

Draft FAQs for CMS on Provider-Operated Pharmacy Residency Programs

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?

A: No, the transmittal does not mean that MACs should disallow residency costs in any circumstances that could suggest a lack of control. Instead, the transmittal language clarifies that the presumption under 42 CFR § 413.85(f)(2) does not relieve providers from satisfying the control requirements of (f)(1). Should MACs find an indicator(s) of lack of control, such negative indicator(s) should be balanced against evidence of control and exercise of decisional authority to determine whether the provider meets the requirements of (f)(1).

Q: Under what circumstances can a hospital that is part of a larger health system operate a pharmacy residency program?

A: A hospital that is part of a larger health system can operate a provider-operated pharmacy residency program if it satisfies the control requirements set forth at 42 CFR § 413.85(f)(1)(i)-(v). Thus, each program operator that is part of a larger health system must retain full independent operational control of its own residency program. Health systems should not be allowed control over, or decisional authority regarding, educational aspects of individual residency program operations, including curriculum development and maintenance, program standards, preceptor requirements.

Q: What types of administrative functions can residency programs contract for or share with a parent health system without violating the control requirement?

Section 413.85(f)(1)(iii) allows a provider to contract with another entity to perform some administrative functions. However, the provider must maintain control over all aspects of the contracted functions. Services that may be contracted out include, but are not limited to, payroll processing, staff orientation and training, employee benefits administration, etc. A provider would violate the control requirement if a health system rather than the program operator dictated residency program curriculum or training requirements.

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)?

A: [NOTE TO CMS: During our meeting you indicated that control in fact/practice was more important than any contractual language. However, given that these are paper audits, we’re unsure how programs could actually demonstrate control in fact other than through

documentation. Thus, we haven't drafted an answer, but suggest some examples could include a memorandum of understanding that any shared operational functions will not interfere with the operational authority of the hospital operator, specific language around control in certain agreements, etc.]

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?

A: Yes. The regulations require that the provider control the administration of the program, but permit another entity to perform administrative functions. The fact that a residency program uses a payroll system maintained by a health system or academic institution is not itself evidence of a lack of control of the program.

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?

A: No, the regulations do not require any particular institutional name or signor authority on the completion certificate. Status as a provider-operated pharmacy residency program is determined based on the control requirements set forth at 42 CFR § 413.85(f)(1)(i)-(v). MACs have been instructed not to rely on a completion certificate issued by the hospital as evidence that a program is provider-operated. *See* CMS Transmittal 2133. Likewise, the appearance of the name of a health system or educational institution affiliated with the hospital, or the signature of an official from such an entity, should not be viewed as evidence of a lack of control.

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?

A: CMS recognizes that the health system CEO's signature may appear on various types of hospital documents. This would not necessarily indicate a lack of control by the operating hospital. MACs should look to whether documents signed by health system officials indicate decisional authority over the residency program, as only in this instance would a health system signature be evidence of 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?

A: The regulations do not impose specific restrictions on marketing or public-facing materials. Providers operating residency programs maintain affiliations with schools of pharmacy for many reasons, including access to clinical experts, enhanced care coordination, operational efficiency, and public branding, that do not compromise the provider's control of its residency program. Use of marketing or other materials bearing the name of an affiliated health system or pharmacy school does not constitute evidence of a lack of control as long as control and decisional

authority regarding the residency program rests with the provider and not the health system or pharmacy school.

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)?

A: Pharmacy residencies can utilize shared educational materials or training provided that the program operator can demonstrate that the activities at issue do not cede operational control to the health system. Evidence that the health system exercises control over the residency curriculum or the overall training of residents would constitute a lack of operational control.