IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, d/b/a CAROLINAS MEDICAL CENTER 1000 Blythe Boulevard Charlotte, NC 28203 *Plaintiff*, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, 200 Independence Avenue SW Washington, DC 20201, *Defendant*.	)	Case No. 3:24-cv-1039

COMPLAINT

INTRODUCTION

The Medicare program has, since its inception and at the direction of Congress, provided funding for hospital-based nursing and allied health ("NAH") educational programs in recognition of their invaluable contribution to the healthcare workforce and to Medicare beneficiaries. Hospitals play a pivotal role in supplying the healthcare workforce with newly trained NAH professionals. This is because many hospitals operate educational programs in nursing and various allied health disciplines such as pharmacy, dietetics, laboratory sciences, radiology, and nuclear medicine. These hospital-based programs have trained generations of NAH professionals.

In turn, the Secretary of Health and Human Services (the "Secretary") has adopted regulations permitting hospitals to claim reimbursement for the Medicare program's share of the costs of running NAH educational programs. Those regulations specify that, to qualify for payment, the hospital must "operate" the programs for which it is claiming reimbursement. In other words, the hospital must be more than just the clinical training site for the program. The hospital must also directly incur the program costs, directly control the curriculum and administration, employ the teaching staff, and supply classroom instruction and clinical training. These requirements are collectively known as the "provider-operated criteria."

For decades, the Secretary, through his Medicare Administrative Contractor ("MAC")—a multi-state, regional contractor responsible for administering Medicare claims—has allowed the plaintiff, The Charlotte-Mecklenburg Hospital Authority, doing business as Carolinas Medical Center, ("CMC") to claim the full costs associated with its accredited NAH education programs. By way of background, CMC first opened its doors in 1940 under the name Charlotte Memorial Hospital. In 1943, CMC, under North Carolina's Hospital Authority Act, became Charlotte

Memorial Hospital Authority of Charlotte, North Carolina, which was later renamed to The Charlotte-Mecklenburg Hospital Authority ("CMHA"). Today, CMC continues to exist as an unincorporated doing-business-as component of CMHA. CMC's NAH education programs are offered through the Carolinas College of Health Sciences ("CCHS"), which is wholly owned, controlled, financed, and operated by CMHA.

Importantly, CMC is a trade name of CMHA and not a separately incorporated entity. CMC does not have its own board of directors or corporate officers. Put simply, all that is CMC is CMHA and CMC does not exist outside of CMHA.

Despite decades of the MAC acknowledging that CMC is CMHA (because it is) and that CMHA, in its capacity as CMC, maintains control of CCHS (because it does), the MAC abruptly and unexpectedly reversed course in 2019. That year, when auditing CMC's cost reports for its reporting periods ending December 31, 2012, and 2013, the MAC eliminated (i.e., disallowed) Medicare support for four of CMC's NAH education programs—nursing, medical laboratory science, radiologic technology, and surgical technology programs (the "Disallowed Programs")—on the incorrect basis that CMC does not operate those programs.

CMC timely filed an appeal before the Provider Reimbursement Review Board (the "Board"), an independent panel to which a Medicare provider of services may appeal if it is dissatisfied with a final determination by its MAC or the Secretary. By decision dated September 30, 2024, the Board sided with the MAC and found *inter alia* that CMC did not meet any of the five provider-operator requirements at 42 C.F.R. § 413.85(f). The Board also ruled that CMHA did not satisfy the exception to the provider-operated requirements because, although CMHA transferred the programs to a wholly owned subsidiary to meet accreditation requirements, the Board refused to impute CMHA's ownership interest in CCHS to CMC. CMC requested that the

CMS Administrator review the Board's decision pursuant to 42 C.F.R. § 405.1875 but the Administrator declined to do so. The Board's decision, therefore, is the final decision of the Secretary. 42 C.F.R. § 405.1871(b)(1).

The Board's decision is unsupported the substantial evidence. The record reflects that the Secretary regards CMC and CMHA as the same entity for Medicare purposes, and that CMHA, in its capacity as CMC, performs all the provider-operated functions of the programs. The Board's decision is also absurd because it would disqualify many hospitals from NAH payment if applied broadly. If the Board were correct that an entity like CMHA could not act in the capacity of an unincorporated hospital that it owns (i.e., CMC), then hospitals that are not separately incorporated would be categorically ineligible to receive pass-through reimbursement for their NAH programs. This is because CMC, like any unincorporated hospital, has no legal existence apart from CMHA, and is therefore legally incapable of performing any provider-operated function in its own capacity.

The Board's decision must be set aside. As described in further detail *infra*, the decision is incorrect and fails to properly apply the requirements of the Medicare statute, regulations, and binding case law. And it carries devastating consequences since the permanent loss of Medicare reimbursement can be financially devastating for hospital-based NAH education programs, like CMC's Disallowed Programs.

CMC alleges the following in support of it claims and request for relief.

PARTIES

1. CMC is a non-profit, 815-bed academic medical center, offering a full range of services to the Charlotte community and beyond. CMC operates as an unincorporated doing-business-as component of CMHA, with its principal place of business at 1000 Blythe Blvd.,

Charlotte North Carolina. CMC's Disallowed Programs are offered through CCHS, which is wholly owned, controlled, financed, and operated by CMHA.

2. The Defendant, Xavier Becerra, is the Secretary of the Department of Health and Human Services, which administers the Medicare and Medicaid programs established under titles XVIII and XIX of the Social Security Act. Defendant Becerra is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

JURISDICTION AND VENUE

3. This action arises under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C § 1395 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* CMC seeks judicial review of a final decision of the Secretary, i.e., the Board's decision, that adversely impacts CMC's Medicare reimbursement.

4. Jurisdiction is proper under 42 U.S.C. § 1395oo(f)(1) and 28 U.S.C. § 1331.

5. Venue is proper in this judicial district under 42 U.S.C. § 1395oo(f)(1) because "[s]uch action shall be brought in the district court for the judicial district in which the provider is located …." Venue is also proper in this judicial district under 28 U.S.C. § 1391.

LEGAL BACKGROUND

A. Medicare Reimbursement for NAH Programs

6. Title XVIII of the Social Security Act establishes a system of federally funded health insurance for certain elderly and disabled persons, commonly known as Medicare. 42

U.S.C. § 1395, *et seq.* This dispute concerns Medicare Part A, which covers hospital inpatient care. 42 U.S.C. § 1395d(a)(1).

7. The Medicare program pays "providers of services," including hospitals, for care provided to Medicare beneficiaries. *See* 42 U.S.C. §§ 1395g (governing payments to "providers of services"); 1395x(u) ("The term 'provider of services' means a hospital . . . ."). From the program's inception in 1965 until 1983, Medicare Part A reimbursed hospitals for inpatient care on a "reasonable cost" basis. 42 U.S.C. § 1395f(b). "Reasonable costs" are defined as the "cost actually incurred" as "determined in accordance with regulations establishing . . . methods to be used . . . in determining such costs . . . ." 42 U.S.C. § 1395x(v)(1)(A).

8. When it established the Medicare program, Congress addressed the need to support hospital-based nursing and allied health education programs, recognizing that "[m]any hospitals engage in substantial educational activities, including . . . the training of nurses, and the training of various paramedical personnel." S. Rep. No. 404, 89th Cong., 1st Sess., 36 (1965). Acknowledging the importance of hospital-based "educational activities," Congress gave the Secretary a mandate to pay hospitals for the reasonable cost of their NAH programs. "[U]ntil the community undertakes to bear such education costs in some other way . . . the net cost of such activities (including stipends of trainees as well as compensation of teachers and other costs) should be considered as an element in the cost of patient care, to be borne to an appropriate extent by the [Medicare] hospital insurance program." *Id.*

9. Congress also added guardrails to the Medicare statute to ensure that Medicare would not be unfairly subsidized by private patients and commercial insurance programs. To that end, Congress required the Secretary to adopt regulations for determining "reasonable costs" to "take into account both direct and indirect costs . . . in order that . . . the necessary costs of

efficiently delivering covered services to individuals covered by the insurance programs established by the subchapter will not be borne by individuals not so covered." 42 U.S.C. § 1395x(v)(1)(A). This is known as Medicare's prohibition on cross-subsidization.

10. In accordance with Congress' directives, when the Secretary first implemented the Medicare program, he adopted regulations permitting hospitals to claim reimbursement from Medicare for the "reasonable costs" of accredited NAH educational programs. 31 Fed. Reg. 14,808, 14,814 (Nov. 22, 1966) (codified at 20 C.F.R. § 405.421).

11. Congress has discontinued "reasonable cost" reimbursement for most services covered by Medicare Part A, but not NAH programs. The Social Security Amendments of 1983 enacted the inpatient prospective payment system ("IPPS"), which to this day reimburses hospitals for most of the inpatient services they provide Medicare beneficiaries. Pub. L. No. 98-21, § 601, 97 Stat. 65, 149 (Apr. 20, 1983). Under IPPS, hospitals receive a fixed payment per discharge instead payment based on their actual costs incurred. 42 U.S.C. § 1395ww(d); 42 C.F.R. Part 412.

12. In enacting IPPS, Congress specified that certain services, including the cost of operating NAH programs, "pass through" IPPS and continue to be paid based on "reasonable cost." *See* 42 U.S.C. § 1395ww(a)(4) (excluding "approved educational activities" from the definition of inpatient operating costs subject to IPPS); *see also* 49 Fed. Reg. 243, 267 (Jan. 3, 1984) ("The costs of approved educational activities 'pass through' PPS and are reimbursed under the reasonable cost system."). Thus, to this day Medicare continues to reimburse hospitals for the reasonable cost of their NAH programs. 42 C.F.R. § 413.85.

B. The Operator Rule

13. The Secretary's eligibility rules for NAH reimbursement have evolved over the years. Initially, any hospital participating in "approved educational activities" qualified for

payment. 20 C.F.R. § 405.421(a) (1966). An "approved educational activity" included any NAH program that was either licensed by the state or approved by an appropriate accrediting body. *Id.* at 405.421(b) (1966).

14. In November of 1975, the Secretary published subregulatory guidance introducing a new eligibility criterion for NAH payment. Under that guidance, only hospitals that "operate" their NAH programs were eligible to receive Medicare reimbursement for the cost of those programs. *See St. John's Hickey Mem'l Hosp., Inc. v. Califano*, 599 F.2d 803, 806 (7th Cir. 1979). As originally adopted, this "operator" rule was intended to police against hospitals claiming reimbursement for NAH programs that belonged to colleges or universities. *See* 57 Fed. Reg. 43659, 43661 (Sept. 22, 1992).

15. The Secretary's operator requirement was predicated on his view that Congress only authorized Medicare to support NAH programs "until the community undertakes to bear such education costs in some other way." S. Rep. No. 404, at 36 (1965). The Secretary has interpreted that instruction as authorizing him to decide, on a case-by-case basis, when the community has undertaken to support a specific NAH program, and to terminate Medicare funding at that time. *See Saint John's Hickey Memorial Hospital Anderson v. Blue Cross Association*, HCFA Adm'r. Dec. No. 1977-D7, *5 (Mar. 14, 1997) ("[C]ommnity recognition and assumption of responsibility for health care education and training programs are established when a non-provider organization . . . assumes legal operation of a program."). In the Secretary's view, if an entity other than the hospital claiming reimbursement for a NAH program "becomes the 'legal operator' of [the] educational program it is an indication that the community has assumed responsibility for the program . . . ." *Los Alamitos Gen. Hosp., Inc. v. Donnelly*, 558 F. Supp. 1141, 1145 (D.D.C. 1983).

16. The Secretary was unsuccessful in his early attempts to enforce his operator rule. The courts faulted him for pronouncing the rule through informal policy statements rather than notice-and-comment rulemaking, and for attempting to enforce it retroactively. *St. John's*, 599 F.2d at 803; *Wash. Adventist Hospital, Inc. v. Califnao*, 512 F. Supp. 932, 934-35 (D. Md. 1981); *Los Alamitos Gen. Hosp., Inc.*, 558 F. Supp. at 1145. The courts also ruled that the Secretary's operator rule violated the prohibition on cross-subsidization by shifting the costs of NAH programs entirely to non-Medicare patients. "Unless the claimed reimbursement is allowed, the burden will fall on the non-Medicare patients even though . . . these are 'necessary costs of efficiently delivering covered services' and . . . should be borne by Medicare beneficiaries to the extent they are served." *St. John's*, 599 F.2d at 812; *see also Washington Adventist Hosp. Inc.*, 512 F. Supp. at 935 ("To require non-medicare patients to bear solely the costs associated with this program would not be consistent with this policy."); *Los Alamitos Gen. Hosp., Inc.*, 558 F. Supp. at 1145 (same).

17. The operator requirement came back into the spotlight in 1983 when the Secretary adopted regulations to implement IPPS. In that rulemaking, the Secretary amended his NAH payment regulation to specify that the costs of NAH programs not operated by a hospital would be regarded as "normal operating costs" paid under IPPS. 49 Fed. Reg. 234, 267 (Jan. 3, 1984); 42 C.F.R. § 405.421(d)(6) (1984). In effect, this meant that if the Secretary determined that a hospital did not operate its NAH programs, it would not qualify to receive reasonable cost reimbursement for those programs.

18. But the Secretary did not provide any guidance for how to determine whether a hospital "operated" a program. The lack of guiding principles made it difficult for even the Secretary's MACs to determine whether hospitals were in compliance with the rule.

19. Congress intervened in the Omnibus Budget Reconciliation Act of 1989 ("OBRA '89"). Therein, Congress barred the Secretary from enforcing his operator requirement retrospectively and directed him to published regulations to further elaborate the contours of the "operator" requirement. Pub. L No. 101-239, § 6205(b)(2)(A), 103 Stat. 2,106, 2,243 (Dec. 19, 1989). Congress instructed that the new regulations should specify "the relationship required between an approved nursing or allied health education program and a hospital for the program's costs to be attributed to the hospital." *Id*. at § 6205(b)(2)(C)(i).

20. Congress directed the Secretary to issue the new regulations "[b]efore July 1, 1990," and specified that they would not take effect until the later of October 1, 1990, or 30 days after the publication of the final rule in the Federal Register. *Id.* at § 6205(b)(2)(B).

21. In response to Congress's mandate, the Secretary published proposed rules on September 22, 1992—over two years after the statutory deadline to publish the *final* rule. 57 Fed. Reg. 43659 (Sept. 22, 1992). The delays did not end there. It was not until over eight years later in 2001 that the Secretary finalized his new operator rule. 66 Fed. Reg. 3358 (Jan. 12, 2001).

22. In his 2001 rule, the Secretary adopted five criteria for determining whether a hospital qualifies as the operator of its NAH programs. A hospital seeking reimbursement for its NAH programs must comply with each of the following criteria:

> (i) Directly incur the training costs.
>
> (ii) Have direct control of the program curriculum. (A provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider must provide all of the courses relating to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program.)
>
> (iii) Control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A

provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)

(iv) Employ the teaching staff.

(v) Provide and control both classroom instruction and clinical training ….

42 C.F.R. § 413.85(f)(1)(i)-(v).

23. Ironically, the rules that the Secretary adopted in response to OBRA '89, which Congress anticipated would clarify the Secretary's operator requirement, had the opposite effect. The Secretary's new provider-operated criteria spawned as many questions as they answered. For example, hospitals labored to understand what it meant to *employ* the teaching staff, and whether independent contractors, which can be regarded as employees for tax purposes, can also be employees for the operator requirement. The precise meaning of *directly* incur the training costs also escaped hospitals, because it is susceptible to multiple interpretations. *See Med. Univ. Hosp. Auth. v. Becerra*, No. 2:19-1755-MBS, 2021 WL 1177860 at *10 (D.S.C. Mar. 29, 2021) (finding that the Board "construed the term 'directly incurred' too narrowly."). In the absence of more granular guidance from the Secretary, hospitals had little choice but to coordinate with each other to identify best practices, and to "[i]mprovise compliance by relying on "a natural reading of the regulation and its implementing language to determine common sense rules for establishing 'direct control' of the residency programs." Brief for the American Society of Health System Pharmacists Supporting Plaintiffs Motion for Summary Judgment, *Med. Univ. Hosp. Auth. v. Becerra*, No. 2:19-1755-MBS (Mar. 29, 2021), at 5.

24. On August 17, 2018, the Secretary published a transmittal titled "Clarification of Policies Related to Reasonable Cost Payment for Nursing and Allied Health Education Programs." CMS Transmittal 2133 (Change Request 10552) (Aug. 17, 2018). This was the first guidance document he published for the provider-operated criteria he adopted 17 years earlier in his 2001

rule. The document itself offered little guidance other than to express the agency's pre-determined conclusion that most hospital-based NAH programs are not provider-operated. "It is a reality that many previously provider-operated programs are no longer complaint with the provider-operated criteria . . . and should not be receiving Medicare pass-through payments." *Id*. at 3. The document also suggests that it is "extremely difficult, if not impossible" for hospitals to simultaneously comply with the provider-operated criteria and modern accreditation standards. *Id*.

C. Exception to the Operator Rule

25. In his 2001 rule, the Secretary acknowledged that in some circumstances it is necessary for hospitals to transfer their NAH programs to wholly owned educational institutions to comply with accreditation standards. 66 Fed. Reg. at 3363. But he refused to create any flexibility in the provider-operated rules to accommodate that scenario. *Id*. In other words, hospitals effectively had to choose between meeting accreditation standards or receiving Medicare funding for their NAH training.

26. Evidently displeased with the Secretary's policy, Congress intervened yet again, this time in the conference report accompanying the Consolidated Appropriations Act of 2003. "It was not the intent of Congress . . . to preclude hospitals from receiving reasonable cost pass-through payments for nursing and allied health educational programs based solely on conflicting accreditation educational standards." H.R. Rep. No. 108-10, 108th Cong., 1st Sess., at 1109 (2003). Accordingly, Congress directed the Secretary to permit pass-through payment in cases where hospitals have relinquished some control of their NAH programs to wholly owned educational institutions to comply with accreditation standards.

> Given the shortage of nursing and allied health professionals, the conferees support the payment of costs on a reasonable cost basis for a hospital that has historically been the operator of nursing and allied health educational program(s) that qualified for Medicare payments . . . but, solely in order to meet educational standards,

> subsequently relinquishes some control over the program(s) to an educational institution, which: meets regional accrediting standards; is wholly owned by the provider; and is supported by the hospital, i.e., the hospital is incurring the costs of both the classroom and clinical training portions of the program.

Id.

27. The Secretary acknowledged Congress's command and amended his NAH regulation on August 1, 2003. "Congress has specifically expressed its intent that providers that have restructured their programs to be operated by a wholly owned subsidiary educational institution in order to meet accreditation standards should continue to receive Medicare reasonable cost payment." 68 Fed. Reg. 45,346, 45,429-33 (Aug. 1, 2023).

28. The Secretary implemented this exception in 42 C.F.R. § 413.85(g)(3). Under that provision, a hospital is entitled to pass-through reimbursement for a program which does not meet the operator requirements of 42 C.F.R. § 413.85(f) if some time prior to October 1, 2003, the program met the provider-operated requirements and was transferred to a wholly owned subsidiary for the purpose of meeting accreditation standards, and the hospital continued to incur the costs and claim reimbursement after the transfer. *Id*. at § 413.85(g)(3).

D. The Medicare Appeals Process

29. The Secretary contracts with Medicare Administrative Contractors ("MACs") to administer payment to hospitals participating in the Medicare program. Hospitals receive interim payments from MACs throughout the year, subject to subsequent adjustment for overpayment or underpayment. Adjustments are determined based on annual cost reports submitted by hospitals that identify the costs they incurred furnishing services to Medicare beneficiaries. 42 C.F.R. § 413.20. Pursuant to the Medicare program's rules and regulations, hospitals will also claim on their cost reports the costs incurred to operate their NAH educational programs, seeking pass-through reimbursement from the Medicare program.

30. CMS requires the MACs to audit hospital cost reports to determine each hospital's Medicare reimbursement for the reporting period, including if applicable the amount of pass-through reimbursement for any hospital-operated NAH educational programs. *Id.* § 405.1803. The MAC will issue a final determination known as a notice of program reimbursement ("NPR"), which itemizes adjustments and states the amount of the approved reimbursement, including the final amount of NAH educational program pass-through reimbursement. *Id*. § 405.1803. MACs are expected to issue final determinations within 12 months of the date that the hospital files its cost report. *See* 42 C.F.R. § 405.1835(c).

31. If a hospital is dissatisfied with the MAC's final determination, it may file an appeal seeking Board review within 180 days after receiving the NPR. 42 U.S.C. § 1395oo(a)(1)(A)(i).

32. A decision of the Board is considered final unless the Secretary reverses, affirms or modifies the decision within sixty (60) days after the hospital is notified of the Board's decision. 42 U.S.C. § 1395oo(f)(1). A hospital may obtain judicial review of a final decision of the PRRB or the Secretary by commencing a civil action within 60 days of the hospital's receipt of the decision. *Id*.; 42 C.F.R. § 405.1877.

FACTUAL BACKGROUND

A. Carolinas Medical Center

33. Carolinas Medical Center (CMC) first opened its doors in 1940 under the name Charlotte Memorial Hospital. In 1943, CMC, under North Carolina's Hospital Authority Act, became Charlotte Memorial Hospital Authority of Charlotte, North Carolina, which was later

renamed to The Charlott-Mecklenburg Hospital Authority ("CMHA"). N.C. Gen. Stat. Ann. § 131E-15 *et seq*.

34. In the decades that followed, CMHA expanded its operations by opening other hospitals and physician practices. But to this day, CMC continues to exist as an unincorporated doing-business-as component of CMHA.

35. CMC does not exist outside of CMHA. All that is CMC is CMHA. The governing body of CMC is CMHA's Board of Commissioners—CMC does not have its own Board of Commissioners or directors, nor does CMC have its own corporate officers. CMC does not even have a license in its own name. The State of North Carolina Department of Health and Human Services issued the license to operate CMC in the name of CMHA. Even CMC's Provider Agreement with Medicare explicitly recognizes that CMC is a mere trade name of CMHA. Exhibit 3 (CMC Medicare Enrollment Form) (listing CMC as the name of the provider with the proviso that "Carolinas Medical Center is a trade name of Charlotte-Mecklenburg Hospital Authority and not a separately incorporated entity ….").

B. CMC's NAH programs

36. CMC has for decades claimed *and received pass-through reimbursement from Medicare* for its programs in nursing, medical laboratory science, radiologic technology, and surgical technology.

37. CMC's nursing program provides training in professional behaviors, communication, assessment, clinical decision making, caring interventions, teaching and learning, collaboration, and managing care. The nursing program is accredited by the National League for Nursing Accrediting Commission, Inc.

38. The medical laboratory science program includes didactic lectures, student laboratory training, and clinical experiences at the Hospital. Students study in the clinical laboratories of chemistry, hematology, immunohematology, immunology, microbiology, and phlebotomy. The medical laboratory science program is accredited by the National Accrediting Agency for Clinical Laboratory Sciences.

39. CMC's radiologic technology program prepares students to use medical imaging in the diagnosis, assessment and treatment of disease. The radiologic technology program is accredited by the Joint Review Committee on Education in Radiologic Technology.

40. CMC's surgical technology program prepares students to perform numerous functions in surgical settings including hospital operating rooms, emergency rooms, and labor and delivery areas, as well as doctors' offices, clinics, and surgery centers. The surgical technology program is accredited by the Accreditation Review Committee on Education in Surgical Technology.

41. Each of CMC's programs are offered through the Carolinas College of Health Sciences, i.e., CCHS, which is wholly owned, controlled, financed, and operated by CMHA. CCHS serves as a "talent pipeline" for meeting CMC's needs for nurses and allied health professionals.

42. Until the early 1990s, CCHS was, like CMC, an unincorporated subdivision of CMHA. But in 1993, CMHA spun off CCHS as a separate corporation, with CMHA as its sole member. The singular purpose of that spinoff, as reflected in CMHA board resolutions from that time, was so that CCHS could qualify for accreditation with the Southern Association of Colleges ("SACS").

43. CMHA, in its capacity as CMC, operates the programs offered through CCHS. First, CMHA directly incurs the training costs because it pays for all the operational expenses of CCHS, including the salaries and benefits of the staff and faculty.

44. CMHA also controls the curriculum of the programs offered through CCHS because it employs nearly all the individuals tasked within making curricular decisions, including 100% of the CCHS staff and most of the members of the CCHS Interdisciplinary Advisory Committee ("IAC"). CMHA also appoints the members of the CCHS board, approves its officers, and, as the sole member of CCHS, is at liberty to take any action that affects CCHS "at any time."

45. CMHA controls the administration of the programs offered through CCHS because it employs the CCHS President, who is responsible for the day-to-day operations of CCHS, collects the tuition for the programs and providers certain administrative services to CCHS.

46. CMHA also employs all the teaching staff at CCHS and provides and controls the classroom instruction and clinical training. All classroom instruction occurs on the CMC campus, as does nearly all clinical training.

PROCEDURAL HISTORY AND BOARD DECISION

47. In its cost reporting periods ending December 31, 2012, and December 31, 2013, CMC claimed reimbursement from Medicare for the costs of its nursing, medical laboratory science, radiologic technology, and surgical technology programs that it offers through CCHS, as it had done for over a decade.

48. On January 8, 2019, the MAC issued NPRs for CMC's cost reporting periods ending December 12, 2012, and December 31, 2013. Therein, the Medicare contractor reclassified the costs associated with all four programs as normal operating costs, which had the effect of denying pass-through reimbursement for the programs. This reduced CMC's Medicare

reimbursement by $2,007,151 in 2012 and $1,779,199 in 2013. In the audit adjustment reports accompanying the NPRs, the MAC asserted that CMC "did not meet the criteria for legal operator of the Program[s], and the Program[s] did not qualify as provider-operated." The MAC did not specify which of the five provider-operated criteria that it believed CMC failed to meet.

49. On January 23, 2019, just over two weeks after the MAC issued its NPRs, members of CMC's leadership team met with CMS staff to discuss the MAC's decision denying pass-through payment for the Disallowed Programs. Five months later, on June 21, 2019, CMS staff informed CMC that it concurred with the MAC's findings that the programs are not provider operated. CMC asked CMS to identify which of the five provider-operated criteria that CMC purportedly failed to satisfy "so that we can work towards making the necessary changes prospectively . . . ." But CMS declined to elaborate, suggesting instead that the MAC would provide this information. CMC was unsuccessful in its efforts to obtain this information from the MAC.

50. Having exhausted all other remedies, CMC filed timely appeals with the Board on July 5, 2019. The appeals specifically challenged the MAC's decision denying reimbursement for the Disallowed Programs. CMC also appealed the calculation of its NAH payment.[1]

51. In briefings filed with the Board, CMC presented evidence that Medicare regards CMC and CMHA as the same entity. That evidence included CMC's application for enrollment into the Medicare program, which identified CMHA as the applicant in its capacity as CMC. The Secretary approved that application. Exhibit 3. CMC also presented evidence that CMS has

[1] Specifically, CMC appealed the adjustments the MAC made to the amount of tuition CMC received for the Disallowed Programs, which would have reduced CMC's reimbursement for the programs. CMC also appealed the calculation of the Medicare Advantage payment attributable to those programs, which was also disallowed in its entirety.

permitted CMHA to satisfy on behalf of CMC several of the conditions of Medicare participation for hospitals, and that CMHA, in its capacity as CMC, performs all the provider-operated functions for the Disallowed Programs.

52. CMC also submitted evidence that it would be entitled to reimbursement for the Disallowed Programs under 42 C.F.R. § 413.85(g)(3) even if it did not operate them. This evidence consisted of the resolutions from the December 14, 1993, meeting of CMHA's Board in which they decided to spin off CCHS so that the Disallowed Programs could receive accreditation from the SACS.

53. The Board conducted a live hearing on CMC's appeals on May 3 and 4, 2023. During the hearing, CMC presented the testimony of CMHA's Vice President David Thomas, who testified on the record that CMC does not exist separate and apart from CMHA. Transcript at 40-45 (May 3, 2023). He further testified that CMHA, in its capacity as CMC, directly paid for the costs of the programs (including payroll for the faculty) using funds drawn from an account owned by CMHA and collected and deposited the tuition for the programs into the same CMHA account. Transcript at 75, 84-85, and 148 (May 3, 2023).

54. CMC also presented the testimony of Dr. Hampton Hopkins, who was the President of CCHS and the Assistant Vice President of Medical Education at CMHA during the periods under appeal. Dr. Hopkins corroborated Mr. Thomas' testimony that CMHA incurs the costs of the Disallowed Programs. He also testified that CMHA controlled the curriculum and administration of the Disallowed Programs and provided classroom instruction and clinical training. Transcript at 188-194, 199 and 207. (May 3, 2023).

55. On September 30, 2024, the Board issued a decision on the merits of CMC's appeals in favor of the Secretary.[2] *See* Exhibit 1. The Board ruled that "the acts and responsibilities of [CMHA] . . . cannot be imputed down to the operating division of CMC (as the provider) *for purposes of meeting or satisfying the Medicare program's* ***provider****-operated requirements* . . . ." Exhibit 1 at 42 (emphasis in original). In reaching its conclusion, the Board found, contrary to the evidence in the record, that Medicare does not regard CMC and CMHA as the same entity in any capacity. *Id*. at 41. The Board did not point to any guidance from the Secretary that would have put CMC on notice that the Secretary has interpreted the provider-operated rules in this manner.

56. Nor did the Board address the absurd implication of its holding that CMHA cannot perform the provider-operated functions on behalf of CMC. Since CMC has no legal existence apart from CMHA, it is legally incapable of performing any of the provider-operated functions in its own capacity (e.g., CMC cannot incur costs in its own name because it cannot own funds or property and cannot employ teaching staff because it cannot issue W-2s). If CMHA cannot perform these functions on behalf of CMC, then hospitals like CMC are categorically disqualified from receiving pass-through payment for their NAH programs.

57. Perhaps recognizing that it would be arbitrary if a hospital's corporate structure could dictate its eligibility for NAH payment, the Board suggested in its decision that CMC could have qualified as the operator of the Disallowed Programs had CMHA personnel working in "the CMC operating division" performed the provider-operated functions. But the Board does not point

[2] The Board's decision did not address the part of CMC's appeals challenging the MAC's adjustment to the amount of tuition collected from the Disallowed Programs, presumably because that issue was obviated by the Board's decision upholding the MAC's disallowance of those programs in their entirety. The Board's decision, however, did address the part of CMC's appeals challenging the calcualtion of the Medicare Advantage component of its NAH payment. The Plaintiff requests that these issues be addressed on remand since they are obviated by the Board's decision upholding the MAC's decision denying reimbursement for these programs,

to any regulation or guidance from the Secretary that would have put CMC on notice that the provider-operated functions had to be performed by individuals in the "the CMC operating division," nor could it because the MAC admitted on the record that no such guidance exists. Transcript at 42, 64 and 148 (May 4, 2023). In either event, the Board's manufactured standard would not work anyway, because even if "CMC operating division" staff controlled the curriculum and administration, and provided classroom instruction and clinical training, CMC would nonetheless be incapable of directly incurring the costs of the programs or employing the teaching staff in its own capacity. *See* 42 C.F.R. § 413.85(f)(1)(i) & (iv).

58. The Board also found that some of the provider-operated functions were performed by CCHS instead of CMC or CMHA. In particular, the Board ruled that CCHS directly incurred the costs of the program because CMHA, in its consolidated trial balance, reported those costs in a "business unit" titled CCHS. Exhibit 1 at 44-46. But the Board overlooked the evidence in the record, including the testimony of Mr. Thomas, that CMHA paid for expenses of the program from its own accounts. Mr. Thomas further testified that CMC's operating expenses were spread over twenty distinct business units, which included the business unit for CCHS. Transcript at 48-59 (May 3, 2023). Thus, the Board read too much into the fact that the costs of the Disallowed Programs were recorded in the CCHS business unit. Furthermore, the Board did not point to any agency guidance that would have put CMC on notice that the costs of the Disallowed Programs, when reported in CMHA's consolidated trial balance, had to be reported in a business unit bearing the name CMC instead of CCHS.

59. The Board found that CCHS also controlled the curriculum and clinical training of the Disallowed Programs, despite evidence in the record that CMHA controls the CCHS Board and faculty, and most of the IAC, and that nearly all clinical training occurs at the CMC campus.

60. Finally, the Board hastily concluded that CMC does not qualify for the exception to the provider-operator requirements in 42 C.F.R. § 413.85(g)(3) because CMHA, rather than CMC, owns CCHS. The Board refused to impute CMHA's ownership interest of CCHS to CMC, despite the evidence in the record that the Secretary regards CMC and CMHA as the same entity for other Medicare reimbursement purposes.

61. On October 15, 2024, CMC timely submitted a request for Administrator review of the Board's decision to CMS's Office of the Attorney Advisor pursuant to 42 C.F.R. § 405.1875(c)(1). Specifically, CMC requested that the Administrator review the part of the Board's decision denying pass-through reimbursement for the Disallowed Programs.[3] CMC argued that Administrator review was warranted because the Board's decision "presents a significant policy issue," contains "erroneous interpretation[s] of law," and requires "clarification, amplification, or an alternative legal basis." 42 C.F.R. § 405.1875(b). CMC's request cited a letter to the Chair of the Senate Subcommittee on Labor, Health and Human Services, Education and Related Entities in which multiple U.S. Senators expressed their concern that the Secretary "has not adequately communicat[ed]" the provider-operated criteria, leaving hospitals to "navigat[e] a maze of compliance requirements with little guidance. . . ." Exhibit 4. CMC expressed its belief that the Board's decision, by discussing all five provider-operated criteria, provided an ideal vehicle for the Administrator to provide urgently needed clarifications.

[3] CMC also explained in its Request to the Administrator that its appeals before the Board challenged adjustments the MAC made to the amount of tuition CMC received for the Disallowed Programs, which would have reduced CMC's reimbursement for those programs if the MAC had not disallowed them in their entirety. As explained above, the Board's decision did not address this issues, presumably because it was obviated by the Board's decision that CMC is not entitled to pass-through payment for these programs. Accordingly, CMC requested that—if the Administrator reverses the Board on the provider-operator issue—the Administrator remand the appeals back to the Board with instructions to adjudicate the tuition offset issue.

62. On November 12, 2024, the Office of the Attorney Advisor informed CMC that the Administrator "has declined to review the decision entered by the [Board]" without further elaboration. Exhibit 2 (Administrator Response).

CAUSES OF ACTION

COUNT ONE
(The Board's Decision is Unsupported by Substantial Evidence)

63. The allegations set forth in the preceding paragraphs are incorporated by reference as if fully set forth herein.

64. The Board's decision is reviewable by this Court pursuant to the provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553; 706, 42 U.S.C. § 1395oo(f).

65. Under the APA, "[t]he reviewing court shall—hold unlawful and set aside agency action, findings, and conclusions found to be—(E) unsupported by substantial evidence[.]" 5 U.S.C. § 706(2)(E); *Djadjou v. Holder*, 662 F.3d 265, 273 (4th Cir. 2011) ("We seek to ensure that the agency's factual findings are supported by substantial evidence.")

66. The Board's decision is not supported by "substantial evidence." *Id*. Contrary to the Board's holding, CMC is entitled to reimbursement for the Disallowed Programs because those programs are operated by CMHA in its capacity as CMC. The Board erred in finding that the provider-operated functions performed by CMHA "cannot be imputed down to the operating division of CMC (as the provider) for purposes of meeting or satisfying the Medicare program's provider-operated requirements . . . ." Exhibit 1 at 42. The Board's conclusion rests on the erroneous premise that the Secretary does not regard CMHA and CMC as the same entity in any capacity. *Id*. at 41. But that theory is belied by evidence in the record that the Secretary permitted CMHA, in its capacity as CMC, to enroll in the Medicare program as a hospital and satisfy the program conditions of participation for hospitals on behalf of CMC. This evidence "was such that

any reasonable adjudicator would have been compelled to conclude to the contrary." *Djadjou*, 662 F.3d at 273.

67. The Board also concluded erroneously that some of the provider-operated functions were performed by CCHS instead of CMC or CMHA. For instance, the Board concluded that CCHS incurred the costs of the Disallowed Programs because those costs were reported in a "business unit" for CCHS within CMHA's consolidated trial balance. Exhibit 1 at 44-46. But the Board disregarded evidence in the record that CMHA pays for all the operational expenses of the programs, including the salaries and benefits of the staff and faculty. Furthermore, the record shows that the CCHS business unit was just one of over twenty distinct business units where CMHA recorded the revenue and expenses for CMC. For example, CMC's operating room and anesthesiology departments, which operated entirely within the four walls of CMC, each had their own dedicated business units.

68. The Board also erred in finding that CCHS, through its Board of Directors and IAC, controlled the curriculum for the Disallowed Programs. Exhibit 1 at 47. The Board overlooked the plethora of evidence demonstrating CMHA's dominion over the program curriculum including that CMHA employs nearly all the individuals responsible for making curricular decisions. In addition, the CCHS bylaws vest CMHA with the authority to appoint the members of the CCHS Board, approve its officers, and take any action that affects CCHS at any time.

69. After erroneously ruling that CMC has not satisfied the operator requirements of 42 C.F.R. § 413.85(f)(1), the Board further erred in concluding that CMC does not meet the exception to the provider-operated criteria in section 413.85(g)(3). Although it is undisputed that CMHA transferred the Disallowed Programs to a wholly owned subsidiary, CCHS, to meet accreditation standards, the Board found that CMC does not meet the exception in section

413.85(g)(3) because CMHA owns CCHS, and the Board had already (wrongly) concluded that CMHA is not CMC in any capacity. The Board's holding was not supported by substantial evidence and therefore must be overturned.

70. The Board also erred in ruling against the hospital with respect to its appeals challenging the amount of reimbursement owed for its NAH programs (i.e., the tuition and Medicare Advantage payment issues).

COUNT TWO
(The Board's Decision is Arbitrary and Capricious)

71. The allegations set forth in the preceding paragraphs are incorporated by reference as if fully set forth herein.

72. The APA also requires a reviewing court to set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Mountain Valley Pipeline, LLC v. N. Carolina Dep't of Env't Quality*, 990 F.3d 818, 826 (4th Cir. 2021) (citing 5 U.S.C. § 706(2)(A)). To that end, the court "must ensure that the agency has . . . articulated a satisfactory explanation for its action." *Id*. (citing *Defs. Of Wildlife v. United States Dep't of the Interior*, 931 F.3d 339, 345 (4th Cir. 2019).

73. The Board's decision denying CMC reimbursement for the Disallowed Programs rests on its theory that the Secretary does not regard CMC and CMHA as the same entity for purposes of meeting the provider-operated criteria. Exhibit 1 at 41-42. The Board, however, failed to "articulate a satisfactory explanation," or any explanation whatsoever, for why the Secretary would regard CMHA and CMC as the same entity for some purposes, such as Medicare enrollment and satisfying the conditions of participation for hospitals, but not for purposes of meeting the provider-operated criteria in 42 C.F.R. § 413.85(f)(1). This oversight is a reversable error.

74. The Board also failed to address or even acknowledge the absurd implications of its decision. CMC has no legal existence apart from CMHA and is therefore legally incapable of performing any of the provider-operated functions in its own capacity. For example, CMC cannot incur costs in its own name (it cannot own funds or property) or employ teaching staff (it cannot issue W-2s in its name). If an entity like CMHA cannot act in the capacity of an operating division like CMC, then hospitals that are not separately incorporated are categorically ineligible to receive reimbursement for NAH programs. Thus, the Board has either "failed to consider an important part of the problem" or its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Mountain Valley Pipeline, LLC*, 990 F.3d at 826.

75. The Board also acted arbitrarily in finding that CMC does not meet the exception to the provider-operated criteria in section 413.85(g)(3) because CMHA owns CCHS. Congress went out of its way to make an exception to the provider-operated criteria for hospitals that are forced to transfer their programs to wholly owned educational institutions to meet accreditation standards. It is inherently arbitrary to conclude that Congress only intended to afford this relief to hospitals that are separately incorporated.

76. The Board's decision is also arbitrary because it is divorced from the objective of the provider-operated criteria. As the Secretary has explained, the purpose of the operator requirement to determine whether a hospital has ceded control of its NAH program to the "community," because he believes that is the point when Medicare should cease to support the program. 66 Fed. Reg. at 3,363 ("The House and Senate Committee reports accompanying [the Social Security Amendments of 1965] reflect that Congress contemplated that Medicare would share the costs of educational activities *until* the community assumed the costs."). It strains credulity to suggest that CMC has relinquished control over the Disallowed Programs to the

"community" simply because those programs are operated by CMHA, of which CMC is a part. A fully integrated health system is no more "the community" than the hospitals within it.

COUNT THREE
(The Board's Decision Fails to Observe Procedure Required by Law)

77. The allegations set forth in the preceding paragraphs are incorporated by reference as if fully set forth herein.

78. A reviewing court must set aside agency action that is "without observance of procedure required by law." *Almy v. Sebelius,* 679 F.3d 297, 302 (4th Cir. 2012) (citing 5 U.S.C. § 706(2)).

79. In its decision, the Board faults CMC for allegedly failing to comply with several previously unannounced interpretations of the Secretary's provider-operated rules. First, the Board concludes that Medicare does not regard CMC and CMHA as the same entity for purposes of the provider-operated criteria, and therefore "the acts and responsibilities of [CMHA] . . . cannot be imputed down to the operating division CMC (as the provider) for purposes of meeting or satisfying the Medicare program's provider-operated requirements . . . ." Exhibit 1 at 41-42. The Board also suggests that CMC could have satisfied the requirement to directly incur the costs of the programs had those costs been reported in the CMC "business unit" within CMHA's consolidated trial balance. Exhibit 1 at 44-46. As for the other requirements, the Board opines that CMC could have satisfied them had CMHA personnel working in the "CMC operating division" within CMHA performed those functions. Exhibit 1 at 40, 44 and 51.

80. The Board also faults CMC for the fact that it does not own CCHS, which in the Board's view means it does not qualify for the exception to the provider-operated rules that Congress directed the Secretary to create in the conference report for the Consolidated Appropriations Act of 2003.

81. Significantly, the Board does not point to any agency regulation, guidance, or public statement that would have put CMC on notice of the aforementioned requirements. Nor can it. Indeed, the witness for the MAC admitted in her testimony that she was not aware of any such guidance. Transcript at 42, 64 and 148 (May 4, 2023).

82. The Medicare statute prohibits the Secretary from enforcing "interpretative rules, statements of policy, and guidelines of general applicability" before they are published in the Federal Register. 42 U.S.C. § 1395hh(c)(1); *see also Chippewa Dialysis Servs. v. Leavitt*, 511 F.3d 172, 176 (D.C. Cir. 2007) (overturning a decision of the Board that was predicated on a standard the Secretary had not published in the Federal Register). The interpretations that the Board announced for the first time in its decision are, at the very least, guidelines of general applicability, and therefore are not enforceable until they are published in the Federal Register.

83. The Medicare statute also prohibits the Secretary from enforcing any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . payment for services" until such rule "is promulgated by the Secretary by regulation . . . ." *Allina Health Servs. v. Azar*, 863 F.3d 937, 942 (D.C. Cir. 2017), *aff'd sub nom. Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019). The new interpretations of the provider-operated rules that the Board announced in its decision are, at the very least, statements of policy that established or changed a legal standard governing payment for NAH programs. Accordingly, they are unenforceable until formally adopted through notice-and-comment rulemaking.

84. Beyond the Medicare statute, reviewing courts have held that agencies "must give full notice of [their] interpretation" of a statute or regulation before using that interpretation "to cut off a party's right." *PMD Produce Brokerage Corp. v. U.S. Dep't of Agric.*, 234 F.3d 48, 52 (D.C. Cir. 2000). The test for determining whether a regulated entity has received fair notice is

whether it could "identify, with ascertainable certainty, the standards with which the agency expects [it] to conform." *Fabi Const. Co. v. Sec'y of Lab.*, 508 F.3d 1077, 1089 (D.C. Cir. 2007). The Board's newly announced interpretations of the provider-operated rules do not pass muster.

85. Furthermore, in past years when the MAC has audited the Disallowed Programs, the MAC has never before indicated that the programs are not in accordance with the operator requirements of subsection 413.85(f). The Secretary's lack of prior enforcement of these standards by itself suggests a lack of fair notice of those standards. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 153 (2012) ("Where, as here, an agency's announcement of its interpretation is preceded by a very lengthy period of conspicuous inaction, the potential for unfair surprise is acute."). The MAC audited the Disallowed programs in 2014 and only made minor adjustments at that time. During its audit, the MAC would have reviewed the very same types of documents and facts that the MAC has reviewed now, including, *e.g.*, the relationship between CMHA, CMC, and CCHS, the administration of the program and collection of tuition, etc. Indeed, these facts were not hidden but were open and obvious. Yet, the MAC raised no serious issues during that audit. The MAC's silence is especially egregious since if the MAC had raised these issues in 2014, CMC could have at least taken steps in 2014 to attempt to meet the MAC's newly announced standards.

86. The MAC's lengthy silence regarding the alleged provider-operated deficiencies was also inconsistent with the Secretary's regulation requiring MACs to complete their audits and issue NPRs within twelve months of receiving a completed cost report. 42 C.F.R. § 405.1835(c)(1). Here, more than 6 years elapsed between the filing of CMC's cost report and the issuance of its NPRs in both the years at issue. To revisit the issue and apply new standards years

later, when CMC no longer had an opportunity to attempt to adhere to the MAC's standards, constitutes a blatant violation of fair notice and the MAC's own timing requirements.

COUNT FOUR

(The Board's Decision is Contrary to Law and in Excess of Statutory Authority)

87. The allegations set forth in the preceding paragraphs are incorporated by reference as if fully set forth herein.

88. A reviewing court must set aside agency action that is "not in accordance with law" or is "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A) & (C).

89. The Medicare statute requires the Secretary to adopt regulations for calculating the reasonable cost of services (including the cost of NAH programs) to ensure that "the necessary costs of efficiently delivering covered services to individuals covered by the insurance program . . . will not be borne by individuals not so covered." 42 U.S.C. § 1395x(v)(1)(A). Recognizing that NAH programs are "an element in the cost of patient care," Congress has mandated that the cost of those programs "be borne to an appropriate extent by the hospital insurance program." S. Rep. No. 404, 89th Cong., 1st Sess., 36 (1965).

90. The Board's decision must be overturned because it would otherwise shift the entire cost of CMC's NAH programs to non-Medicare beneficiaries. *Med. Univ. Hosp. Auth.*, 2021 WL 1177860 at *10 ("[T]the Board's decision grossly underestimates [the hospital's] entitlement to reimbursement and results in the shifting of costs to non-Medicare patients, in contravention of 42 U.S.C. § 1395x(v)(1)(A)")).

91. Additionally, the Board's decision will increase the cost of patient care. Indeed, Congress has recognized that a shortage of nurses will inevitably increase the cost of patient care. This is why Congress has throughout the years expressed concern "about the growing national shortage of nursing and allied health professionals." H.R. Rep. No. 108-10, 108th Cong., 1st Sess.,

at 1109 (2003); *see also* H.R. Rep. No. 117-96, 117th Cong., 1st Sess., at 200 (directing HHS to report how it can exercise its discretion to "address shortfalls in the nursing and allied health workforce").

92. In light of this history of the ongoing nursing shortage, it is clearly unreasonable and inconsistent with the intent of Congress for CMS and its contractors to terminate support for nursing programs like the one operated by CMC. The state of North Carolina is in particular need of nursing programs like CMC's to replenish the state's ever-diminish ranks of nurse professionals. North Carolina is among the top ten states with the largest projected nursing shortage in 2035. *American Association of Colleges of Nursing*, Fact Sheet: Nursing Shortage (May 2024).[4]

COUNT FIVE
(Violation of the Administrative Procedure Act)

93. The allegations set forth in the preceding paragraphs are incorporated by reference as if fully set forth herein.

94. When an agency is engaged in rule making, the agency must: (1) publish a general notice of proposed rulemaking in the Federal Register that includes "the terms or substance of the proposed rule or a description of the subjects and issues involved"; (2) give "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments"; and (3) "[a]fter consideration of the relevant matter presented ... incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(b), (c); *N. Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 763 (4th Cir. 2012).

95. Providing the public a meaningful opportunity to comment on the proposed rule is a critical component of the notice and comment procedure. "Notice and comment gives affected

[4] https://tinyurl.com/tk4n5vdc

parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision." *Allina Health Servs.*, 587 U.S. at 582. (citing 1 K. Hickman & R. Pierce, Administrative Law §4.8 (6th ed. 2019)); *see also*, *N. Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 763 (4th Cir. 2012) ("The agency benefits from the experience and input of comments by the public, which help ensure informed agency decisionmaking") (citing *Spartan Radiocasting Co. v. F. C. C.*, 619 F.2d 314, 321 (4th Cir. 1980)) (internal quotation marks omitted). Moreover, the notice and comment process further ensures "that the agency maintains a flexible and open-minded attitude towards its own rules … because the opportunity to comment must be a *meaningful opportunity*. *Id.* (internal quotation marks omitted) (emphasis added). The benefits of notice and comment rulemaking are particularly acute in a program as consequential as Medicare "where even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Azar v. Allina Health Servs.*, 587 U.S. 566, 582 (2019). It is not surprising, therefore, that "[a]s Medicare has grown, so has Congress's interest in ensuring that the public has a chance to be heard before changes are made to its administration." *Id*. at 569.

96. In September 1992, HCFA issued proposed regulations to elaborate on the parameters of the operator requirement as directed by Congress in OBRA '89. HCFA did not finalize those regulations for over eight years. This nearly decade long delay between when comments were solicited and when the rule was finalized subverted the rights of stakeholders to meaningfully comment pursuant to section 553(c) of the APA.

97. In the ever-changing landscape of the healthcare industry generally, and allied health programs in particular, comments made in 1992 could not possibly reflect the relevant

developments and considerations that applied nearly a decade later when the rule was finally finalized in 2001. Likewise, comments made in 1992 certainly could not reflect the comments of hospitals that either did not exist in 1992 or did not operate nursing and allied health programs in 1992. CMS's over eight-year gap from when it solicited comments to when it finalized its policy is even more troubling given Congress's specific command for the agency to issue a final rule by July 1, 1990. OBRA '89 at § 6205(b)(2)(A). Instead of finalizing the rule based on stale and necessarily incomplete comments, HCFA should have reopened the comment period to allow hospitals interested and effected by the issue in 2001 to comment based on the facts and circumstances that existed in 2001.

98. Congress itself has recognized the potential notice-and-comment problems with issuing a final rule many years after the proposed rule. To prevent this from happening, Congress has since created a bright-line standard prohibiting the Secretary from adopting regulations more than three years after the proposed rule was issued. 42 U.S.C. § 1395hh(a)(3) (stating that the Secretary "shall establish and publish a timeline for the publication of final regulations based on the previous publication of a proposed regulation" and such timeline "shall not be longer than 3 years except under exceptional circumstances."). While this three-year limitation was not in effect when the Secretary finalized its provider-operated rule at issue here, it is nonetheless proof that Congress recognized that there must be some nexus in time between a proposed rule and a final rule since, at a certain point, comments become too "stale" to be meaningful. Although there was no bright-line cut-off in effect in 2001, it remains the case that a gap of over eight years is inherently unreasonable under the APA since it fails to provide the regulated public a meaningful opportunity to comment.

99. Therefore, even if CMC did not meet the operator requirement set forth in 42 C.F.R. § 413.85(f), it would still be entitled to pass-through reimbursement for the disallowed programs because the operator provision of the regulation is unenforceable.

RELIEF REQUESTED

CMC requests that this Court enter an Order:

(a) Setting aside the Board's decision at issue;

(b) Ordering the Secretary to reimburse CMC for the Disallowed Programs that the MAC erroneously reclassified as normal operating costs;

(c) Remanding CMC's appeals back to the Board with instructions to adjudicate the tuition offset issue and Medicare Advantage payment issue;

(d) Order the Secretary to pay CMC interest pursuant to 42 U.S.C. § 1395oo(f)(2);

(e) Requiring the Secretary to pay the legal fees and cost of suit incurred by CMC; and

(f) Providing such other relief as the Court may consider appropriate.

Respectfully submitted,

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