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

MEDICAL UNIVERSITY HOSPITAL AUTHORITY, Plaintiff, v. ALEX M. AZAR, II, Secretary, United States Department of Health and Human Services, Defendant.	Case No. 2:19-cv-1755-MBS

BRIEF OF AMICUS CURIAE THE AMERICAN SOCIETY OF HEALTH SYSTEM PHARMACISTS IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTEREST OF AMICUS CURIAE[1]

The American Society of Health-System Pharmacists (ASHP) is a not-for-profit professional association representing pharmacists who serve as patient care providers in acute and ambulatory settings. Established in 1942, ASHP's more than 55,000 members include pharmacists, student pharmacists, and pharmacy technicians.

As part of its broader operations, ASHP operates a national pharmacy residency accreditation program that establishes criteria for training pharmacists to achieve professional competence in the delivery of patient-centered care and pharmacy services. ASHP accredits the Medical University Hospital Authority's (MUHA) residency program. ASHP also operates the national program that matches applicants with postgraduate residency programs. Because of ASHP's involvement as an accreditor and in running the match program, it can offer a unique perspective on the Centers for Medicare & Medicaid Services (CMS) regulations and guidance governing these programs. This case involves CMS's failure to provide consistent guidance regarding structure and operations of residency programs, and the potentially devastating impact of CMS's recent trend of enforcing new and unknown requirements on those programs. In light of ASHP's membership (which includes pharmacy residents, residency program directors, and pharmacists who precept residents), operations, and involvement as accreditor of pharmacy residency programs, it is well-suited to provide assistance to the Court on this issue and more broadly on the importance of stable pharmacy residency programs to public health.

[1] No counsel for a party authored this brief in whole or part, and no party other than amicus or its counsel made a monetary contribution to the preparation or submission of the brief.

ARGUMENT

Pharmacy residency programs feed a vital patient care pipeline. Damaging them will threaten care quality, patient access, and established interprofessional care delivery models. CMS's failure to provide pharmacy residency programs with consistent guidance regarding rules governing operations and structure has placed residency programs at existential risk. Specifically, CMS has failed to clearly articulate, on a prospective basis, the precise structural and operational requirements for Medicare reimbursement. Further, the minimal guidance that has been provided constitutes new, and in some cases unworkable, requirements that are being unfairly applied retroactively, placing many of these programs at risk of losing CMS pass-through funding. Absent such funding to support postgraduate year one (PGY-1) training, hospitals and health systems facing losses from COVID-19 may be forced to shutter residency programs.

I. Pharmacy Residency Programs Are Essential to Patient Care.

The practice of pharmacy transcends the prototypical example of the community pharmacist who fills prescriptions at the local drug store. Today, pharmacists in hospitals and ambulatory clinics work with physicians, nurses, and other providers on interprofessional teams to manage patients' medications and ensure appropriate care transitions. In addition to their Doctor of Pharmacy degrees, these clinical pharmacists often complete one to two years of specialized pharmacy residency training, known as postgraduate year one (PGY1) and postgraduate year two (PGY2) in a process roughly analogous to residency for medical doctors.

Due to scientific advancements and the evolution of care delivery models, pharmacy residencies are now essential to performing certain patient care services. In fact, residencies are prerequisites for positions within specialties such as solid organ transplantation, clinical

pharmacogenomics, psychiatry, infectious diseases, critical care, cardiology, oncology, and pediatrics, among others.

Inclusion of highly-trained pharmacists on the healthcare team delivers a significant return on investment in both patient outcomes and real dollars.[2] For every dollar invested in clinical pharmacy services in all types of practice settings (hospital, clinics, government, etc.), health systems realize an average savings of $4.[3] Numerous studies attest to the benefits of fully engaging and integrating pharmacists into healthcare teams.[4]

Without high-quality pharmacy residency programs, patient access and care quality will suffer. At present, there are 1,328 PGY1 programs eligible for CMS pass-through funding nationwide. In 2018, three-quarters of the jobs filled by PGY1 program graduates required residency training — that amounts to approximately 3,500 positions annually. Almost 1,300 of these PGY1 graduates go on to PGY2 positions in a variety of specialized practice areas. Any decrease or weakening of pharmacy residency programs risks severely limiting the number of pharmacists available to fill positions, resulting in provider shortages and curtailing patient access to care.

II. CMS's Failure to Provide Consistent Guidance Has Harmed Programs.

Recognizing the value of allied health education, including pharmacy residency programs, CMS has historically "shared in the costs of educational activities sponsored by participating

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[2] C.A. Bond & C.L. Raehl, *Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates*, 27 Pharmacotherapy 481-93 (2007).

[3] *See e.g.*, G.T. Schumock et al., *Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996–2000*, 23 Pharmacotherapy 113–32 (2003); G.R. Matzke et al., *Impact of a Pharmacist-Physician Collaborative Care Model on Patient Outcomes and Health Services Utilization*, 75 Am. J. Health-Sys. Pharm. 1039-47 (2018); S. Gunadi et al., *Development of a Collaborative Transitions-of-Care Program for Heart Failure Patients*, 72 Am. J. Health-Sys. Pharm. 1147-52 (2015); J. Litke et al., I*mpact of the Clinical Pharmacy Specialist in Telehealth Primary Care*. 75 Am. J. Health-Sys. Pharm. 982-86 (2018); T. Fera et al., *Diabetes Ten City Challenge: Final Economic and Clinical Results*, 49 J. Am. Pharm. Assoc. 383-91 (2009).

providers . . . .” 66 Fed. Reg. 3358 (Jan. 12, 2001). Recent CMS actions – including the publication of Transmittal 2133 (the “Transmittal”), a guidance document for Medicare Administrative Contractors (MACs) that functions as a retroactively applied reinterpretation of 42 C.F.R. § 413.85 made without the benefit of notice and comment rulemaking – threaten programs. *See* Centers for Medicare & Medicaid Services, *Transmittal 2133: Clarification of Policies Related to Reasonable Cost Payment for Nursing and Allied Health Education Programs* (Aug. 17, 2018) https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R2133OTN.pdf. Relying on the Transmittal, MACs are conducting pharmacy residency program audits that jeopardize program financial viability by applying new and, at times, unworkable requirements to residency training that occurred years earlier.

A. Absent Clear CMS Guidance, Residency Programs Have Been Forced to Improvise Compliance Best Practices.

Due to both its accreditation program and the interest of its members, ASHP carefully monitors CMS programmatic changes and announcements related to residency programs. Historically, CMS expectations regarding residency program structure and operations have been communicated through the main programmatic regulation at 42 C.F.R. § 413.85, the implementing language in the final rule for that regulation at 66 Fed. Reg. 3358 (Jan. 12, 2001), and CMS audit findings. Residency programs have relied on a natural reading of the regulation and its implementing language to determine common sense rules for establishing “direct control” of residency programs. However, in 2018, CMS published the Transmittal, which effectively reinterprets 42 C.F.R. § 413.85 and applies that reinterpretation retroactively, rendering previously acceptable residency program operations suddenly noncompliant.

Residency programs have long shared audit findings and resulting best practices in a good faith effort to meet CMS standards. Over the years, this approach has sometimes resulted in adverse audit findings based on auditor misinterpretations or erroneous reinterpretations of CMS rules, but has largely been effective. However, in 2018, CMS published the Transmittal. That year, programs began to report adverse audit findings at an alarming rate. ASHP and hospitals were perplexed—the residency programs had not changed and the regulations had not been updated, but suddenly auditors were finding fault with residency program operations and structures that had passed muster during previous years' audits. Given that residency programs historically relied upon prior year audits to inform compliance, programs struggled to understand and comply with seemingly new requirements that were being applied retroactively and without prior notice.

B. CMS Guidance to Medicare Administrative Contractors Fails to Address Audit Findings.

In June 2019, ASHP requested a meeting with CMS Administrator Seema Verma to discuss and attempt to remedy the issue. Prior to the meeting, CMS sent ASHP a copy of the Transmittal. In the Transmittal, CMS states, "[w]e are clarifying our existing policy below; we are not changing policy on this matter." Nevertheless, in practice this "clarification" performed like a new agency interpretation of the regulations—residency program operations previously blessed by auditors guided by CMS's policy were now challenged as noncompliant based on the Transmittal. MAC auditors interpreted and applied the Transmittal in ways clearly contrary to the plain meaning of 42 C.F.R. § 413.85, drawing new bright line requirements that programs could not conceivably have extrapolated from the Transmittal's text. The change was so stark that one auditor informed a residency program that he had disallowed costs for every single hospital-operated residency program he had audited in 2019. By contrast, in previous years only a handful of programs per year received adverse findings that resulted in disallowance of pass-through funding—and in some

cases, such as MUHA, those programs were also subject to auditor misinterpretations or application of clarifications that amounted to reinterpretation of the programmatic regulation. In MUHA's case, CMS disallowed all of its programmatic costs based on the agency's interpretation of 42 C.F.R. § 413.85 to require a hospital to incur all program costs first and to prohibit the hospital from reimbursing any programmatic costs, even when incurred by a related party—a requirement CMS never spelled out in guidance and which could not be readily extrapolated from the regulation.

On December 5, 2019, ASHP staff met with CMS staff to raise concerns regarding the increasing numbers of adverse pharmacy residency audit findings, and to discuss the need for specific program guidance to clarify standards for compliance. ASHP noted the inconsistent and arbitrary nature of audit findings. Specifically, relying on the Transmittal's interpretation of the "direct control" requirements at 42 C.F.R. § 413.85(f), Medicare Administrative Contractors (MACs) disallowed costs on the basis of everything from off-site rotations[5] , which are a staple of residency programs, to the name on a residency program's completion certificate, to shared payroll systems. ASHP questioned how these granular findings could be extrapolated from the Transmittal, as it does not provide any precise information regarding what would be considered indicia of lack of "direct control." Adding to programs' confusion, the justification for the Transmittal itself does not seem applicable to pharmacy residency programs. Referring specifically to nursing and allied health education, and not to programs for pharmacists, the Transmittal states:

> As the accreditation requirements have evolved and the trend in nursing and allied health education has grown toward degree-issuing programs from colleges or universities, hospitals have tried to restructure their programs and make

[5] Off-site rotations are limited clinical training that occurs at site or in a setting other than the hospital to increase the breadth of the pharmacist's training.

arrangements with colleges or universities in order to simultaneously provide a degree to their graduates, and meet the provider-operated criteria.

In fact, by virtue of pharmacy education structure, while pharmacy residencies may issue a certificate upon completion, such completion certificates do not confer a degree or even a credential that follows a pharmacist's name.[6] Pharmacy residents graduate from pharmacy school *before* they begin residency, so there is no incentive for hospitals to restructure programs to provide a pharmacy or other degree while providing residency training. Further, the pharmacy residency match process is competitive, so pharmacy schools cannot and do not guarantee students placement in residency programs upon pharmacy school graduation.

During the December 5th meeting, CMS staff did acknowledge that the auditors were perhaps overzealous in their application of certain elements of the Transmittal. Specifically, CMS acknowledged that the use of shared payroll systems and the name or signatory on a completion certificate should not form the basis for a finding of lack of direct control. To mitigate confusion and to assist programs in compliance, ASHP requested that CMS provide guidance specific to residency programs that clearly outlines CMS's expectations for program operations and structure. The agency verbally declined to promulgate new formal guidance. However, CMS staff did agree to consider developing a "Frequently Asked Questions" (FAQ) document to address questions ASHP received from members regarding recent audits and audit findings. The questions ASHP recommended that CMS include in an FAQ document are straightforward and were developed by ASHP based on our reading of the Transmittal and our conversation with CMS. The questions illustrate both the specificity of auditor findings and the degree of confusion related to foundational

[6] Unlike a degree-granting program, or even board certification, completion of a residency program does not confer any honorific.

requirements for residency program structure and operations as outlined in the Transmittal and applied by MAC auditors:

> Q: The 2018 Transmittal instructed MACs to look for evidence of a lack of control, specifying that "absent evidence to the contrary" means that the hospital "must first demonstrate that there is no evidence showing that the program is not provider-operated." Does this mean MACs should assume that any indication of a potential lack of control means that the operator does not control the program?
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> Q: Under what circumstances can a hospital that is part of a larger health system operate a pharmacy residency program?
>
> Q: What types of administrative functions can residency programs contract for or share with a parent health system without violating the control requirement?
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> Q: When a program operator determines that it is necessary to share services with its parent health system, what types of documentation would aid auditors in confirming that the hospital retains operational control pursuant to 42 CFR 413.85(f)(1)(iii)?
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>
> Q: Can a provider-operated pharmacy residency program pay its teaching staff and/or residents using the same payroll system as the health system or academic medical center?
>
> Q: Are provider-operated pharmacy residency programs required to have the name of the provider on the completion certificate? Are there any requirements or restrictions regarding the name of the institution or the authority of the signor on the completion certificate?
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> Q: If a hospital is part of a health system, can the health system CEO's signature be used on hospital documents requiring a CEO signature? Would this be viewed as a lack of control?
>
> Q: Are marketing materials for a provider or residency program that bear the name of an affiliated health system or pharmacy school evidence that a pharmacy residency program is not provider-operated?
>
> Q: Would utilization of certain educational resources (e.g., standard OSHA training, etc.) provided by the health system rather than directly by the program operator violate the control requirements at 42 CFR § 413.85(f)(1)(i)-(v)?

ASHP provided the foregoing questions in an FAQ document to CMS on January 29, 2020. As of the date of this filing, ASHP has not received any further substantive response from the agency regarding the FAQ, nor has the agency offered residency programs any additional information to assist them in compliance. To our knowledge, CMS has also not provided any additional guidance to MACs to improve the consistency and fairness of pharmacy residency program audits since ASHP raised concerns.

III. Loss of CMS Funding Jeopardizes Pharmacy Residency Programs and Hurts Our Healthcare System.

Even under ideal conditions, loss of CMS pass-through funding could jeopardize the continued operation of pharmacy residency programs. However, the stress COVID-19 has placed on hospital finances may effectively weaponize adverse audit findings. Retrospective audits based on the Transmittal or other new requirements that were not previously published put programs at risk of losing years' worth of funding. The lack of clarity and consistency regarding CMS requirements for residency program operations and structure compounds the problem. As a result, hospitals may consider residency programs a liability, putting them at high-risk of elimination to protect hard-hit hospital budgets. This would be a particularly absurd result because the pandemic has highlighted the criticality of residency training—residency-trained pharmacists have played an outsized role in managing COVID-19 medications and shortages and in developing and implementing COVID-19 therapeutic regimens.

Pharmacy residency programs are essential to public health. It took more than 50 years to grow a vibrant nationwide network of pharmacy residency programs. Absent CMS action to provide workable and prospective guidance rooted in the regulation and crafted in collaboration with industry stakeholders to programs, and to redress arbitrary action by MACs and their auditors,

a half century of healthcare innovation, and the consequent improved patient access and care quality it provides, may soon be irretrievably lost.

CONCLUSION

MUHA's audit now appears to be merely the beginning of a broader and accelerating trend of applying new and unknown requirements to make wholesale retroactive disallowances of programs with long-standing histories of receiving pass through funding. For the reasons stated above, therefore, the Court should set aside the Provider Reimbursement Review Board determination and direct CMS to return all disallowed funds to MUHA.

Respectfully submitted,

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