



Paul W. Abramowitz, PharmD, ScD (Hon), FASHP
Chief Executive Officer

November 2, 2023

The Honorable Xavier Becerra
Secretary
Department of U.S. Health & Human Services
200 Independence Ave. SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-Lasure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave. SW
Washington, D.C. 20201

Dr. Neera Tanden
Director
Domestic Policy Council
Room 469
Eisenhower Executive Office Building
Washington, D.C. 20502

RE: CMS Audits of Pharmacy Residency Programs

Dear Secretary Becerra, Administrator Brooks-LaSure, and Dr. Tanden,

As I mentioned during a meeting with you at the White House earlier this year, pharmacy residency programs are struggling with problematic audits targeting Centers for Medicare & Services (CMS) pass-through funding for the first year of post-graduate (PGY1) residency training. Specifically, since 2019, PGY1 programs across the country have been hit with arbitrary cost disallowances on the basis of cost accounting procedures that had been acceptable in previous years and/or to different auditors, despite the fact that there have been no regulatory changes. I am asking for your help to stop clawbacks of pharmacy residency funding until CMS provides meaningful guidance on how PGY1 programs should comply with CMS requirements.

These are not high-dollar programs, with annual funding per program generally running around \$100,000, but with audits jeopardizing multiple years of funding, some hospitals are now considering eliminating their PGY1 training programs, jeopardizing the already limited supply of new pharmacists with clinical training.

Despite ASHP's repeated and clear requests¹, CMS has refused to provide any specific programmatic guidance and/or technical assistance to PGY1 programs. ASHP even went as far as drafting a Frequently Asked Questions document based on our conversations with CMS officials regarding the audits for the agency to adapt into subregulatory guidance, which never came to fruition. Similarly, when Congressional offices have requested

¹ See Attachment 1: ASHP Correspondence with CMS Officials regarding the Audits of PGY1 Pharmacy Residency Programs. American Society of Health-System Pharmacists • 4500 East-West Highway, Suite 900, Bethesda, MD 20814 • 301-657-3000 • www.ashp.org

information from CMS about the PGY1 audits, they have received little in the way of clarifying information beyond a restatement of the current regulations, which fail to take into account basic elements of health system and residency program operations.² There is an increasing perception among residency program operators that Medicare Administrative Contractor (MAC) auditors are seeking to maximize cost disallowances based on tenuous justifications, rather than auditing residency programs against any objective standard.

The root of the problem is auditors' far-reaching interpretation of the "direct control" requirement (42 C.F.R. §413.85, requiring that the hospital operating the program retain direct control over all program operations). MACs have disallowed costs on the basis of everything from off-site rotations (a staple of residency programs) to the name on a program's diploma/certificate. Programs' funding has also been disallowed for basic operational efficiencies like using shared payroll services between a hospital and health system, despite the fact that the program regulations explicitly allow for shared services (42 C.F.R. §413.85(f)(1)(iii)). It is particularly frustrating that CMS staff have verbally acknowledged that the factors MAC auditors have used to challenge residency funding are inconsistent with CMS' intent, yet the Agency has failed to provide clarifying guidance.

CMS's 2018 guidance to auditors³ is inconsistent with the plain language of the regulation, which states that "[a]bsent 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 the regulation. As a result, auditors routinely disallow residency funding even when the totality of the evidence indicates that the hospital controls the program. Further compounding the issue, the transmittal merely restated the regulations, offering no practical guidance regarding how to make an evaluation of direct control or how to consider basic operational efficiencies when residency programs are operated by hospitals that are part of health systems or affiliated with schools of pharmacy or medicine. As a result, audit findings have been wholly inconsistent and programs have been left with little idea of how to structure a compliant program, beyond relying on information gleaned from other programs' audits, which is of limited utility because each program is unique.

In a recent court case litigating one such audit, a federal district court ruled against CMS.⁴ Despite the likelihood that other courts will view these issues similarly, CMS has continued its problematic audit practices, leaving programs with little recourse but financially draining litigation. Without detailed guidance regarding what auditors will consider compliant with the regulations, programs have little certainty for operations moving forward. Stripping programs of funding on the basis of questionable auditor decision-making risks critical healthcare educational infrastructure that has been over four decades in the making, at a time when maintaining a sufficient number of clinicians is a public health imperative.

Pharmacy residency programs feed a vital patient care pipeline. Damaging them threatens care quality, patient access, and established interprofessional care delivery models. 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,

² See Attachment 2: CMS Responses to the Office of Senator Tina Smith and the Office of Representative Buddy Carter.

³ See CMS Transmittal R2133OTN (Aug. 17, 2018), *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018-Transmittals-Items/R2133OTN>.

⁴ *Medical Univ. Hosp. Auth. v. Becerra*, C/A No. 2:19-1755-MBS (Mar. 26, 2021).

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

Furthermore, these arbitrary MAC decisions are undercutting programs while we are facing national shortages of primary care physicians and other clinicians. Pharmacists are critically important to filling these care gaps. There are currently approximately 1,370 PGY1 programs eligible for CMS pass-through funding. In 2022, 72% of the jobs filled by PGY1 program graduates required PGY1 training — that amounts to 2,587 positions annually. More than 1,400 of these PGY1 graduates go on to PGY2 positions in a variety of specialized practice areas, including behavioral health and substance use disorder (SUD). Any decrease or weakening of pharmacy residency programs risks severely limiting the number of pharmacists available to fill positions, potentially exacerbating existing shortages or even creating new ones. If anything, public health would be better served by increasing funding for PGY1 programs and extending that funding to PGY2 programs, particularly newer programs such as those focused on behavioral health and SUD.

ASHP has exhausted every avenue for resolving this issue with CMS, and we are now requesting your direct intervention. Specifically, we ask that you direct the relevant program officials to halt all PGY1 funding clawbacks on the basis of the direct control requirement until the agency provides meaningful guidance that addresses compliance requirements for the following fundamental aspects of operating a residency program at a hospital affiliated with a health system or educational institution:

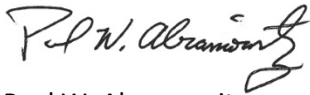
- Shared services: We ask that CMS indicate how common shared administrative functions (e.g., payroll, hiring, employee benefits, etc.) between a hospital operating a residency program and the larger health system should be organized and documented to comply with the direct control requirement, and under what circumstances would these basic operational aspects of a health system not be acceptable. Given that shared services save money and reduce administrative burden within the healthcare system, the circumstances in which a hospital would be expected to have its own systems simply for the purposes of its PGY1 program should be extremely limited. Additionally, we would like CMS to address the following:
 - We ask CMS to clarify which types of documentation would aid auditors in confirming that the hospital retains operational control pursuant to 42 CFR 413.85(f)(1)(iii) when a hospital shares services with a parent health system?
 - How should a hospital document its utilization of certain educational resources (e.g., standard OSHA training, etc.) provided by the health system rather than directly by the hospital program operator in order to maintain compliance with the control requirements at 42 CFR § 413.85(f)(1)(i)-(v)?
- Health System Engagement: We request that CMS provide guidance as to how a residency program operated by a hospital within a health system can benefit from its operational, educational, and clinical affiliation with the larger health system or educational institution, without violating the direct control requirement. Specifically, we would like CMS to answer the following:
 - Are pharmacy residency programs required to have the name of the hospital on the completion certificate? Are there any requirements or restrictions regarding the name of the institution or the authority of the signatory on the completion certificate?
 - 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?

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- 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?
- Can a PGY1 program establish a clinical rotation at another site within the health system provided that the hospital carves out the costs associated with the off-site rotation(s) from its PGY1 cost reports?

ASHP looks forward to working with you to protect our nation's vital pharmacy residency programs. We would welcome an opportunity to discuss this in greater detail and/or act as a resource as CMS develops meaningful guidance for PGY1 residency programs. Please direct any questions or requests for information to Jillanne Schulte Wall, Senior Director of Health & Regulatory Policy, at jschulte@ashp.org or (301) 664-8698.

Sincerely,



Paul W. Abramowitz

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Attachment 1: ASHP Correspondence with CMS Officials regarding the Audits of PGY-1 Pharmacy Residency Programs

Jillanne Schulte

From: Jillanne Schulte
Sent: Tuesday, April 20, 2021 11:35 AM
To: Blackford, Carol W. (CMS/CM)
Cc: Cheng, Ing Jye (CMS/CM); Tom Kraus; Thompson, Donald (CMS/CM); Moll, Benjamin H. (CMS/OFM); Stephen Ford; Fisher, Patrick (CMS/OFM)
Subject: RE: December 5th Meeting with ASHP: Thank you and Follow-Up.

Dear Carol, Ing Jye, Don, Ben, and Patrick,

I hope you're all well! Now that COVID-19 is coming under control, we are hoping to circle back on a possible residency program guidance. With the recent MUSC decision, programs are really hoping to get some prospective technical assistance from the agency. As I noted in the my previous email, COVID-19 has strained budgets, calling into question even valued programs that might present an ongoing audit risk. While conditions are improving, without some compliance certainty, the threat to programs remains, and we're struggling to provide meaningful advice without additional agency input.

Would it be possible to have a follow up call to touch base? Please don't hesitate to let me know if we can provide any additional information.

Best,

Jillanne

From: Jillanne Schulte
Sent: Wednesday, April 22, 2020 3:46 PM
To: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>
Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>; Hiller, Elinor <Elinor.Hiller@alston.com>; Thompson, Donald (CMS/CM) <Donald.Thompson@cms.hhs.gov>; Moll, Benjamin H. (CMS/OFM) <Benjamin.Moll@cms.hhs.gov>; Stephen Ford <SFord@ashp.org>; Fisher, Patrick (CMS/OFM) <Patrick.Fisher@cms.hhs.gov>
Subject: RE: December 5th Meeting with ASHP: Thank you and Follow-Up.

Dear Carol, Ing Jye, Don, Ben, and Patrick,

I hope you're all well! Recognizing that you all are almost certainly swamped with COVID-19 response, I wanted to make you aware of some new, pressing concerns related to the pharmacy residency program audits.

As we discussed during our in-person meeting in December, auditors' interpretation of the current audit guidance is threatening the existence of some programs. These concerns have been significantly exacerbated by the impact of COVID-19 on hospital finances. Because programs are at risk of losing years' worth of funding and remain unsure of how to comply fully with CMS requirements, they are at high risk of being targeted for elimination by hospitals that are being forced to cut as much as they can to conserve dollars.

ASHP is very concerned that not only is this not the outcome CMS intended, but that it will be extremely detrimental to the healthcare system over the long term. Residency-trained pharmacists have played an outsized role in managing COVID-19 medications and shortages and in developing and implementing therapeutic regimens. If anything, the pandemic has highlighted just how essential this education is to protecting public health.

As noted above, we recognize that you all are facing numerous demands on your time and resources, but any clarifying guidance from CMS would go a long way to preventing unintended damage to programs.

We also ask that CMS pause audits, including finalization of findings, for at least the next two months until COVID-19 abates and the financial picture for hospitals stabilizes a bit more. Hospitals operating residency programs are in the thick of COVID-19 response and the pending audits are an additional source of stress – as well as a potential liability even for those programs that have clean audits as hospitals reconsider all costs. We know of at least two programs in the Pacific Northwest that are currently at risk because COVID-19 has placed additional pressure on the outcome of pending audits. These programs are more than willing to meet CMS program criteria, but they are still struggling to determine exactly how to do so without additional agency clarification.

Thank you for your consideration of our requests. Anything that you can do to help preserve these critical training programs would be greatly appreciated. We are more than willing to provide any information that might be helpful – including linking you with residency program directors, providing data, etc. Please don't hesitate to let us know if you have questions, etc.

Best,

Jillanne

From: Jillanne Schulte

Sent: Wednesday, February 12, 2020 10:28 AM

To: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>

Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>; Hiller, Elinor <Elinor.Hiller@alston.com>; Thompson, Donald (CMS/CM) <Donald.Thompson@cms.hhs.gov>; Moll, Benjamin H. (CMS/OFM) <Benjamin.Moll@cms.hhs.gov>; Stephen Ford <SFord@ashp.org>; Fisher, Patrick (CMS/OFM) <Patrick.Fisher@cms.hhs.gov>

Subject: RE: December 5th Meeting with ASHP: Thank you and Follow-Up.

Dear Carol, Ing Jye, Don, Ben, and Patrick,

I just wanted to touch base to confirm that you received the draft FAQs we sent on January 29th – I'm happy to resend the document if necessary. Additionally, as always, please don't hesitate to let us know if we can provide any additional information or assistance regarding the residency programs.

Best,

Jillanne

From: Jillanne Schulte

Sent: Wednesday, January 29, 2020 4:01 PM

To: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>

Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>; Hiller, Elinor <Elinor.Hiller@alston.com>; Thompson, Donald (CMS/CM) <Donald.Thompson@cms.hhs.gov>; Moll, Benjamin H. (CMS/OFM) <Benjamin.Moll@cms.hhs.gov>; Stephen Ford <SFord@ashp.org>; Fisher, Patrick (CMS/OFM) <Patrick.Fisher@cms.hhs.gov>

Subject: RE: December 5th Meeting with ASHP: Thank you and Follow-Up.

Dear Carol, Ing Jye, Don, Ben, and Patrick,

As promised, attached is the first set of questions and proposed answers for the FAQ. Based on our December conversation, we focused the initial question set on areas that appeared more clear cut and perhaps easier to address. The second set is likely to delve into the thornier “home office” and pharmacy school affiliation questions. We hope to send it in the next few weeks.

Again, we very much appreciate your willingness to work with us. Please don't hesitate to let us know if we can provide additional information or any other assistance.

Best,

Jillanne

From: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>
Sent: Monday, December 16, 2019 2:46 PM
To: Jillanne Schulte <JSchulte@ashp.org>
Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>; Hiller, Elinor <Elinor.Hiller@alston.com>; Thompson, Donald (CMS/CM) <Donald.Thompson@cms.hhs.gov>; Moll, Benjamin H. (CMS/OFM) <Benjamin.Moll@cms.hhs.gov>; Stephen Ford <SFord@ashp.org>; Fisher, Patrick (CMS/OFM) <Patrick.Fisher@cms.hhs.gov>
Subject: RE: December 5th Meeting with ASHP: Thank you and Follow-Up.

Thank you Jillanne. We will keep an eye out for your follow-up email and will certainly reach out should we need any further information. I hope you have a wonderful holiday season.

--Carol

Carol Blackford
Director, Hospital and Ambulatory Policy Group
Center for Medicare, CMS
(410) 786-5909

From: Jillanne Schulte <JSchulte@ashp.org>
Sent: Monday, December 16, 2019 2:29 PM
To: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>
Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>; Hiller, Elinor <Elinor.Hiller@alston.com>; Thompson, Donald (CMS/CM) <Donald.Thompson@cms.hhs.gov>; Moll, Benjamin H. (CMS/OFM) <Benjamin.Moll@cms.hhs.gov>; Stephen Ford <SFord@ashp.org>; Fisher, Patrick (CMS/OFM) <Patrick.Fisher@cms.hhs.gov>
Subject: December 5th Meeting with ASHP: Thank you and Follow-Up.

Dear Carol, Ing Jye, Don, Ben, and Patrick,

Thank you all again for taking the time to meet with us on December 5th. We deeply appreciated your willingness to listen and your recognition of the value of pharmacy residency programs.

We particularly appreciated the opportunity to discuss the differences between the Pharm.D programs and residency programs. Although earning a Pharm.D is a prerequisite to getting a residency, the residency programs are completely separate from Pharm.D education, with slots competitively awarded through a national matching program. Residency training is not required to practice as a pharmacist in all care settings, but it is commonly required for hospital and health system pharmacists.

We also appreciated the chance to better understand CMS's goals regarding the 2018 transmittal to the MACs. While this guidance has resulted in increased audit activity, many of the issues that have been raised in audits of ASHP members fall outside the four corners of the transmittal. Specifically, these include: including the names of health systems and CEOs on completion certificates; off-site clinical rotations; and shared payroll systems for hospitals within health systems.

Based on our conversation, we understand that one of CMS's primary concerns in assessing "direct control" of residency programs centers on "home office" issues, meaning a concern that programs at sites that are part of a larger health system may be controlled not by the program operator but by the health system. We also recognize that CMS is concerned that program affiliation with schools of pharmacy might suggest that the school exerts control over the program. As we discussed, particularly with respect to schools of pharmacy, while faculty might be involved in training and might be mentioned in marketing materials, in the arrangements we are familiar with, the schools themselves do not exercise any control over training or curriculum, nor do they have any incentive to involve themselves in the structuring or oversight of residency training.

Thank you for your willingness to work with ASHP to develop additional guidance for our members in the form of "Frequently Asked Questions". We greatly appreciate the acknowledgement that certain issues – such as shared payroll systems that are used throughout an entire health system and for all employees at a hospital operating a program, or the name that appears on completion certificates – may be relatively easy to clarify as not indicative of a lack of control. While we understand that the practical effect of arrangements between residency programs and universities, for example, will ultimately factor into auditors' review of programs, we continue to believe that CMS can help to address questions our members have regarding how best to structure compliant programs at sites within health systems or that have affiliations with teaching institutions.

We will follow up in the coming weeks with a draft set of written questions about residency program structure and demonstration of "direct control" as envisioned by the regulations. In the interim, please don't hesitate to let us know if we can provide any additional information about pharmacy education, residency program accreditation, etc. We can also arrange for you to speak with individual residency program directors and pharmacy school deans if that would be beneficial.

We look forward to a productive partnership to ensure that clinical training for pharmacists meets the highest quality and care standards while maintaining compliance with CMS requirements.

Best,

Jillanne

Jillanne Schulte Wall, J.D.

Senior Director, Health and Regulatory Policy
Government Relations

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Bethesda, MD 20814

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From: Jillanne Schulte
Sent: Wednesday, December 4, 2019 8:24 PM
To: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>
Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>; Tom Kraus <TKraus@ashp.org>
Subject: RE: Our meeting tomorrow

Hi Carol,

Thanks for sending the letter. Attached you'll find our slide deck for tomorrow's meeting. Thank you again for agreeing to meet with us and we look forward to meeting you in person tomorrow.

Best,

Jillanne

From: Blackford, Carol W. (CMS/CM) <Carol.Blackford@cms.hhs.gov>
Sent: Wednesday, December 4, 2019 3:00 PM
To: Jillanne Schulte <JSchulte@ashp.org>
Cc: Cheng, Ing Jye (CMS/CM) <IngJye.Cheng@cms.hhs.gov>
Subject: Our meeting tomorrow

Jullianne,

I wanted to pass along CMS' written response to ASHP's letter raising concerns with recent CMS audits of pharmacy residency programs. CMS's response was signed and mailed before Thanksgiving so you may have already received our response. If not, please find the attached response for your information. I look forward to our meeting tomorrow.

Regards,

Carol

Carol Blackford
Director, Hospital and Ambulatory Policy Group
Center for Medicare, CMS
(410) 786-5909

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November 2, 2023
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Attachment 2: CMS Responses to the Office of Senator Tina Smith and the Office of Representative Buddy Carter

Jillanne Schulte

Subject: RE: Pharmacy Residency Funding Issues in Minnesota

From: Becky Wifstrand <bwifstrand@mnhospitals.org>

Sent: Thursday, November 17, 2022 3:33 PM

To: Jillanne Schulte <JSchulte@ashp.org>

Subject: RE: Pharmacy Residency Funding Issues in Minnesota

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Jillanne,

Sen. Smith's office finally shared their response from CMS (see below) – unfortunately nothing new that you/we haven't heard. From ASHP's perspective – what are the next steps in your advocacy on this issue? Are you still circulating the congressional letter and are there any other opportunities to connect with CMS? We are definitely ready to help and would like to collaborate. Thanks!

Circling back on this, there has been no recent change in regulations, I've attached the policy guidance highlighting the criteria on Medicare payment for nursing and allied health programs. The review process of cost reports is a longstanding policy and it may be that this is the first time that NGS has found issues of non-compliance with these providers. I've included language for **42 C.F.R. §413.85** below and highlighted the areas of the regulations that are in question. A hospital must meet all of these criteria to qualify for the reasonable cost payment.

The MACs are in communication with hospitals throughout the process of reviewing cost reports. If a hospital is found to be non-compliant with certain policies, the MAC discusses and presents this information to the provider in advance of issuing the [Notice of Program Reimbursement](#) (NPR). NGS has been in communication with a number of hospitals throughout this process to provide general outreach and education to help ensure hospitals reach compliance with these policies. If a hospital receives an NPR for its cost report they have 180 days, from the date of the notice, to appeal to the Provider Reimbursement Review Board. Attached are details on the appeal process that have also been previously sent to the provider(s).

42 CFR 413.85(d)(2):

(ii) "A 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 in § 413.24. These 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."

42 CFR 413.85(f)(1):

- (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.

Becky Wifstrand, MPH

Director of Federal Policy and Regulatory Affairs | Minnesota Hospital Association
2550 University Ave. W., Ste. 350-S, Saint Paul, MN 55114 | bwifstrand@mnhospitals.org
Phone: 651-603-3498 | Cell: 630-229-3964 | www.mnhospitals.org
Twitter.com/MNHospitals | Facebook.com/MinnesotaHospitalAssociation

From: Becky Wifstrand

Sent: Tuesday, November 1, 2022 10:54 AM

To: Jillanne Schulte <JSchulte@ashp.org>

Subject: RE: [External] RE: Pharmacy Residency Funding Issues in Minnesota

Hi Jillanne,

Yes, I heard the same from her staff last week. They said they were still reviewing the response with the Klobuchar staff and will follow up with us soon. I will keep you posted!

Becky Wifstrand, MPH

Director of Federal Policy and Regulatory Affairs | Minnesota Hospital Association
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Phone: 651-603-3498 | Cell: 630-229-3964 | www.mnhospitals.org
Twitter.com/MNHospitals | Facebook.com/MinnesotaHospitalAssociation

From: Jillanne Schulte <JSchulte@ashp.org>

Sent: Tuesday, November 1, 2022 10:30 AM

To: Becky Wifstrand <bwifstrand@mnhospitals.org>

Subject: RE: [External] RE: Pharmacy Residency Funding Issues in Minnesota

Hi Becky,

We heard that Smith's office got a response back from CMS regarding the residency audit issue. Have you all seen it?

Jillanne Schulte Wall, J.D.

Senior Director, Health and Regulatory Policy
Office of Government Relations
ASHP
4500 East-West Highway, Suite 900
Bethesda, MD 20814
www.ashp.org
JSchulte@ashp.org

Jillanne Schulte

From: Martino, Maria (CMS/OL) <Maria.Martino@cms.hhs.gov>
Sent: Friday, October 13, 2023 3:19 PM
To: Ganter, Jack
Cc: Chadwick, Alpheus (CMS/OL); Khalid, Zunaira (CMS/OL)
Subject: RE: April 26th E&C Hearing: "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care"

Hi Jack—we pulled together some information on your pharmacy residency program questions. If you need additional clarification, please let us know.

Under Medicare regulations, Pharmacy Residency Programs must meet certain requirements in order to claim pass-through payments from Medicare. These regulations (42 CFR § 413.85) require providers to meet a number of requirements with respect to training costs, curriculum, instruction, and program administration. Specifically, with respect to program administration, the regulations state that the operator must “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.)” For example, staff and student W-2 forms must be issued by the hospital, not by a related academic institution or home office. Hospital-employed staff, not staff employed by an educational or related institution, must be responsible for controlling, managing, and operating the program financially and administratively on a daily basis, such as, but not limited to, enrollment, collection of tuition, human resources matters, and payroll. While §413.85(f)(1)(iii) states that a provider may contract with another entity to perform some administrative functions of day to day operations, the provider must maintain control over all aspects of the contracted functions. The hospital cannot have an arrangement with an educational institution where there are certain functions for which the hospital has no involvement and no oversight. If educational institution personnel are involved, hospital staff must have final decision making authority.

The January 12, 2001 final rule provides additional guidance on what “direct control” of the curriculum means. Although the accrediting agency often dictates which courses and the order of the courses that must be completed by each student, to the extent where there is some flexibility provided by the accrediting body, it must be the hospital, not another educational institution deciding upon the order of the coursework, and the manner its students will accomplish the coursework that will allow the program to be accredited. In addition, there may be certain courses that are unique to the hospital, and the hospital decides what those courses are and when they are taught. Furthermore, control of the curriculum means the

hospital actually provides all of the courses, or, with respect to the basic courses required for completion of the program (e.g., English 101), the hospital arranges for an outside organization to provide those academic courses necessary to complete the course work. (See 66 FR 3364).

From: Ganter, Jack <Jack.Ganter@mail.house.gov>

Sent: Monday, October 2, 2023 4:49 PM

To: Martino, Maria (CMS/OL) <Maria.Martino@cms.hhs.gov>

Subject: April 26th E&C Hearing: "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care"

Hey, Maria –

Rep. Carter submitted questions to the record for the E&C hearing on April 26th: "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care."

Unfortunately, there was a communication error and the committee didn't [submit them](#). So, I wanted to send them over to you in hopes that you can pass this along to the Administrator.

Could we get a written response back by any chance?

The Honorable Chiquita Brooks-LaSure

I represent Georgia's First Congressional District, and as a pharmacist, I saw firsthand how the vanishing rural hospital system impacted my constituents. In fact, Charlton Memorial Hospital closed in August 2013, depriving my community of 15 hospital beds. That closed hospital sadly represents one of the 149 closed and converted rural hospitals in the last 13 years. The Affordable Care Act's Section 6001, which became law 13 years ago, created a moratorium on physician-owned hospitals. If that moratorium did not exist, doctors in my community could have had the option to purchase and rescue Charlton Memorial Hospital before it shut its doors. Do you agree that we can improve the accessibility of health care for rural Americans by repealing the moratorium on physician-owned hospitals?

Do you agree that using NADAC (National Average Drug Acquisition Cost) as a basis for reimbursement in Medicaid managed care will make drug pricing more transparent than the current model where spread pricing is rampant?

Will ensuring retail pharmacy participation in NADAC surveys improve the index by obtaining more pharmacy price points thus making it even more reflective of market prices.

Due to the complexity of pharmacy practice, many pharmacy students undertake a residency in a hospital. Pursuant to federal regulation, pharmacy residency programs operated by hospitals that are affiliated with or owned by a health system or academic medical center are required to be directly controlled by those hospitals. (42 C.F.R. §413.85) These hospitals receive a passthrough payments from Medicare. However, due to a lack of clarity and Medicare Administrative Contractors' (MACs) inconsistent interpretation of what is needed to meet the "direct control" requirement, hospitals and affiliated health systems need greater clarity from the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to ensure compliance. Please answer the following questions to provide greater clarity on what hospitals need to do to ensure they have direct control over their residency programs and thus remain in compliance with regulatory compliance:

May hospitals share or contract for administrative functions the health systems, without violating 42 CFR § 413.85(f)(1)(i)-(v)? What documentation would aid CMS in confirming that the hospital retains control of the residency program? May hospitals utilize shared employee resources (e.g., standard Occupational Safety and Health Administration training) provided by health systems? Is any particular documentation needed?

May hospitals pay their teaching staff and/or residents using the same payroll systems as the affiliated health system or academic medical center?

May hospitals utilize employees of health systems, academic medical centers, and affiliated schools as faculty for their residency programs and how should such arrangements be structured?

May hospitals allow residents to participate in rotations at other facilities affiliated with a health system or academic medical center?

May hospitals use the name of an affiliated health system on the residency completion certificate?

What efforts are being undertaken to ensure MACs consistently enforce requirements in this area?

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