DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

February 28, 2024

Paul W. Abramowitz, PharmD, ScD (Hon), FASHP
Chief Executive Officer
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4500 East-West Highway, Suite 900
Bethesda, MD 20814

Dear Dr. Abramowitz:

Thank you for your outreach regarding concerns about audits of hospital pharmacy residencies. The Centers for Medicare & Medicaid Services (CMS) greatly appreciate you bringing your concerns and suggestions to our attention.

I understand that there has been a significant amount of interest regarding audits of hospital pharmacy residencies. I hope the following will address your concerns. In your letter, you request that CMS "halt all PGY1 funding clawbacks on the basis of the direct control requirement until the agency provides meaningful guidance that addresses compliance requirements" in the context of a hospital that is part of a healthcare system or associated with an educational institution. This response addresses the challenges that healthcare systems raise related to a hospital's qualification for Medicare pass-through funding.

Section 1861(v) of the Social Security Act and regulations at 42 C.FR section 413.85 ("Cost of approved nursing and allied health education activities"), sets out the requirements that a hospital must meet to qualify for reasonable cost payment for provider-operated nursing and allied health (NAH) education programs. Key factors enumerated in these regulations include that the hospital itself must "directly" incur the training costs, employ the teaching staff of the educational program, have direct control of the program curriculum, control the maintenance of payroll records of teaching staff or students, and provide and control the administrative functions and classroom and clinical training. In addition, an important and long-standing limitation on payment set out in our regulations at section 413.85(d)(2)(ii) is that a hospital's "*total allowable education costs . . .* do ***not*** include patient care costs, *costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider* or costs that have been or are currently being provided through community support" (emphasis added).

I recognize as the healthcare industry has evolved, many hospitals currently are components of larger healthcare systems. In many cases, central offices or other related entities may be providing consolidated non-clinical and administrative functions. This evolution has complicated the ability of hospitals to demonstrate eligibility by meeting the "provider-operated," "direct control" requirements for Medicare pass-through funding for NAH programs. Thus, the audit challenges some hospitals are experiencing may not result from inappropriate auditing, but rather are a consequence of the central office or corporate headquarters facility

performing certain functions rather than the hospital itself. More specifically, a corporate headquarters is a related organization to the hospital; it is not the hospital itself. As stated in the Provider Reimbursement Manual CMS Pub. 15-2, chapter 39, section 3900:

> "The home office of a chain is not in itself certified by Medicare. Therefore, its costs may not be directly reimbursed by Medicare. The relationship of the home office to Medicare is that of a related organization to participating providers."

Likewise, the January 12, 2001, Medicare Program; Payment for Nursing and Allied Health Education final rule (66 FR 3367) states:

> [O]ur 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." That is, the hospital itself would have to actually pay for the costs of the NAH program from their own funds (e.g., cash, accounts payable entries). Therefore, if a home office is incurring costs associated with the program, such as salary costs, holding the W-2s of the teaching staff and residents, operating payroll or providing other administrative functions, these factors would be evidence that the hospital itself is not "directly" incurring the costs, nor would the hospital be in control of the payroll records of teaching staff or students in such a case. CMS has encountered scenarios, such as when a related organization first incurs the costs and then the hospital reimburses those costs, or when a related organization executes "intercompany transfers" via various accounting practices to reflect those "costs" on the hospital's Medicare cost report. Each of those scenarios either (1) represents evidence of "indirect" rather than "direct" incurring of costs, or (2) does not reflect actual cash transactions from the hospital's own funds. We continue to stress that in all cases, the burden of proof is on the hospital to demonstrate that its program is meeting all five criteria listed at §413.85(f)(1) for provider-operated status. In instances where the hospital has not proved that it has directly incurred the training costs, CMS disallows pass-through payment. While it is true that the regulations at section 413.85(f)(1)(iii) state that "A provider may contract with another entity to perform some administrative functions," the regulations also state that "the provider must maintain control over **all** aspects of the contracted functions" (emphasis added). Furthermore, because of the explicit regulation stating that costs incurred by related organizations are not allowable educational costs to the hospital, the scenarios mentioned above, where a home office provides payroll management or initially incurs certain salary or other program costs, do not comply with the regulations requiring the hospital to directly incur training costs and operate the program. Accordingly, the costs associated with a program that does not qualify for Medicare reasonable cost payment passed through the IPPS would instead be considered normal operating costs included in the IPPS (see 49 FR 234 January 3, 1984, and 66 FR 3362 January 12, 2001).

A provider who is dissatisfied with a NAH payment determination can appeal to the Provider Reimbursement Review Board (PRRB). The PRRB is an independent panel to which a Medicare provider of services may appeal if it is dissatisfied with a final determination by its Medicare Administrative Contractor or CMS. Information regarding this appeals process is

available at https://www.cms.gov/medicare/regulations-guidance/provider-reimbursement-review-board.

I understand that Medicare funding for a pharmacy residency can be critical in promoting long term access to these important services within a hospital and its community. Hospitals may wish to re-evaluate certain functions that are occurring at the corporate headquarters level and determine whether those functions can be provided by the hospital itself in a reasonably efficient or cost-effective manner.

I hope that such key modifications, aimed at allowing NAH programs to meet the "provider-operated," "direct control" criteria outlined above, will allow more hospitals to remain or become eligible for reasonable cost-based payments for NAH programs going forward.

Sincerely,

Chiquita Brooks-LaSure