

specialized residency before allowing those pharmacists to specialize on a particular group or type of patients. For example, before a pharmacist may work exclusively to design, implement, and monitor a course of treatment for oncology patients, some hospitals require that the pharmacist complete a residency in oncology pharmacy. However, many hospitals may employ pharmacists who have only completed a pharmacy practice residency to treat these groups or types of patients, including oncology patients.

As we explained above in response to the comments on CPE, in the May 19, 2003 proposed rule (68 FR 27210), we proposed to revise the regulations at § 413.85(h)(3) to state that activities treated as normal operating costs include "Educational seminars, workshops, and continuing education programs in which the employees participate that enhance the quality of medical care or operating efficiency of the provider and, effective October 1, 2003, do not lead to certification required to practice or begin employment in a nursing or allied health specialty." We proposed to add a conforming definition of "certification" for purposes of nursing and allied health education under § 413.85(c) to mean "the ability to practice or begin employment in a specialty as a whole." However, it is apparent from the comments we received that our proposed definition of "certification" was not clear. Some commenters believed we intended, through the proposed definition, to allow pass-through payments for the costs of a program that would only enhance an individual's set of skills. However, that was not our intent. We believe it would have been more appropriate to use the word "and" instead of the word "or" to further emphasize that pass-through payment would only apply to activities that enable an individual to practice *and* begin employment in a specialty, but would *not* apply to activities that serve to add to or enhance an individual's current skill set.

In addition, based on the comments received, we understand that there may be several distinct levels of training in a given health profession, and each level of training may be a requirement in order for an individual to work in a new capacity or "specialty" in that profession, but *not* a requirement to practice or begin employment in the specialty "as a whole." Since a second level of training is not required to begin practicing in a profession, under the proposed definition, we would not have been able to allow for pass-through

payments for a second (or potentially a third) level of training. Therefore, we understand that inclusion of the words "as a whole" in the proposed definition of "certification" was misleading. Consequently, where a subsequent level of training is a requirement to practice in a new specialty in a given profession, pass-through payment may be made for the subsequent level of training.

Finally, we have concluded that it is not necessary to include a specific definition of "certification" in the regulations at § 413.85. In this final rule, we are deleting the proposed definition of "certification" from § 413.85(c), and amending § 413.85(h)(3) by removing the words "certification required" and inserting the words "the ability." We are also changing the word "or" to "and". Specifically, we are amending the proposed § 413.85(h)(3) to state that activities treated as normal operating costs include "Educational seminars, workshops, and continuing education programs in which the employees participate that enhance the quality of medical care or operating efficiency of the provider and, effective October 1, 2003, do not lead to the ability to practice and begin employment in a nursing or allied health specialty."

As we stated above in response to the comments concerning CPE, our view of a "specialty" in the nursing and allied health education context is based on what the health care industry views as the standard of practice in a specific area within a profession. We are defining "industry norm" to mean that more than 50 percent of hospitals in a random, statistically valid sample require the completion of a particular training program before an individual may be employed in a specialty. (We understand that, in some instances, due to the unique staffing circumstances faced by many smaller hospitals, inclusion of small hospitals in the sample would introduce factors that are not typically representative of the industry as a whole and would skew the results inappropriately. In such cases, we would consider excluding hospitals with less than 100 beds, which would still retain over 75 percent of all hospitals in the sample universe.)

Based on comments received, we believe that it is currently the "industry norm" for hospitals to generally hire only pharmacists who have completed a pharmacy practice residency to work directly in patient care. Specifically, without having completed a pharmacy practice residency, a pharmacist would typically be employed by a hospital as a staff or distribution pharmacist, but not as a clinical pharmacist who works directly with patients to develop

treatment plans. Since completion of a pharmacy practice residency has become a requirement by hospitals to practice or begin employment in a position that involves direct patient care, we would view "hospital pharmacy" as a "specialty" of the pharmacy profession. Accordingly, pharmacy practice residency training programs that meet the requirements under § 413.85, including accreditation by a nationally recognized accrediting body, direct operation by a provider, and lead to certification that is a requirement for employment, may be eligible for Medicare reasonable cost pass-through payment.

However, it is apparent from the comments that it is *not* unusual for a hospital to employ a pharmacist that has only completed a pharmacy practice residency in an area in which an accredited second-year program exists (that is, geriatrics, cardiology, or oncology), without requiring the pharmacist to first complete that second-year residency program. For example, we would view further training in oncology pharmacy or cardiology pharmacy as specializations within the pharmacy field under the policy in this final rule. However, these second-year residencies would *not* qualify for reasonable cost pass-through payment because, based on information received from commenters, it is not currently the "industry norm" to require completion of these programs before beginning work in these specialties. If we find in the future that it has become the "industry norm" for hospitals to require second-year pharmacy residencies, we may allow the hospitals operating those programs to be reimbursed for the costs of those programs on a reasonable cost basis.

### 3. Programs Operated by Wholly-Owned Subsidiary Educational Institutions of Hospitals

Another matter that has come to our attention since publication of the January 12, 2001 final rule (66 FR 3363) on nursing and allied health education concerns the preamble language of the rule, which states:

"Concerning those hospitals that have established their own educational institution to meet accrediting standards, we believe that, in some cases, these providers can be eligible to receive payment for the classroom and clinical training of students in approved programs. If the provider demonstrates that the educational institution it has established is wholly within the provider's control and ownership and that the provider continues to incur the costs of both the classroom and clinical