IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Medical University Hospital Authority, Plaintiff, vs. Xavier Becerra, Secretary, U.S. Department of Health and Human Services, Defendant.	C/A No. 2:19-1755-MBS **ORDER AND OPINION**

This case arises under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, et seq. Plaintiff Medical University Hospital Authority ("MUHA") is a not-for-profit acute care hospital in Charleston, South Carolina. MUHA filed a complaint on June 19, 2019 against Defendant Alex M. Azar II,[1] Secretary of the United States Department of Health and Human Services ("HHS"). MUHA seeks judicial review of a final decision of HHS that adversely impacted MUHA's Medicare reimbursement. Specifically, MUHA alleges that HHS erred in determining MUHA failed to meet the requirements of 42 C.F.R. § 413.85(f)(1), such that MUHA is not entitled to Medicare reimbursement for costs MUHA incurs operating its Pharmacy Program.

I. FACTS AND PROCEDURAL HISTORY

Title XVIII of the Social Security act establishes a system of health insurance for the aged and disabled. Pursuant to 42 U.S.C. § 1395c,

> The insurance program for which entitlement is established by sections 426 and 426-1 of this title provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care in accordance with this part for (1) individuals who are age 65 or over and are eligible for retirement benefits under subchapter II of this chapter (or would be eligible for such benefits if certain

[1] The United States Senate confirmed Xavier Becerra to replace Alex M. Azar, II on March 18, 2021.

> government employment were covered employment under such subchapter) or under the railroad retirement system, (2) individuals under age 65 who have been entitled for not less than 24 months to benefits under subchapter II of this chapter (or would have been so entitled to such benefits if certain government employment were covered employment under such subchapter) or under the railroad retirement system on the basis of a disability, and (3) certain individuals who do not meet the conditions specified in either clause (1) or (2) but who are medically determined to have end stage renal disease.

Pursuant to 42 U.S.C. § 1395f(b), HHS reimburses eligible providers for certain services rendered to such aged or disabled individuals. Prior to 1983, hospitals were reimbursed the lower of their reasonable costs or customary charges for services provided to Medicare beneficiaries. In 1983, Congress eliminated the lesser-of-cost-or-changes provision in favor of a prospective payment system (PPS) that reimburses acute care facilities for inpatient housing operating and capital costs according to prospectively determined payment rates. See An Act to assure the solvency of the Social Security Trust Funds, to reform the medicare reimbursement of hospitals, to extend the Federal supplemental compensation program, and for other purposes, Public Law 98-21, April 20, 1983, 97 Stat. 65; 42 U.S.C. §§ 1395f, 1395ww.

HHS also is mandated to share in the reasonable costs of nursing and allied health education programs operated by providers pursuant to 42 U.S.C. § 1395x(v). See 42 U.S.C. § 1395ww (amended by American Rescue Plan Act of 2021, Public Law 117-2, March 11, 2021, 135 Stat. 4). "The provider's total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles [set forth in 42 C.F.R. § 413.24]." 42 C.F.R. § 413.85(d)(2)(ii). Approved education activities means formally organized or planned programs of study of the type that (1) are operated by providers; (2) enhance the quality of health care at the provider; and (3) are

licensed by state law, or accredited by the recognized national professional organization for the particular activity. Id. § 413.85(d)(1)(i), (e). A "provider of services" is a "hospital, critical access hospital, rural emergency hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395n(e) of this title, a fund." 42 U.S.C. § 1395x(u).

The reasonable-costs-incurred methodology was retained for approved nursing and allied health educational activities. See Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, Nov. 5, 1990, 104 Stat. 1388; 42 C.F.R. § 413.85. "Reasonable cost" is the cost actually incurred, "excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services[.]" 42 U.S.C. § 1395x(v)(1)(A).

In order to be considered the operator of an approved nursing or allied health education program, a provider must:

> (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 (where classroom instruction is a requirement for program completion), subject to the parenthetical sentence in paragraph (f)(1)(ii) of this section.

Id. § 413.85(f)(1).

Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in § 413.85(f)(1) and to be the operator of the program. Id. § 413.85(2).

A provider must submit a cost report at the close of its fiscal year that shows both its costs incurred and the appropriate portion of those costs to be allocated to the Medicare program. See 42 U.S.C. § 413.20. The cost report is reviewed and audited by a Medicare Administrative Contractor (MAC), an entity that contracts with the federal government to review and/or adjudicate claims, determinations and/or decisions. Id. § 405.902. The MAC issues a final determination of reimbursement due to the provider known as the Notice of Amount of Program Reimbursement (NPR). A provider may appeal the determination to the Provider Reimbursement Review Board. Id. § 1395oo(a). The Board has the power to affirm, modify, or reverse a final determination of the MAC with respect to a cost report and to make any other revisions on matters covered by such cost report. Id. § 1395oo(d). The Centers for Medicare and Medicaid Services (CMS) Administrator, on behalf of the Secretary, can review the Board's decision and adopt, reverse, or modify the decision in whole or in part. The decision of the Board, or the CMS Administrator, whichever is pertinent, becomes the final decision of HHS sixty days after the date on which notice of any final decision is received. The final decision is subject to judicial review pursuant to 42 U.S.C. § 1395oo(f).

In its complaint, MUHA states that it has operated an accredited Paramedical Education Pharmacy Residency Program since 1955 in collaboration with the Medical University of South Carolina (MUSC) College of Pharmacy. The Pharmacy Program enhances the quality of care at MUHA's facility by providing inpatient, outpatient, and retail pharmacy services to patients there. Prior to 2000, MUHA's predecessor, the MUSC Medical Center, transferred funds on a monthly basis to MUSC to reflect expenses incurred by MUSC Medical Center but initially recorded on MUSC's ledger. MUHA states that MUSC Medical Center then would submit claims to Medicare reporting these expenses as its own, and it always was allowed to claim the full amount of its costs on its Medicare cost report.

MUSC Medical Center and MUSC were legally the same entity until 2000, when the South Carolina General Assembly approved a resolution to formally recognize MUHA as a separate entity but still a component of MUSC, rather than a divisional unit. MUSC Medical Center ceased to exist, and MUHA and MUSC entered into an affiliation agreement specifying the financial and operational obligations of each entity. The agreement required MUHA to provide sufficient funding to pay MUSC for salaries and other expenses associated with the operation of the residency program. Some costs were paid initially by MUSC and MUHA transferred funds to MUSC on a monthly basis to cover those costs. The monthly payments were reconciled at year end and the costs appeared fully on MUHA's books after reconciliation. MUHA states the reconstitution of the MUSC Medical Center as a new entity did not result in any operational changes in the Pharmacy Program. MUHA states that it retains full and ultimate authority and control over the program.

The affiliation agreement provided:

- The ongoing administrative oversight of the Program is delegated to the Chair

of the Department of Pharmacy Practice (for the College) and to the Director of Pharmacy Services (for the Medical Center.)

- The on-going operation and coordination of the Program is delegated to the Director of Graduate Pharmacy Education (GPE) who reports directly to the Chair of Pharmacy Practice and the Director of Pharmacy Services.

- Residency Program Directors (RPDs) are responsible for the operation of the individual residency experiences.

- Residents will also work with Preceptors within specific practice areas or areas of expertise.

- A Residency Committee, chaired by the Director of GPE, will serve as a forum to deal with all matters associated with the operation of the Program. All recommendations emanating from the committee will be forwarded by the Director of GPE to the Chair of Pharmacy Practice and the Director of Pharmacy Services for their approval and then to the Dean for final approval and implementation.

ECF No. 30, 7.

Dr. Paul W. Bush served as MUHA's Director of Pharmacy Services and Director of Graduate Pharmacy Education during the time periods at issue. He managed the Residency Program and reported to MUHA's Administrator for Clinical Services. MUHA states that some administrative services were contracted to MUSC, but Dr. Bush retained control and oversight of those functions. MUHA's Director of Finance, John Cooper, along with its CEO and Chief Financial Officer, oversaw the annual budget for the residency program. MUHA issues a degree, diploma, or other certificate upon successful completion of the Pharmacy Program.

According to MUHA, CMS had allowed MUHA and its predecessor, MUSC Medical Hospital, to claim the full amount of its costs associated with the Pharmacy Program in the paramedical pass-through cost center of its annual Medicare cost report. MUHA alleges that, however, in fiscal years ending June 2007 and June 2008, the MAC asserted for the first time that

MUHA did not meet all of the requirements of 42 U.S.C. § 413.85(f)(1) so was not the operator of the Pharmacy Program. The MAC reclassified the costs and statistics associated with MUHA's Pharmacy Program to the medical education cost centers, which resulted in the elimination of Medicare support for the Pharmacy Program.

MUHA appealed the MAC's decision to the Board. The Board found that MUHA had not met all five requirements under 42 C.F.R. § 413.85(f)(1) because it did not "directly incur" the costs of the program; rather, it reimbursed MUSC for the costs MUSC incurred. See 42 C.F.R. § 413.85(f)(1)(i). The Board determined that the plain meaning of the statute is that the costs must be directly borne by the provider in the first instance. The Board also determined that MUHA did not control the administration of the Pharmacy Program, because the Dean of the School of Pharmacy, a MUSC employee, has ultimate control of the program, while MUHA exercises only day-to-day control. The Administrator declined to review the Board's decision. Therefore, the Board's decision became the "final decision" for purposes of judicial review.

MUHA seeks an order setting aside the Board's decision and requiring HHS to reimburse MUHA for its education costs, plus interest and costs of the litigation, for years 2007 and 2008. MUHA filed a motion for summary judgment on June 15, 2020. An amicus brief in support of MUHA was filed on July 23, 2020 by the American Society for Health System Pharmacists.[2] HHS filed a cross-motion and response in opposition on August 21, 2020. MUHA filed a reply and response to the cross-motion on September 21, 2020, to which HHS filed a reply to MUHA's response on October 28, 2020. The court held a hearing via videoconference on November 17, 2020.

[2]The court thanks the American Society for Health System Pharmacists for its insightful amicus brief.

II. DISCUSSION

A. The Decision of the Board

The relevant discussion provides:

A. ISSUE 1 – PARAMEDICAL EDUCATION COSTS

MUHA contends that it meets the requirements specified in 42 C.F.R. § 413.85(f) pertaining to the PRP and should receive pass-through costs pursuant to the requirements of 42 C.F.R. § 413.85(d). Specifically MUHA argues that it was the operator of the PRP [Pharmacy Residency Program] and directly incurred the costs of training.

In 1983, Congress enacted the Medicare Inpatient Prospective Payment System ("IPPS"). In 1990, it began to allow for the payment of certain approved nursing and allied education activities on a reasonable cost or "pass-through" basis when, among other conditions, a provider is the operator of the program. In order to be considered the operator of an approved nursing or allied health program, a provider must meet all 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 classroom instruction and clinical training where classroom instruction is a requirement for program completion), subject to the parenthetical sentence in paragraph (f)(1)(ii) of this section.

MUHA contends that it was the operator of the PRP, as it had full, ultimate authority and control over the PRP. MUHA provided support for this contention by explaining that, for example, the program was run by an MUHA employee. Specifically, Paul W. Bush, Pharm. D., served as MUHA Director of Pharmacy Services and Director of Graduate Pharmacy Education during the time periods at issue in this appeal. Although Dr. Bush had a faculty appointment in the College of Pharmacy, he reported through MUHA, including reporting to the Administrator of Clinical Services for MUHA, Dr. Marilyn Schaffner. As Director of Graduate Pharmacy Education, Dr. Bush was responsible for the "on-going operation and coordination of the [PRP.]" Through his roles, Dr. Bush controlled the PRP budget, including approving all expenditures. Although certain administrative functions (including portions of the payroll system) were contracted to MUSC, MUHA argues that it retained control and oversight for those functions. Dr. Bush also gave final approval for all human capital decisions, including the offering of residency positions and disciplinary action against residents.

MUHA also contends that it directly incurred the costs of the PRP because "[a]ll that is required . . . is that the costs appear on the provider's 'books and records,' not that the provider have incurred the costs first." The Provider argues "the use of the word 'before' strongly suggests that the cost does not have to appear on the provider's books 'first'; it merely must appear on the provider's books 'before' it will be allowed." Ultimately, MUHA believes it did "directly" incur the costs as it "fully reimbursed MUSC for all outstanding costs, and those payments were reflected on the hospital's general ledger."

The Board disagrees that MUHA is the operator of the PRP because MUHA did not meet all the criteria in 42 C.F.R. § 413.85(f)(1). Specifically, MUHA did not directly incur the costs of the PRP program. Rather, MUSC directly incurred the PRP costs and MUHA reimbursed MUSC for those costs. The Board finds the Provider's argument on this issue to be unpersuasive as reimbursement of costs to another entity, even a related entity, is not the equivalent of directly incurring the costs.

The Board's finding is mandated by the plain language of § 413.85(f)(1)(i) – the claimed costs must be "directly incur[red]," not merely incurred, before a provider may be considered to be the operator of the training program. CMS's interpretation of the regulation has been clear from its promulgation: "With respect to educational costs . . . our policy has been that the provider, rather than the related organization, must directly incur the costs on its books and records before the costs will be recognized for Medicare payment purposes. Otherwise, the principle that Medicare payment for medical education costs should not result in a redistribution of costs from the educational institution to the provider would be violated."

The Board's finding is also consistent with longstanding rules of statutory and

> regulatory construction. Where the HHS Secretary includes particular language in one section of a regulation, but omits it in another, it is generally presumed that the Secretary acts intentionally and purposely in the disparate inclusion or exclusion. Similarly, a basic principle of statutory or regulatory interpretation is that courts should "give effect, if possible, to every clause and word of a statute[.]" "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . ." Here, the Secretary has included the word "directly" in the regulation setting out the mandatory criteria for a finding that a training program is provider-operated: a provider must "directly incur the training costs."
>
> This same provision of the regulations clearly contemplates that a provider may contract with another entity regarding certain aspects of the training program. However, the Secretary has mandated – within his rulemaking authority – that if a provider wishes to be paid on a pass-through basis for allied health training costs, even if some of the functions related to that training program are legitimately contracted to a non-provider entity, the provider must directly incur in the first instance those costs it claims for reimbursement. To find otherwise would require ignoring the word "directly," which the Board cannot do.
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> The Board also finds that MUHA did not control the administration of the PRP, as required under § 413.85(f)(1)(iii). Specifically the Affiliation Agreement states that the Dean of the School of Pharmacy, a MUSC employee, has ultimate control of the PRP, while MUHA exercises day to day control.
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> In summary, as a result of its finding that MUHA does not directly incur the cost of the PHP or have ultimate control of the PHP, the Board concludes, based on 42 C.F.R. § 413.85(f)(1), that MUHA does not qualify for pass-through reimbursement for the reasonable cost of the PRP.

ECF No. 1-1 (Decision dated 2.19.19).

B. Standard of Review

Pursuant to 5 U.S.C. § 706,

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--
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> (1) compel agency action unlawfully withheld or unreasonably delayed; and

> (2) hold unlawful and set aside agency action, findings, and conclusions found to be--
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> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
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> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
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> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.
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> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

"An agency decision is arbitrary and capricious 'if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.' " Spence v. NCI Info. Sys., Inc., 530 F. Supp. 2d 739, 743-44 (D. Md. 2008) (quoting Motor Vehicle Mfrs. Ass's of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 44 (1983)). The Supreme Court has adopted the rebuttable presumption that "'the power authoritatively to interpret its own regulations is a component of the agency's delegated lawmaking powers.'" Kisor v. Wilkie, 139 S. Ct. 2400, 2412 (2019) (quoting Martin v. Occupational Safety and Health Review Comm'n, 499 U.S. 144, 151 (1991)). Thus, the Court has presumed that Congress intended for

courts to defer to agencies when they interpret their own ambiguous rules. Id. at 2414. However, if there is only one reasonable construction of a regulation, "then a court has no business deferring to any other reading, no matter how much the agency insists it would make more sense. Deference in that circumstance would 'permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation.'" Id. (quoting Christensen v. Harris Cnty., 529 U.S. 576, 588 (2000)).

If a genuine ambiguity exists in the rule, the agency's reading of the rule must be reasonable. Id. at 2415 (citing Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 515 (1994)). The regulatory interpretation must be the agency's authoritative or official position. Id. at 2416. Further, the agency's interpretation must in some way implicate its substantive expertise, and the agency's reading of the rule must reflect fair and considered judgment. Id. at 2417. A court may not defer to a new interpretation, whether or not introduced in litigation, that creates "unfair surprise" to regulated parties. Id. at 2418 (citing Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158, 170 (2007)).

Law/Analysis

The questions before the court are (1) must MUHA incur the reasonable costs of the Pharmacy Program in the first instance in order to satisfy the prerequisites of § 413.85(f)(1)(i); and (2) is MUHA's day-to-day control of the Pharmacy Program adequate to satisfy the prerequisites of § 413.85(f)(1)(ii)-(v) such that MUHA can be identified as an operator eligible for pass-through Medicare reimbursement for costs of approved nursing and allied health education services.

C. MUHA's Motion for Summary Judgment

MUHA first argues that the Board created a new standard in determining that MUHA is not an "operator" because some of the costs of MUHA's educational program had been paid "in the first

instance" by MUSC. MUHA asserts that the term "directly incur" does not mean "in the first instance," as determined by the Board. MUHA argues that a provider "directly incurs" a cost if its liability for that cost inevitably and necessarily follows from the expenditure. MUHA states that its affiliation agreement with MUSC provides MUHA is liable for the payment of all costs of the Pharmacy Program, without qualification. MUHA urges that its legal obligation to pay all costs of the Pharmacy Program, including reimbursing MUSC for any costs it incurs in the first instance, demonstrates that MUHA "directly incurs" those costs.

By way of analogy, MUHA notes that § 413.85(f)(1)(ii) requires a provider to have "direct control" of the program curriculum in order to be deemed the operator of a residency program. MUHA observes that § 413.85(f)(1)(ii) allows a provider to "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 courses relating to the theory and practice of nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program." MUHA argues that the Board's interpretation of "directly" is nonsensical in the context of § 413.85(f)(1)(ii), which allows a provider to contract with a school to furnish courses, but to maintain "direct control" as long as the provider does not surrender its ultimate authority to approve or reject the content of those courses.

MUHA further asserts that its interpretation of "directly incurs" is consistent with Medicare Program; Payment for Nursing and Allied Health Education, 66 Fed. Reg. 3358, 3367. The Secretary stated therein that HHS's "policy has been that the provider, rather than the related organization, must directly incur the costs on its books and records before the costs will be recognized for Medicare payment purposes." MUHA reads this sentence as meaning the cost must

appear on the provider's books as its own expense before it will be allowed. Thus MUHA "directly incurs" a cost once it has reimbursed MUSC for costs MUSC paid in the first instance, so that the cost appears on MUHA's books and records.

Next, MUHA contends that the Board created a new standard to hold that MUHA did not control the administration of the Pharmacy Program. MUHA argues that the Board arbitrarily relied on a provision in the affiliation providing that the Dean of the School of Pharmacy, an MUSC employee, had ultimate control over the Pharmacy Program. According to MUHA, the Board should have made a functional inquiry into the evidence regarding the operation of the Pharmacy Program, rather than relying on one phrase in the affiliation agreement that authorizes the Dean of the School of Pharmacy, an MUSC employee, to exercise ultimate control over the Program. MUHA argues that the conduct of the parties demonstrates MUHA exercises actual control over the Pharmacy Program through its day-to-day oversight. MUHA further contends that it exercises control because it "has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution." 42 C.F.R. § 413.17(b)(3) ("Control exists if an individual or organization has the power directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.").

MUHA next contends that the Board disregarded the regulatory mandate that MUHA must be presumed to operate the educational program. MUHA bases its argument on the alternate test set forth in 42 C.F.R. § 413.85(f)(2), which states that the provider that issues the degree, diploma, or other certificate upon successful completion of an approved program is assumed to meet the criteria of § 413.85(f)(1). MUHA asserts that the language in § 413.85(f)(1) providing that its provisions control "[e]xcept as provided in paragraph (f)(2)" shows that § 413.85(f)(2) takes priority. MUHA

states that the MAC testified in proceedings before the Board that § 413.85(f)(2) did not apply because MUHA issued diplomas in conjunction with MUSC. MUHA argues, however, that nothing in § 413.85(f)(2) requires the provider be the only entity that issues a diploma. MUHA notes that the regulation contemplates situations wherein a provider can enter into an agreement with an educational institution to furnish basic academic courses, which arrangement would anticipate both entities would play a role in issuing the diplomas.

Finally, MUHA argues that the Board did not give fair notice that it would deny payment to MUHA based on standards that had not been adopted through notice-and-comment rulemaking. MUHA contends the program expenditures that initially appeared on MUSC's portion of its consolidated financial statement before being "trued up" were just a matter of accounting convenience. MUHA asserts that the accounting methodology could have been revised had MUHA been on notice that the treatment mattered for Medicare payment purposes. MUHA also points out that the claims were allowed both before and after MUHA became a separate entity in 2000, and that it was not until 2012 the expenditures were disallowed.

D. HHS's Cross-Motion and Response to MUHA's Motion

HHS sets out the following facts in support of its position that MUHA is not an operator of the Pharmacy Program:

> Residents of the Program are employees of MUSC and are paid directly by MUSC. (AR-00809, 236). Resident employee records and payroll records are stored by the Human Resources department at MUSC. (AR-00239, 254). Some of the teaching staff for the Program, including preceptors and Resident Program Directors are employees of MUSC while others are employees of MUHA. (AR-01070, 976, 232). Payroll for MUSC employees is handled by MUSC Human Resources. (AR-00239). The portion of salary and benefits of MUSC-employed faculty attributable to the Program are "initially incurred by MUSC." (AR- 00048; 01071, ¶ 11). MUHA employee salaries are "initially paid by MUHA directly." (AR-00049).

> The costs of the Program, including payroll records, "are recorded in the ledger of MUSC." (AR-01062, ¶ 7). MUHA makes "intra-component" transfers to MUSC with a year-end true up of costs. (AR-01604, ¶ 11). Costs included in the "true-up" include "resident salary ("resident support"), certain pharmacy faculty costs ("personal service unclassified" for faculty, "personal service classified" for administrative staff, and overtime expenses), and fringe benefits for residents and salary." (AR-01065, ¶ 11). "For MUSC employees where MUHA paid a portion of salary and benefits, the paid amount is meant to reflect the proportion of time the faculty worked on behalf of the Residency Program." (AR-01065, ¶ 11).

ECF No. 30, 8-9.

HHS argues the Board's determination that MUHA did not directly incur the training costs of the Pharmacy Program is supported by substantial evidence. According to the Board, MUSC incurred the costs of the Program in the form of salaries to its own employees. The costs were included on MUSC's books and records, the ledger costs for MUSC, and in its annual budget. According to HHS, MUSC was an intervening agency that incurred the costs in its books and records prior to the costs being incurred by MUHA. HHS states that the Board's interpretation is consistent with long-standing Medicare policy that a provider's net cost of approved allowable educational costs does not include "redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support." 42 C.F.R. § 413.85(d)(2)(ii). "Community support" means "funding that is provided by the community and generally includes all non–Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act." Id. § 413.85(c)(3). "Redistribution of costs" means

> an attempt by a provider to increase the amount, or to expand the types, of the costs of educational activities that are allowed for Medicare payment purposes by claiming costs that previously were not claimed by the provider and were considered costs of

> an educational institution. For example, costs for a school of nursing or allied health education or a medical school that were incurred by an educational institution and were not allowable to the provider in its prospective payment or rate-of-increase limit base year cost report, or graduate medical education per resident amount calculated under §§ 413.75 through 413.83, are not allowable costs in subsequent fiscal years.

Id.

HHS acknowledges that MUHA received Medicare pass-through reimbursement for the Pharmacy Program in previous years. However, according to HHS, once MUHA became a separate legal entity, it shifted the Program costs from MUSC, a state-funded educational institution, to MUHA, a separate legal entity, with its revenues and expenses separately stated from MUSC. HHS contends that the majority of the costs of the program were for salaries of MUSC's own employees that were included on MUSC's general ledger and its budget.[3] According to HHS, the shift of costs violated the spirit of Medicare's anti-distribution and community support policy.

HHS next argues that MUHA did not meet the requirements of § 413.85(f)(1)(iii) because the Dean of the College of Pharmacy is ultimately responsible for the Program. HHS also points out that the Chair of Pharmacy and Clinical Sciences for the College of Pharmacy had equal authority to Dr. Bush in his role for MUHA and equal administrative oversight of the Pharmacy Program. HHS contends that MUHA did not control the maintenance of payroll records of teaching staff or students. HHS also argues that, just because the Dean of the College of Pharmacy did not exercise his responsibilities under the agreement between MUSC and MUHA does not mean that the Dean could not enact substantial changes to the Pharmacy Program at any time. In addition, HHS observes that both MUSC and MUHA have the power to direct the actions or policies of the

[3]HHS bases this argument on the fact that the residents were employees of MUSC and their salaries were paid by MUSC before being reimbursed by MUHA. Stated differently, the residents' salaries were not "directly incurred" by MUHA.

Pharmacy Program. MUSC contends such shared control does not support a finding that MUHA should be considered the operator of the Program under 42 C.F.R. § 413.85(f).

Next, the Board disagrees with MUHA's interpretation of § 413.85(f)(2) as mandating operator status just because a provider issues a certificate upon successful completion of an approved program. HHS argues that the words "absent evidence to the contrary" in the statute means that if a provider does not issue a diploma, there is no assumption of operator status in the provider's favor. On the other hand, if the provider issues the diploma, there is an assumption that the provider meets the requirements of § 413.85(f)(1) "absent evidence to the contrary." HHS contends the record shows ample evidence that MUHA does not meet the requirements of § 413.85(f)(1) to be identified as an operator.

Finally, HHS contends that the standards applied by the Board were adopted through notice and comment rulemaking. HHS argues that the Board applied the language in § 413.85(f) to make its determination. Likewise, according to HHS, the Board's reading of § 413.85 reflects "fair and reasoned judgment" and did not amount to "unfair surprise" as the result of the agency substituting "one view of a rule for another." ECF No. 30, 26 (quoting Kinsor v. Wilkie, 139 S. Ct. 2400, 2417-18 (2019). HHS contends that the Board's interpretation was made by the agency (the CMS administrator having declined review), implicates the Board's substantive expertise, and is reasonable. For all these reasons, HHS urges that the Board's decision is entitled to substantial deference.[4]

[4]Both MUHA and HHS filed reply briefs in which they reiterated the arguments set forth in their cross-motions for summary judgment. MUHA argues, however, that HHS's justifications were not those adopted by the Board, and therefore are not entitled to consideration.

E. The Court's Decision

"It is a "foundational principle of administrative law" that judicial review of agency action is limited to "the grounds that the agency invoked when it took the action." Dep't of Homeland Sec. v. Regents of the Univ. of Calif., 140 S. Ct. 1891, 1907-08 (2020) (citations omitted). Thus, the court must confine its discussion to the justifications advanced by the Board in support of its decision, and will disregard any new arguments offered by HHS in its cross-motion for summary judgment.

At issue are the Board's conclusions that MUHA is not entitled to pass-through Medicare reimbursement because (1) MUHA does not directly incur the cost of the Pharmacy Program, and (2) MUHA does not have ultimate control of the Pharmacy Program, both as mandated by 42 C.F.R. § 413.85(f)(1).

1. Whether MUHA is entitled to the presumption that it qualifies as an operator under 42 U.S.C. § 413.85(f)(2). As discussed above, the Board did not address the implications of § 413.85(f)(2). Nevertheless, MUHA's argument appears to be foreclosed by 66 Fed. Reg. 3358-01, 3363 in which HHS responded to the following comment:

> Comment: One commenter described a CRNA program in which the hospital is allowed to grant a certificate to a student upon completion of the program. This may occur when an affiliated university also grants a degree to the same student. According to the commenter, the Council on Accreditation of Nurse Anesthetist Programs does not prohibit the awarding of an "anesthesia certificate" in addition to the award of the master's degree for a hospital-based program. The commenter believed that this could be interpreted as the hospital meeting the criteria to be the operator of the program since the hospital awards a certificate, and requested that we clarify this in the final rule.
>
> Response: The program described above where the hospital awards a certificate and an affiliated university confers a degree upon the same student appears to be a university-controlled nursing or allied health program. The certificate awarded by the

> hospital seems to be an adjunct to the actual degree awarded by the educational institution. In fact, as indicated by the commenter, the certificate is awarded "in addition" to the master's degree awarded by the university. This indicates the program is under the control of the university and the hospital has merely provided support to that program. We note, however, that if the hospital described by the commenter can show that it, in fact, meets the criteria of § 413.85(e) (§ 413.85(f) in this final rule) of operating the program, it may receive pass-through payment.

It appears from the record that MUHA issues a certificate upon successful completion of the Pharmacy Program in conjunction with the degree issued by the MUSC College of Pharmacy. The court finds that MUHA is burdened with showing it meets the criteria of § 413.85(f) of operating the Pharmacy Program. The court therefore turns to the findings made by the Board.

2. The requirement that MUHA incur costs of the Pharmacy Program in the first instance. The Board determined that MUHA's interpretation of "directly incurred" impermissibly reads out the term "directly," in contravention of the use of the term in § 413.85(f)(1)(i). In the court's view, the Board construed the term "directly incurred" too narrowly. By not undertaking a comprehensive review of all allowable costs incurred and paid by MUHA in the administration of the Pharmacy Program, the Board's decision grossly underestimates MUHA'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).

As a policy matter, the court finds compelling the decision of the Court of Appeals for the Seventh Circuit in a somewhat analogous case, Loyola Univ. of Chicago v. Bowen, 905 F.2d 1061 (7th Cir. 1990). In Bowen, the issue involved faculty-physicians who both provided teaching and research services in the Foster G. McGaw Hospital, the Burke Ambulatory Care Center, and the Stritch School of Medicine, all of which were owned and operated by Loyola University as separate entities within the Loyola University Medical Center. Faculty-physicians both provided teaching and

research duties at the medical school as well as practiced medicine at the hospital and care center, where they supervised and trained students, interns, and residents of the medical school. The faculty-physicians were paid a fixed salary from the medical school for teaching, research, and administrative activities, and a percentage of revenue resulting from patient care activities at the hospital and care center. Id. at 1064. The remaining percentage of revenue was allocated to the University in various ways, including to research and education accounts in the medical school departments in which the faculty-physicians were faculty members.

Loyola University filed costs reports with a MAC, claiming reimbursement for its overall costs of clinical medical education, including salaries paid to medical residents and interns working in the hospital and care center. The MAC disallowed reimbursement for fifty percent of the costs attributable to the time residents and interns spent at the care center, and also reduced Loyola University's claimed overall clinical education costs by the amounts set aside for research and education accounts on the ground that these funds were restricted gifts and grants designated for payment of specific costs included within Loyola University's reimbursement claim. Id.

On appeal from judicial review, the Seventh Circuit found that the funds transferred to the research and education accounts did not constitute donor-restricted funds or grants, gifts, or income from endowments, or that the research and education funds were designated for paying specific operating costs of the hospital. Ultimately the Seventh Circuit determined that:

> Finally, from our review of the record, we are of the opinion that there is no impermissible shifting of costs from educational to patient care institutions. The Hospital seeks reimbursement only for the residents' patient care activities involving Medicare beneficiaries, and the Secretary does not argue that the Hospital has included any inappropriate educational expenses within its claim. Thus, we conclude that the costs of resident and intern training in the Hospital and the BACC are properly shifted to the patient care institution and its Medicare beneficiaries.

> Moreover, to disallow these costs would cause the cost of providing services to Medicare beneficiaries to be shifted to other patients within the Hospital and the BACC. We will not be a party to allowing the Secretary to violate the specific and clear congressional intent expressed in 42 U.S.C. § 1395x(v)(1)(A) that "the necessary costs of efficiently delivering covered services to individuals covered by the [Medicare] insurance programs . . . will not be borne by individuals not so covered."

Id. at 1073.

In this case, the court finds no evidence that approving costs that were not incurred by MUHA in the first instance, but were reimbursed to MUSC in accordance with their affiliation agreement, impermissibly shifts costs from educational to patient care institutions. The court also finds that the Board's interpretation of "directly incurs" results in costs being borne by individuals not covered by Medicare. The Board's decision is arbitrary and capricious and not supported by substantial evidence.

3. The requirement that MUHA exert complete administrative control over the Pharmacy Program. The Board found that MUHA did not establish "control" because the ultimate authority over the Pharmacy Program is the Dean of the College of Pharmacy. The court again finds that the Board construed the term "control the administration of the program" too narrowly. As urged by MUHA, the Board was required to make an extensive review of the record to determine whether MUHA collected tuition (where applicable); controlled the maintenance of payroll records of teaching staff or students, or both (where applicable); and was responsible for day-to-day program operation. 42 C.F.R. § 413.85(f). The regulation requires more than simply identifying the titular head of the organization. Moreover, both MUSC and MUHA are governed by the same president and board of trustees; following the Board's decision to its logical conclusion, the president and the board of trustees retained ultimate control over the administration of the Pharmacy Program, and not

the Dean of the School of Pharmacy.

A more comprehensive review of the record would demonstrate that MUHA exercised sufficient control over the Pharmacy Program to be identified as an "operator." The record demonstrates that each residency program within the Pharmacy Program is managed by a residency program director. The residency program directors establish rotational schedules, ensure residents are meeting their requirements, and provide evaluations of the residents. The residency program directors reported to Dr. Paul Bush, MUHA Administrator of Pharmacy Services and Director of Graduate Pharmacy Education. Dr. Heather Easterling has since assumed these two positions. ECF No. 12-1, 52, 58. Dr. Bush also had the final say in all human capital decisions, including the offering of residency positions and all disciplinary actions; publishing the Pharmacy Residency Program Manual; controlling the Pharmacy Program budget; and chairing the Pharmacy Program residency committee. Id. at 61-62.

This and other information in the record demonstrates that the Board's decision regarding who controls the Pharmacy Program, particularly when taken in context of § 413.85(f)(1)(iii)'s admonition that an operator "be responsible for the day-to-day program operation," is arbitrary and capricious and not supported by substantial evidence.

III. CONCLUSION

For the reasons stated, the court finds that the Board's narrow construction of § 413.85(f) is arbitrary and capricious and not supported by substantial evidence. MUHA's motion for summary judgment is **granted**. HHS's motion for summary judgment is **denied**. The Board's decision dated February 19, 2019 is **reversed and vacated**. The cause is remanded to HHS with directions to reimburse MUHA, on a reasonable cost basis, for its nursing and allied health education costs

associated with the Pharmacy Program for Fiscal Years 2007 and 2008, plus interest pursuant to 42 U.S.C. § 1395oo(f)(2), plus costs of the within action.

IT IS SO ORDERED.

/s/ Margaret B. Seymour
Senior United States District Judge

Charleston, South Carolina

March 26, 2021