaded.

Much of AnMed's argument turns on the fact that "[t]he regulation establishing the mileage standard is stated in the singular," referring to "'the front entrance of the hospital,' not to entrances or hospitals." Dkt. 16-1 at 39. But, as the Secretary explained, the reference to a single hospital is unremarkable, since "there [is] always only one Hospital" for purposes of the SCH rule, even if that single "Hospital has more than one location or campus[] operating under [the single] provider agreement." AR 21. Indeed, if anything, the reference to a single hospital supports that Secretary's reasoning, which starts with the premise that "[*t*]*he* hospital" must be more than 25 miles "from other like hospitals," *see* 42 C.F.R. § 412.92(a)(1) (emphasis added), and then observes that when, as here, "the hospital" "is comprised of two campuses that are providing IPPS services," "the hospital" must satisfy the mileage requirement "for both campuses in order to qualify as an SCH," AR 18.

Nor is the Court persuaded that the reference to "*the* front entrance of the hospital" means the front door of the "main" campus of a multicampus hospital. In AnMed's view, "[i]t is simply nonsensical to suggest that a hospital can have 'the front entrance' on two buildings." Dkt. 16-1 at 39. But that contention places far too much weight on the use of the singular in a provision that merely defines the terms "miles" and "improved roads" and that says nothing about multicampus hospitals. Before considering AnMed's specific argument, it bears note that reading a singular reference to include the plural—in a particular context—is far from nonsensical. Indeed, in the analogous realm of statutory interpretation, courts are required to read a singular reference to include the plural, "unless the context indicates otherwise," 1 U.S.C. § 1 ("In determining the meaning of any Act of Congress, unless the context indicates otherwise[,] words importing the singular include and apply to several . . . things"), and there is

no reason why that common sense practice should not apply to regulatory interpretation as well, at least when warranted by the circumstances.

For several reasons, the Court is convinced that this is such a case. Most significantly, the regulatory language that AnMed seizes upon appears in a provision that says nothing about multicampus hospitals and, instead, merely requires the Secretary to measure mileage "over improved roads" and then defines "improved road[s]" to include government maintained roads "available for use by the general public" and "paved surface[s] up to the front entrance of the hospital." 42 C.F.R. § 412.92(c)(1). Read in this context, the disputed clause—"up to the front entrance of the hospital"—is best understood to address the relevant portions of the road to measure, and not whether a multicampus hospital can have more than one front entrance. For this reason, AnMed's *ipse dixit* assertion that "its front entrance is located at" its main North Fant Street Campus, Dtk. 16-1 at 40, misses the point. In defining "miles" and "improved roads," the Secretary said nothing about multicampus hospitals and certainly did not specify, as AnMed contends, that only the main campus of a multicampus hospital counts for purposes of satisfying the SCH distance requirement. *See* AR 21 (noting that "there is no reference to the 'main hospital'" in 42 C.F.R. § 412.92(c)(1)).

The provision's regulatory history confirms that its purpose was to define how CMS should measure miles, and not how it should decide which location(s) of a hospital must satisfy the distance requirements. Prior to 2001, the agency defined "miles" using the existing language (with minor grammatical differences) but without the last sentence that refers to the "front entrance of the hospital." *See* 42 C.F.R. § 412.92(c)(1) (2000). In 2001, the Secretary promulgated a rule adding the "front entrance of the hospital" language to the SCH regulations. *See* FY 2002 IPPS Final Rule, 66 Fed. Reg. 39,828, 39,874–75 (Aug. 1, 2001). The Secretary

explained that he "consider[ed] 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." *Id.* at 39,874. In other words, the Secretary added "paved surface up to the front entrance of the hospital" to the definition of "miles" because that surface is part of a patient's commute to a hospital, and he wanted hospitals to make accurate approximations of patients' travel requirements. That consideration, of course, has nothing to do with the proper treatment of multicampus hospitals.

AnMed has a different take on the regulatory history. As the preamble to the FY 2002 IPPS Final Rule explains, the Secretary amended the definition of "miles" in the SCH regulations to clarify that CMS should measure mileage for purposes of the SCH rule over "improved roads" because the public uses "the paved surface up to the front entrance . . . to access the hospital," and thus the definition of mileage should include "this portion of the distance." *Id.* AnMed, however, focuses on the next sentence of preamble, which states: "This definition provides consistency with the interpretation of the MGCRB when considering hospital reclassification applications." *Id.* That sentence is important, according to AnMed, because when "a hospital with more than one campus in the same wage index area submits a request for reclassification, the MGCRB measures distance from only the main campus." Dkt. 16-1 at 41–42. From these premises, AnMed then concludes that "[i]n order to reconcile the Secretary's statements that the definition of miles is consistent for purposes of the MGCRB reclassifications and SCH designations, the Secretary should have measured distance only from AnMed's main campus when he evaluated AnMed's SCH application." Dkt. 16-1 at 42.

This argument mixes apples and oranges. The fact that the Secretary adopted a definition of "mileage" that is consistent with the definition used by "the MGCRB when considering

hospital reclassification applications," 66 Fed. Reg. at 39,874, does not mean that he also adopted the MGCRB's procedures relating to the treatment of multicampus hospitals. Those are different questions, and all the Court can conclude from the preamble to the FY 2002 IPPS Final Rule is that the Secretary intended for the same understanding of "improved roads" to apply for purposes of both MGCRB reclassification and SCH status—that is, "improved roads" should "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." *Id.* In rejecting AnMed's (and the Board's) position, the Secretary made just this point, noting that the preamble to the FY 2002 IPPS Final Rule says nothing about a "main hospital." AR 21.

Surprisingly, the only MGCRB definition of "mile" that AnMed cites in its briefs merely provides, as does the first portion of the SCH definition, that "the term (road) miles means 'the shortest distance in miles measured over improved roads'" and that "[a]n improved road . . . is any road that is maintained by a local, State or Federal government entity and which is available for use by the general public.'" Dkt. 16-1 at 41 (quoting MGCRB Interim Final Rule, 55 Fed. Reg. 36,754, 36,761 (Sept. 6, 1990); MGCRB Final Rule, 56 Fed. Reg. 25,458, 25,471–72 (June 4, 1991)). Indeed, at least before this Court, AnMed fails to cite to *anything* supporting the proposition that "the MGCRB measures distance only from the main campus." *Id.* at 42. The Court does not doubt that MGCRB generally considers only the main campus for purposes of making reclassification decisions, but, as the Secretary notes, the MGCRB applies an entirely different statutory regime. AR 21 n.21.

The provenance of AnMed's contention, moreover, casts further doubt on its argument. In its Final Position Paper before the Board, AnMed asserted that, "[i]f a hospital with a main campus and remote location in the same metropolitan statistical area . . . applies . . . for wage

index reclassification, the MGCRB considers only the mileage from the front entrance of the main campus to determine whether the hospital meets the proximity criteria." AR 253. AnMed then cited to an email chain between its counsel and two CMS employees from January 2018, in which one of the CMS employees explains that, as long as both campuses of a multicampus hospital are located in the same labor market area, only the main campus needs to satisfy the "15 mile criteria" for purposes of wage index reclassification to a different Metropolitan Statistical Area. AR 376–78. There is no reason to believe that this correspondence—from seventeen years after the FY 2002 IPPS Final Rule was promulgated and which says nothing about the definition of "mileage"—formed the basis for the contested sentence in the preamble. More importantly, there is no evidence that the MGCRB ever defined "mile" or "mileage" to mean anything more than the shortest distance over improved roads, including the paved surface up to the front of the entrance.

Finally, any possible doubt regarding the permissibility of the Secretary's interpretation of the definition of "miles" contained in the SCH regulations is put to rest by AnMed's concession that, "[i]f an agency has issued regulations under statutorily delegated authority, a reviewing court must analyze the regulation[s] under the standards set for in *Kisor v. Wilkie*." Dkt. 21 at 8. Here, AnMed merely argues that the definition unambiguously favors its position, Dkt. 16-1 at 40, and hints (without developing the argument) that the Secretary's decision "does not reflect fair and considered judgment" and, instead, is "merely [a] convenient litigating position," Dkt. 21 at 9 (internal quotations omitted). None of these contentions advance AnMed's position. For the reasons explained above, even without any deference, the Court is persuaded that the Secretary's reading of the definition of "miles" represents the better view. But even if one might plausibly argue that the definition implicitly deals with the question of

multicampus hospitals, that argument is, at best, plausible and does not provide a basis for the Court to reject the Secretary's (convincing) interpretation of his own regulation. *See Kisor*, 139 S. Ct. at 2415; *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Nor has AnMed shown that the Secretary's reading of the mileage regulation was unconsidered or unreasonable or that he adopted it merely as a litigation expedient.

The Court, accordingly, rejects AnMed's contention that the definition of "miles" contained in the SCH regulations addresses the question of multicampus hospitals and requires CMS to measure the relevant distance from the main campus of a multicampus hospital.

C. Prior Interpretations of the SCH Distance Measurement

Next, AnMed argues that "[t]he Secretary has made numerous statements, and [has] taken numerous actions over the span of many years, that contradict his reasons for denying AnMed's SCH application." Dkt. 16-1 at 40. AnMed's first example of such contradictory action merely repeats AnMed's contentions that the Secretary adopted the MGCRB's definition of "miles" for purposes of the SCH regulations and that, under that definition, CMS may consider only the location of the main campus of a multicampus hospital. For the reasons explained above, that argument fails.

AnMed's second example fares no better. For this example, AnMed points to statements that the Secretary made in the CY 2008 OPPS Final Rule regarding the distance requirements for Critical Access Hospital classification. In that rulemaking, the Secretary added a new provision to the CAH regulations specifying that, "[i]f a CAH . . . operates an off-campus provider-based location . . . including a . . . remote location, . . . that was . . . acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of . . . this section only

if the off-campus provider-based location or off-campus distinct part unit is located more than a 35-mile drive . . . from a hospital or another CAH." 42 C.F.R. § 485.610(e)(2); 72 Fed. Reg. at 66,880–81. As AnMed notes, one commenter "stated that its Medicare designation as a sole community hospital has geographic limitations, but that it should not be threatened with the loss of its special reimbursement status if it meets community needs by developing provider-based or off-campus services" and "questioned why CMS is treating CAHs differently." *Id.* at 66,880. In response to that comment—and a host of other comments expressing concern about limiting access to healthcare services for the residents of their communities—the Secretary responded at length, noting among other things that "the [CAH] distance requirement is a statutory requirement that reflects the intent of the CAH program to provide hospital-level services in essentially small rural communities," and that the proposed rule "reflects this understanding and the special status of CAHs (as opposed to other rural entities) and should not limit access to care." *Id.* at 66,880–81. According to the Board and AnMed, this comment demonstrates that—at least in 2008—the SCH regulations "did not address multicampuses." AR 47; *see also* Dkt. 16-1 at 43-44.

The Secretary was unpersuaded, explaining that "[t]he Provider incorrectly states that [the CY 2008 OPPS Final Rule preamble] specifically suggested that distance rules would not apply to the remote location of SCH applicants and that, [if] [the Secretary] was applying such a rule to SCHs, [he] would have explicitly stated" that he was doing so. AR 21. Moreover, the Secretary continued, it is far from evident that the response to the comment "was addressing or even suggesting [that] SCH remote location hospitals would be exempt from the distance requirements [needed] to retain their [SCH] status." AR 22. Instead, the "response recognize[d] the special statutory basis for CAHs and the unique situation for CAHs where even the CAH's

provider-based clinic(s) . . . and excluded units are considered part of the CAH and are paid the same as the CAH." AR 23. He then concluded that "[t]he 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 not properly addressed in" the CY 2008 OPPS rulemaking. *Id.*

The Court agrees with the Secretary that the Board and AnMed place undue weight on a single sentence responding to a comment raised in an unrelated rulemaking. As the Secretary explained in the CY 2008 OPPS proposed rule, prior to January 1, 2006, "[s]tates were permitted to waive the CAH minimum distance eligibility requirement by certifying that a CAH was a ['']necessary provider['']." 72 Fed. Reg. at 42,806. Congress amended the CAH statute in 2003, however, to eliminate the ability of states to waive the distance criteria through "necessary provider" designations after January 1, 2006. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 405(h)(1) (2003). Following that amendment, the statute now provides only that a hospital shall be designated as a CAH if it is "more than a 35-mile drive . . . from a hospital, or another facility described" in the CAH subsection. 42 U.S.C. § 1395i-4(c)(2)(B)(i)(I). The agency interpreted the distance requirement—now that it is no longer accompanied by the "necessary provider" exemption—as a mandatory provision that must apply to all of a hospital's locations. 72 Fed. Reg. at 42,806.

The SCH statute is different; it allows hospitals to be classified as SCHs even if they are fewer than 35 miles from other hospitals, according to criteria set by the Secretary. *See* 42 U.S.C. § 1395ww(d)(5)(D)(iii)(II)–(III). Against this backdrop, the Secretary's brief response to the comment from an SCH in the CY 2008 OPPS rulemaking is best understood merely to clarify that the rulemaking focused on "the special status of CAHs"—as opposed to other entities, like

SCHs—and that the CY 2008 OPPS rulemaking "should not limit access to care." 72 Fed. Reg. at 66,881.

Moving beyond these examples, AnMed also contends that the Secretary "has had numerous opportunities to explain that the distance measurement for SCHs should be taken from remote locations[] but has never done so." Dkt. 16-1 at 48. That is an odd argument. Even assuming that the Secretary could have clarified how to treat multicampus hospitals before the FY 2019 IPPS Final Rule, he was under no obligation to so, particularly where the SCH regulations have long required that "[t]he hospital" be located at least 25 miles "from other like hospitals" and the definition of "hospital" has long included remote campuses of a provider-based facility. Adopting a clarifying rule is helpful but not a requirement, nor is there any reason to conclude that a provider is entitled to reimbursement based on its preferred reading of a rule merely because the regulations might have been clearer. It bears mention, moreover, that CMS did explain the distance requirement to AnMed in 2010 when AnMed unsuccessfully applied for SCH status. *See* AR 20; *see also* AR 198–202. AnMed was thus aware of CMS's position and merely "decided to submit [the] second request" so that it could bring this challenge. AR 77 ([Q]: And can you please explain [why] AnMed decided to submit that second request? [A:] We disagreed with the ruling the first time . . . [and] decided to request it again so that we could take it to appeal.").

Finally, AnMed argues that the Secretary's "assertion [in the FY 2019 IPPS Final Rule] that he [was] merely clarifying his existing policy is at odds with his admissions in the preamble to the" rulemaking. Dkt. 16-1 at 49. In particular, AnMed equates language in the preamble noting that the rulemaking was prompted by the "increasing number of inquiries [received by CMS] regarding the treatment of multicampus hospitals as the number of multicampus hospitals

has grown in recent years," 83 Fed. Reg. at 41,369, with an admission by the Secretary "that he had not previously adopted [the] requirement [to include remote hospitals when measuring distance] and that the Secretary expected that existing SCHs [might] lose their SCH status as a result of th[e] regulatory change," Dkt. 16-1 at 50. That is a non sequitur. The reason to adopt a clarifying amendment is to address questions and uncertainty. But that does not mean that the rule represented a change in policy.

The Court, accordingly, rejects AnMed's contention that the decision at issue in this proceeding is inconsistent with prior SCH policy or prior interpretations of the SCH statute or regulations.

D. The Prohibition on Retroactive Rulemaking

Finally, AnMed contends that the Secretary engaged in retroactive rulemaking by applying the distance criteria that CMS adopted in the FY 2019 IPPS Rule to AnMed's 2016 application for SCH classification. "It is well settled that an agency may not promulgate a retroactive rule absent express congressional authorization." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 13 (D.C. Cir. 2011) (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). The Medicare statute provides that rules may not be "applied (by extrapolation or otherwise) retroactively" unless the Secretary determines that (1) "such retroactive application is necessary to comply with statutory requirements" or (2) "failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A). Because the Secretary does not contend that either of those exceptions applies here, the Court must set aside the Secretary's decision if it retroactively applied a new rule—that is, 42 C.F.R. § 412.92(a)(4)—to AnMed's application for SCH status. *See* Dkt. 16-1 at 55.

Had the Secretary applied § 412.92(a)(4) to AnMed's application, he could have resolved the dispute in a single paragraph: All agree that AnMed's remote North Campus qualifies for provider-based status and is located less than 25 miles from another like hospital, and the amended regulation provides that multicampus hospitals that qualify for provider-based status "must demonstrate that the main campus and its remote location(s) [must] each independently satisfy the" distance criteria. 42 C.F.R. § 412.92(a)(4). And, had he done so, AnMed might well have sound basis to challenge the decision as an impermissible retroactive application of a "substantive change" in a regulation, interpretative rule, or statement of policy. 42 U.S.C. § 1395hh(e)(1)(A). But that is not what the Secretary did. Rather, for all the reasons explained above, the Secretary reasonably construed the then-existing rule to require that CMS measure the distance from "the hospital," which the Secretary explained included a remote location that qualifies for provider-based status. That reading was consistent with the statute and regulations as they existed at that time, and it is consistent with the D.C. Circuit's observation that "the Medicare statute defines 'hospital' as an 'institution' that provides a number of medical services" and, in various provisions, "make[s] clear that a 'hospital' can encompass institutions with multiple campuses and facilities," *Anna Jacques Hosp.*, 797 F.3d at 1164–65. Critically, AnMed identifies no evidence that the Secretary's decision effected "a substantive change from the agency's prior regulation or practice" or "altered the past legal consequences of past action." *Ne. Hosp. Corp.*, 657 F.3d at 14 (citations omitted). To the contrary, for all the reasons explained above, it was AnMed that sought a change in policy, and the Secretary merely rejected that entreaty.

AnMed relies, in part, on *Northeast Hospital Corporation v. Sebelius*, 657 F.3d 1 (D.C. Cir. 2011). That case concerned the Secretary's implementation of the "disproportionate share

hospital" ("DSH") adjustment to IPPS payments, under which the Secretary pays more for services provided by hospitals that "serve[] a significantly disproportionate number of low-income patients." 657 F.3d at 3 (quoting 42 U.S.C. § 1395ww(d)(5)(F)(i)(I)). The amount a hospital receives in DSH adjustments depends on the "Medicare fraction," which is calculated according to a formula established in CMS regulations. *Id.* at 3–4. In *Northeast Hospital*, the plaintiff hospital "claimed it was owed an additional $737,419 in Medicare payments [for 1999–2002] as a result of the intermediary's improper calculation" of the Medicare fraction. *Id.* at 4. The Secretary upheld the intermediary's calculation based on an interpretation of the Medicare statute that had been adopted through notice-and-comment rulemaking in 2004, after the payment period at issue. *See id.* at 5, 14. As here, the Secretary did not explicitly apply the 2004 rule in her decision, and the Secretary argued that the 2004 rule merely adopted the agency's "longstanding policy." *Id.* at 15. Notwithstanding that assertion, the D.C. Circuit concluded that the 2004 rule did not codify longstanding policy, and it held that the Secretary's application of the interpretation that "stem[med] from" the 2004 rule could not be applied to the plaintiff hospital's payments for 1999-2002. *Id.* at 14–17.

In holding that the Secretary engaged in impermissible retroactive rulemaking, the D.C. Circuit relied upon four considerations. First, the court noted that "[i]n two recent [Board] hearings, [Medicare] providers submitted evidence based on hundreds of cost reports from numerous hospitals that between 1999 and 2004, [and] the Secretary routinely" calculated the Medicare fraction according to the plaintiff hospital's preferred method, and not the method codified in the 2004 rule. *Id.* at 15. Second, the court cited evidence that, prior to 2004, the Secretary instructed some hospitals *not* to submit data that would have been necessary to calculate the Medicare fraction according to the 2004 rule. *Id.* Third, the Secretary conceded

that she "routinely failed" to follow the purportedly longstanding policy prior to 2004. *Id.* And finally, the court cited statements in the Federal Register characterizing the 2004 rule as a "policy change" and an "adopt[ion] of policy." *Id.* at 16.

AnMed's reliance on *Northeast Hospital* is misplaced. In that case, substantial evidence demonstrated that the 2004 rule constituted a change in the Secretary's methodology for calculating the Medicare fraction, and, on that basis, the D.C. Circuit rejected the Secretary's claim that the 2004 rule represented a codification of "longstanding policy." Here, in contrast, AnMed has offered no such evidence, and, indeed, has failed to identify a single instance in which the Secretary declined to consider the location of a remote, provider-based campus of a multicampus hospital when measuring distance under the SCH rule. Notably, the only evidence in the record regarding a similar decision is the Secretary's denial of AnMed's application for SCH classification in 2010.

On the record before it, the Court is unpersuaded that the 2018 rule represented a "substantive change" in policy. 42 U.S.C. § 1395hh(e)(1)(A). To be sure, the new regulation is "clearer and remove[s] any possible ambiguity" in the preexisting regulations. *Baptist Mem'l Hosp.-Golden Triangle v. Sebelius*, 566 F.3d 226, 229 (D.C. Cir. 2009). But that alone is insufficient to show that the Secretary's decision was unlawful. *See id.* ("[W]hen [an agency] adopts a new clarifying law or rule, it does not necessarily follow that an earlier version did not have the same meaning.").

The Court, accordingly, will not set the Secretary's decision aside on the ground that it constitutes the retroactive application of a new, substantive rule.[7]

[7] Although AnMed also raises a claim under 42 U.S.C. § 1395hh(a)(2) in its complaint, Dkt. 1 at 21 (Compl. ¶ 75), it makes only passing reference to this provision in its motion for summary

CONCLUSION

For the foregoing reasons, the Court will **DENY** AnMed's motion for summary judgment, Dkt. 16, and **GRANT** the Secretary's cross-motion for summary judgment, Dkt. 18.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: September 15, 2022

judgment and opposition to defendant's cross-motion and, as far as the Court can discern, does not seek relief on the basis of this provision or the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). But, in any event, had AnMed does so, its argument would fail for the same reasons discussed above. The Secretary did not "establish[] or change[]" a "substantive legal standard governing the scope of benefits," 139 S. Ct. at 1809, but, rather, reasonably construed an existing regulation to condition SCH status on the distance between "the hospital"—which includes a remote, provider-based campus—from "other like hospitals," 42 C.F.R. § 412.92(a)(1); *see also* 42 U.S.C. § 413.65(d) (provider-based status); *Anna Jacques Hosp.*, 797 F.3d at 1165 (noting that "'hospital' can encompass institutions with multiple campuses and facilities").