

Beginning in 2019, the Centers for Medicare & Medicaid Services (CMS) overhauled its audit process for allied health residencies, including postgraduate year 1 (PGY1) programs. Unfortunately, CMS's directive to its auditors has resulted in significant cost disallowances, some over a number of years. Many of these cases involve arbitrary and inconsistent application of cost-reporting requirements as well as substandard and poorly organized audit processes. Based on their own interpretation of the "direct control" requirement (42 C.F.R. §413.85), Medicare Administrative Contractors (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 or certificate. Pharmacy residency programs in hospitals that are part of larger health systems and those affiliated with schools of pharmacy have been at particular risk of findings regarding a lack of direct control.

ASHP has repeatedly reached out to CMS to request the agency provide PGY1 programs with technical assistance focused on compliance. However, to date, CMS has failed to provide meaningful guidance, so ASHP advocacy continues with federal policymakers. In the interim, ASHP has developed the following list of best practices based on CMS audit findings reported to us by ASHP members. Utilizing these suggestions is not a guarantee that a CMS auditor will consider a program compliant, but they represent our current best understanding of how auditors assess compliance with the direct control requirement. Please note that we have seen wide variation in auditor interpretations, so operationalizing this advice does not guarantee that your program will be considered compliant under CMS audit standards.

## PGY1 COMPLIANCE BEST PRACTICES:

### I. **Develop and maintain a paper trail documenting direct control of the program.**

Adverse audit findings have largely focused on the "direct control" requirement. Developing a paper trail that demonstrates that the hospital retains full and complete control over all elements of the residency program may help protect against adverse audit findings. This will be particularly beneficial for hospitals that are part of a larger health system, as auditors have raised concerns about health systems, rather than individual hospitals, controlling residency program operations. Specifically, we suggest the following:

- **PGY1 Program Materials:** Ensure that all residency program materials (marketing, agreements, educational materials, residency completion certificates) include only the hospital name, not the health system name.
  - » Auditors have penalized residencies for having marketing materials or completion certificates that include the name of a health system or schools of pharmacy, rather than the sponsoring hospital.
  - » Even in health systems with multiple residencies, we recommend against grouping them under the health system name due to CMS's outsized concern regarding any indication that a health system, rather than a hospital, exercises control over the residency program.
  - » When possible, health system executives' names should not be used on residency completion documents or other materials – reference only those directly employed by the hospital operating the residency program.

- **Rotations:** Rotations can provide a valuable training experience for residents, including by providing exposure to clinical services not available at the sponsoring site. However, the sponsoring hospital must still maintain control of the residency experience, even when the resident is participating in an off-site rotation.
  - » If you opt to have a residency rotation site, even at another site within the same health system, develop a memorandum of understanding or other agreement memorializing the site curricula and documenting that the hospital sponsoring the residency program has *full* control over resident's experience at the rotation site.
  - » Have a hospital-specific Residency Advisory Committee (RAC) that oversees the residency program and develops policies and procedures. Even if other hospitals in your system have residency sites, each site needs its own independent RAC.
  - » Any agreements for the purposes of the residency program, including affiliation agreements, such as those used for rotation sites, should be established directly between individual hospitals, rather than their health systems. This should apply even if the hospitals are part of the same health system.
- **Health System Engagement:** CMS is very focused on situations where a health system versus an individual hospital is controlling a residency program. If the hospital is part of a larger health system, ensure that all documentation related to the program clearly outlines that the hospital retains *sole and full* authority over the program, with no decision-making or involvement of the larger health system.
  - » Some programs have seen success by working with their finance teams to create residency program-specific cost centers and tying all program expenses back to those cost centers. The results of this approach may vary based on auditor familiarity with residency programs and the structure of the residency program itself.
- **Shared Services:** Auditors have raised concerns about shared services between hospitals and their parent health systems. While the regulations specifically allow shared services, the use of the services should be carefully documented, and affiliation agreements with hospital control of the PGY1 program should be clearly outlined.
  - » If your hospital shares payroll services with the health system, document the residency payroll expenses carefully to provide auditors with backup documentation.
  - » This does not mean you shouldn't use shared payroll, just that hours and payroll practice administered by the health system, on behalf of the hospital, should be documented and tracked closely. If your hospital does not directly employ any clinicians (e.g., a separately incorporated but related entity employs everyone), ensure that you have documentation to that effect for your auditors.
- **Pharmacy School Affiliations:** Affiliations with schools of pharmacy can be valuable, but these arrangements can create questions for auditors around program control. CMS is also very focused on whether other community organizations (e.g., pharmacy schools) are providing support that would undermine the need for CMS funding.
  - » Residency preceptors must be employed by the sponsoring hospital, rather than the school of pharmacy.
  - » Any affiliation agreement between a residency program and a school of pharmacy should document that the sponsoring hospital, rather than the school of pharmacy, has *full* control over the resident's training.

## II. Plan for how your program will respond to a CMS audit.

Advance preparation for an audit can help protect your program and reduce burden associated with the audit. It is important to note that CMS audit regulations are different from ASHP accreditation standards. While ASHP's standards focus on the clinical aspects of the program, CMS audit standards focus solely on tracking the dollars associated with pass-through funding, without regard for program quality or offerings. To best position your program for a CMS audit, we recommend the following:

- Ensure that documentation for all elements of the residency program clearly delineates the hospital's full and complete control over the residency program operations, curricula, and staffing. Documentation should also clearly indicate that the residency program director maintains authority over the program. Residency programs have encountered challenges when other hospital or health system personnel are engaging in decision-making around, or oversight of, a residency program. Be prepared to provide this documentation to auditors.
- Engage your hospital's finance staff and general counsel early in the audit process, especially if auditors challenge aspects of the program.
- Push auditors to specify how they arrived at a potentially adverse finding. For example:
  - » If an auditor questions an element of the program, request that the auditor cite the program regulations in question. If they cite "direct control" as the issue but are raising questions about something like the use of shared payroll services, ask them to point you to exactly where in the auditor transmittal or regulations the prohibition appears. In many cases, we've encountered auditors who realize they can't adequately cite the regulations supporting a disallowance.
  - » If an auditor requests additional documentation regarding any aspect of the program, challenge them to provide specifics as to exactly what type of documentation they expect to see. If the expectations are unreasonable and the auditor won't change course, consider engaging their supervisor(s).
- Should auditors begin questioning aspects of the program, contact ASHP as early as possible. ASHP does not provide legal advice but can work with programs and their hospital's finance and general counsel colleagues to address these issues, as it is much easier to fight potential disallowances before an auditor submits his/her report.