

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 412 and 413
[CMS-1470-F]
RIN 0938-AL89
Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates
AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this final rule, we are describing changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2003. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the IPPS that are paid on a cost basis subject to these limits.

Among other changes that we are making are: changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)-DRGs and relative weights; the introduction of updated wage data used to compute the wage index; the approval of new technologies for add-on payments; changes to the policies governing postacute care transfers; payments to hospitals for the direct and indirect costs of graduate medical education; pass-through payments for nursing and allied health education programs; determination of hospital beds and patient days for payment adjustment purposes; and payments to critical access hospitals (CAHs).

EFFECTIVE DATES: The provisions of this final rule, except the provisions of § 412.230(e)(2)(ii)(A) (because it grants an exemption) and § 412.278(f)(2)(i), are effective on October 1, 2003. The provisions of § 412.230(e)(2)(ii)(A) and § 412.278(f)(2)(i) are effective on August 1, 2003. This rule is a major rule as defined in 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), we are submitting a report to Congress on this rule on August 1, 2003.

FOR FURTHER INFORMATION CONTACT:

Stephen Phillips, (410) 786-4548, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Patient Transfers, Counting Beds and Patient Days, and Hospital Geographic Reclassifications Issues.

Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Nursing and Allied Health Education, Graduate Medical Education, and Critical Access Hospital Issues, and Long-Term Care (LTC)-DRGs.

Sandra Hetrick, (410) 786-4542, RCE Limits.

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Acronyms

AHIMA American Health Information Management Association
 AHA American Hospital Association
 CAH Critical access hospital
 CBSAs Core Based Statistical Areas

CC Complication or comorbidity
 CMS Centers for Medicare & Medicaid Services
 CMSA Consolidated Metropolitan Statistical Areas
 COBRA Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272
 CPI Consumer Price Index
 CRNA Certified registered nurse anesthetist
 DRG Diagnosis-related group
 DSH Disproportionate share hospital
 FDA Food and Drug Administration
 FQHC Federally qualified health center
 FTE Full-time equivalent
 FY Federal fiscal year
 GME Graduate medical education
 HIPC Health Information Policy Council
 HIPAA Health Insurance Portability and Accountability Act, Pub. L. 104-191
 HHA Home health agency
 ICD-9-CM International Classification of Diseases, Ninth Revision, and Clinical Modification
 ICD-10-PCS International Classification of Diseases Tenth Edition, and Procedure Coding System
 IME Indirect medical education
 IPPS Acute care hospital inpatient prospective payment system
 IRF Inpatient Rehabilitation Facility
 LDP Labor, delivery, and postpartum
 LTC-DRG Long-term care diagnosis-related group
 LTCH Long-term care hospital
 MCE Medicare Code Editor
 MDC Major diagnostic category
 MDH Medicare-dependent small rural hospital
 MedPAC Medicare Payment Advisory Commission
 MedPAR Medicare Provider Analysis and Review File
 MEI Medicare Economic Index
 MGCRB Medicare Geographic Classification Review Board
 MPFS Medicare Physician Fee Schedule
 MSA Metropolitan Statistical Area
 NECMA New England County Metropolitan Areas
 NCHS National Center for Health Statistics
 NCVHS National Committee on Vital and Health Statistics
 O.R. Operating room
 PPS Prospective payment system
 PRA Per resident amount
 ProPAC Prospective Payment Assessment Commission
 PRRB Provider Reimbursement Review Board
 RCE Reasonable compensation equivalent

Comment: Several hospitals who were interested in reclassifying, as a group, for purposes of the wage index, commented that their efforts to reclassify as an urban group have been unsuccessful primarily because they fail to meet the established requirement set forth in § 412.234(c)(2) that the requesting hospitals must demonstrate that their costs exceed their current payments by 75 percent of the additional payments they would receive through reclassification. The commenters submitted several recommendations for our consideration to clarify or improve our policies and regulations. They recommended that we consider:

- Allowing hospital groups to seek geographic reclassification for purposes of the wage index or standardized amount;
- Allowing hospital groups seeking geographic reclassification to areas where the reclassification would not result in a different standardized amount to seek reclassification for purposes of the wage index without having to satisfy the criteria applicable to hospitals seeking reclassification for purposes of the standardized amount;
- Allowing hospitals in NECMAs to seek reclassification to another MSA under the alternative criteria at § 412.236(c);
- Lowering the cost-to-payment threshold used to evaluate group reclassification applications; or
- In order to evaluate the interrelationship between the area where the hospitals are located and the target area in which they are seeking to reclassify, replacing the cost comparison criteria used to evaluate reclassification eligibility for purposes of the standardized amount with a better indicator of the connection such as, census commuting patterns.

Response: We appreciate the comments and recommendations presented by the hospitals and the importance of this issue. We note that, in developing the proposed rule, we did consider including a proposal to allow urban hospitals to reclassify as a group either for wage index or the standardized amount, or both. However, we did not go forward with the proposal because, upon further review, the criterion that hospitals demonstrate that their costs are in excess of their payments seemed appropriate. We will consider the commenters' recommendations in the future.

Comment: One commenter recommended that CMS consider lowering the applicable qualifying thresholds at § 412.230(c)(1)(iii) and (iv) for urban hospitals seeking

reclassification for purposes of the wage index. The commenter specifically suggested that the threshold be lowered from 108 percent of the average hourly wage of hospitals in the area in which the hospital is located, and 84 percent of the average hourly wage of hospitals in the area to which the hospital seeks reclassification, to 106 percent and 82 percent, respectively, for urban hospitals. The commenter further recommended that, if the lower thresholds cannot be reduced for all urban hospitals, CMS consider implementing the lower thresholds for urban hospitals in areas where they are paid as if they are rural.

Response: As pointed out by the commenter, this issue was discussed, in detail, in the August 1, 2000 **Federal Register** (65 FR 47089 through 47090). While we will consider the recommendations for possible inclusion in a future proposed rule, we did not propose any changes or clarifications to the existing policy. Therefore, we are not adopting this comment.

E. Costs of Approved Nursing and Allied Health Education Activities (§ 413.85)

1. Background

Medicare has historically paid providers for the program's share of the costs that providers incur in connection with approved educational activities. The activities may be divided into the following three general categories to which different payment policies apply:

- Approved graduate medical education (GME) programs in medicine, osteopathy, dentistry, and podiatry. Medicare makes direct and indirect medical education payments to hospitals for residents training in these programs. Existing policy on direct GME payment is found at 42 CFR 413.86, and for indirect GME payment at 42 CFR 412.105.
- Approved nursing and allied health education programs operated by the provider. The costs of these programs are excluded from the definition of inpatient hospital operating costs and are not included in the calculation of payment rates for hospitals paid under the IPPS or in the calculation of payments to hospitals and hospital units excluded from the IPPS that are subject to the rate-of-increase ceiling. These costs are separately identified and "passed through" (that is, paid separately on a reasonable cost basis). Existing regulations on nursing and allied health education program costs are located at 42 CFR 413.85.
- All other costs that can be categorized as educational programs and activities are considered to be part of

normal operating costs and are included in the per discharge amount for hospitals subject to the IPPS, or are included as reasonable costs that are subject to the rate-of-increase limits for hospitals and hospital units excluded from the IPPS.

In the May 19, 2003 proposed rule, we proposed to clarify our policy governing payments to hospitals for provider-operated nursing and allied health education programs. Under the regulations at § 413.85 ("Cost of approved nursing and allied health educational activities"), Medicare makes reasonable cost payment to hospitals for provider-operated nursing and allied health education programs. A program is considered to be provider-operated if the hospital meets the criteria specified in § 413.85(f), which means the hospital directly incurs the training costs, controls the curriculum and the administration of the program, employs the teaching staff, and provides and controls both clinical training and classroom instruction (where applicable) of a nursing or allied health education program.

In the January 12, 2001 **Federal Register** (66 FR 3358), we published a final rule that clarified the policy for payments for approved nursing and allied health education activities in response to section 6205(b)(2) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) and sections 4004(b)(1) and (2) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508).

Section 6205(b)(2) of Pub. L. 101-239 directed the Secretary to publish regulations clarifying the rules governing allowable costs of approved educational activities. The Secretary was directed to publish regulations to specify the conditions under which those costs are eligible for pass-through, including the requirement that there be a relationship between the approved nursing or allied health education program and the hospital. Section 4004(b)(1) of Pub. L. 101-508 provides an exception to the requirement that programs be provider-operated to receive pass-through payments. The section provides that, effective for cost reporting periods beginning on or after October 1, 1990, if certain conditions are met, the costs incurred by a hospital (or by an educational institution related to the hospital by common ownership or control) for clinical training (as defined by the Secretary) conducted on the premises of the hospital under an approved nursing or allied health education program that is *not* operated by the hospital are treated as pass-through costs and paid on the basis of

reasonable cost. Section 4004(b)(2) of Pub. L. 101-508 sets forth the conditions that a hospital must meet to receive payment on a reasonable cost basis under section 4004(b)(1).

2. Continuing Education Issue for Nursing and Allied Health Education

Since publication of the January 12, 2001 final rule on nursing and allied health education, we have encountered questions concerning the substantive difference between provider-operated *continuing education* programs for nursing and allied health education (which would *not* be reimbursable under Medicare on a reasonable cost basis) and provider-operated approved programs that are eligible to receive Medicare reasonable cost payment. In that final rule, we stated that Medicare would generally provide reasonable cost payment for "programs of long duration designed to develop trained practitioners in a nursing or allied health discipline, such as professional nursing or occupational therapy. This is contrasted with a continuing education program of a month to a year in duration in which a practitioner, such as a registered nurse, receives training in a specialized skill such as enterostomal therapy. While such training is undoubtedly valuable in enabling the nurse to treat patients with special needs and in improving the level of patient care in a provider, the nurse, upon completion of the program, continues to function as a registered nurse, albeit one with special skills. Further distinction can be drawn between this situation and one in which a registered nurse undergoes years of training to become a CRNA. For these reasons, the costs of continuing education training programs are not classified as costs of approved educational activities that are passed-through and paid on a reasonable cost basis. Rather, they are classified as normal operating costs covered by the prospective payment rate or, for providers excluded from the IPPS, as costs subject to the target rate-of-increase limits" (66 FR 3370).

Accordingly, upon publication of the final rule, we revised § 413.85(h)(3) to include continuing education programs in the same category as "educational seminars and workshops that increase the quality of medical care or operating efficiency of the provider." Costs associated with continuing education programs, as stated above, are recognized as normal operating costs and are paid in accordance with applicable principles.

Prior to the issuance of the May 19, 2003 proposed rule, we received an

inquiry requesting further clarification on what is meant by continuing education. It is our belief that provider-operated programs that do not lead to any specific certification in a specialty would be classified as continuing education. In the proposed rule (68 FR 27210), we stated that our use of the term "certification" does not mean certification in a specific skill, such as when an individual is certified to use a specific piece of machinery or perform a specific procedure. Rather, we stated that we believe certification means the ability to perform in the specialty as a whole.

Although, in the past, we believe we have allowed hospitals to be paid for operating a pharmacy "residency" program, in the May 19, 2003 proposed rule, we stated that it has come to our attention that those programs do not meet the criteria for approval as a certified program. Once individuals have finished their undergraduate degree in pharmacy, there are *some* individuals who go on to participate in 1-year hospital-operated postundergraduate programs. It is our understanding that many individuals complete the 1-year postundergraduate program practice pharmacy inside the hospital setting. However, we also understand that there are pharmacists who *do not* complete the 1-year postundergraduate program, but have received the undergraduate degree in pharmacy, who also practice pharmacy inside the hospital setting. Because pharmacy students need not complete the 1-year residency program to be eligible to practice pharmacy in the hospital setting, the 1-year programs that presently are operated by hospitals would be considered continuing education, and therefore, would be ineligible for pass-through reasonable cost payment.

We stated that we understood that *all* individuals who wish to be nurses practicing in a hospital must either complete a 4-year degree program in a university setting, a 2-year associate degree in a community or junior college setting, or a diploma program traditionally offered in a hospital setting. Since participants that complete a provider-operated diploma nursing program could not practice as nurses without that training, the diploma nursing programs are *not* continuing education programs and, therefore, may be eligible for pass-through treatment.

Because of the apparent confusion concerning the distinction between continuing education programs and approved education programs in the context of reasonable cost pass-through payments for nursing and allied health

education activities, in the May 19, 2003 proposed rule, we proposed to revise § 413.85(h)(3) to state that 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, would be treated as educational activities that are part of normal operating costs. We also 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."

Comment: A large number of commenters responded to our proposal to clarify that, effective October 1, 2003, activities that do not lead to certification required to practice or begin employment in a nursing or allied health specialty would be treated as educational activities (continuing education) that are part of normal operating costs, and not as approved programs that are eligible for reasonable cost reimbursement. Many commenters strongly disagreed with the section of the proposed rule that included clinical pastoral education (CPE) as continuing education and stated that CMS must have been badly misinformed when writing the proposed rule. The commenters argued that CPE is a rigorous and structured education program accredited by the Association for Clinical Pastoral Education, Inc. (ACPE). The commenters stressed that, in varying amounts, CPE is a requirement for graduation for the master of divinity degree and for professional certification by the Association of Professional Chaplains (APC) as a health care chaplain, or as a CPE supervisor. Many commenters also noted prior Provider Reimbursement Review Board (PRRB) rulings that recognized chaplaincy as an allied health discipline, and asserted that hospitals that receive Medicare reasonable cost pass-through payment for CPE do so for the purpose of their professional CPE programs, not as continuing education for individuals already qualified to practice in hospital chaplaincy. Many commenters mentioned that the Joint Commission on Accreditation of Healthcare Organizations also recognizes chaplains as allied health professionals and considers them "primary care providers." Similarly, commenters referred to various studies that have

shown the positive spiritual and therapeutic benefits of pastoral care. The commenters warned that removal of funding for CPE would represent a huge step backward for American health care. The commenters urged CMS to ensure continuing pass-through payments for CPE.

Response: In the May 19, 2003 proposed rule (68 FR 27210), we stated that we received an inquiry requesting further clarification of what is meant by continuing education. We proceeded to explain what constitutes "continuing education" for the purpose of determining whether a nursing or allied health education activity would or would not qualify for Medicare reasonable cost pass-through payments. We acknowledge that the definition of "continuing education" for Medicare payment purposes may differ from the academic view of what, in general, constitutes such activities. In the proposed rule, we stated that we believed that provider-operated programs that do not lead to any specific certification or the ability to perform in the specialty would be classified as "continuing education."

Our intent is to ensure that Medicare pass-through payments are only provided for programs that enable an individual to be employed in a capacity that he or she could not have been employed without having first completed a particular education program. We believe that, for Medicare purposes, training that enhances an individual's competencies, but does not permit that individual to be employed in a new capacity in which he or she could not have been employed without completing the additional training, would not qualify for Medicare reasonable cost pass-through payment. Medicare provides payments for such educational activities, but only under the methodology applicable to payment of normal operating costs. Our intent was simply to provide clarification for the purpose of distinguishing between those educational programs that qualify for reasonable cost pass-through payment (that is, programs that enable an individual to begin employment in a specialty as a whole) and those programs that should be paid as normal operating costs (that is, activities that are intended to enhance the current skill set of an individual's profession or advance an individual's professional career).

Since publication of the proposed rule, we have learned from information provided by the ACPE and the APC that there are several levels of CPE. Specifically, the ACPE accredits three different levels of CPE. The first level of

CPE is generally geared to interns and beginning residents. The second level of CPE is generally geared to residents doing specialization and preparation for chaplaincy certification. The third level is supervisory training, which is geared toward preparation for certification by the ACPE as a CPE supervisor.

We understand that, as a part of the requirements for a master of divinity degree, many theological schools and seminaries require or strongly recommend completion of an internship, or 1 unit of CPE for graduation. A unit of CPE is 400+ hours of supervised CPE in a health care or institutional setting. Students taking either 1 or 2 units of CPE are generally referred to as interns. In addition, many faith groups require, at their national or regional levels, that individuals complete at least 1 unit of CPE in order for them to be ordained into professional ministry. Theological schools that offer doctoral degrees (for example, a doctor of philosophy, a doctor of ministry, or a doctor of theology) with specialties in pastoral counseling and related fields also generally require some amount of CPE as a part of those degree programs. Upon completion of a CPE internship, the health care institution typically reports to the theological school in which the student is enrolled that the student has successfully completed the internship, and the theological school subsequently awards credit for the training. Based upon information received from the commenters, we understand that completion of only an internship, or 400+ hours of CPE, would not qualify an individual for employment as a chaplain in a hospital setting.

In contrast to CPE internships, CPE residents generally participate in a 1-year, or occasionally a 2-year, full-time CPE program. A 1-year residency typically consists of 4 units of postgraduate CPE (that is, 1,600+ hours of supervised CPE), in a health care or institutional setting. Generally, individuals who undertake 1,600 hours of CPE do so in order to become a board-certified chaplain. The ACPE has established 4 units, or 1,600 hours of supervised CPE, as the national minimum amount of CPE that is required to become a board-certified chaplain. However, some certifying boards or particular programs may require some additional hours of CPE for board certification. We note that, in instances where academic credit is granted for completion of 1 unit, or 400 hours, of CPE prior to receipt of a degree, an individual seeking to become a board-certified chaplain generally

must complete an additional 1,600 hours of CPE training.

The board certification of chaplains is carried out by nationally recognized organizations that are part of the Commission on Ministry in Specialized Settings (COMISS), an umbrella network for pastoral care organizations that share the same standards of educational preparation and clinical training. These organizations include the Association of Professional Chaplains (APC), the National Association of Catholic Chaplains (NACC), the National Association of Jewish Chaplains (NAJC), and the Canadian Association for Pastoral Practice and Education (CAPPE). The ACPE accredits CPE training for all of these certifying organizations.

Based on information received from the commenters, we understand that most health care organizations that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) advertise for and recruit only board-certified chaplains, which means that qualified applicants for employment as hospital chaplains will usually have completed at least 1,600 hours of CPE.

Individuals who seek to develop a health care chaplaincy specialization (for example, hospice, pediatrics, cardiology, rehabilitation, neurology) may undertake a second year of CPE residency. A second year of residency consists of an additional 4 units of CPE (or 1,600+ hours of supervised CPE). However, there is currently no established board certification process for residents completing a second year of CPE residency training.

To be eligible to apply for supervisory CPE training, an individual must have completed at least 4 units (1 year) of CPE training. Upon completion of supervisory training, an individual becomes certified by the ACPE as a CPE supervisor and is qualified to develop and conduct CPE training for all ACPE-accredited programs.

Based on information submitted by the commenters on the different levels of CPE training, two important points relative to Medicare reimbursement have become clear to us. First, in instances where internship training is completed as a prerequisite for a degree granted by an educational institution other than a hospital, such training is *not* provider-operated, and, therefore, does *not* qualify for Medicare reasonable cost pass-through payment under § 413.85. Under § 413.85(f), a program is considered to be provider-operated only if the hospital directly incurs the training costs, directly controls the curriculum and the administration of

the program, employs the teaching staff, and provides and controls both clinical training and classroom instruction (where applicable). While a hospital may serve as the site for a CPE internship, such training is provided to satisfy curriculum requirements of a theological school, which grants the master degree upon completion of the internship. While the hospital might incur training costs and employ the supervising faculty, it would not ordinarily meet the other "provider-operated" criteria concerning controlling the curriculum and providing both the didactic and clinical training necessary for the degree. Thus, a CPE internship, or any other CPE training that is a requirement for a degree, whether it is undergraduate, graduate, or doctoral, is not eligible for Medicare reasonable cost pass-through payment.

Secondly, a CPE residency consisting of 1,600 hours of training could be a provider-operated program and could also lead to certification and the ability to be employed in a new or different capacity. Specifically, a CPE residency consisting of approximately 1,600 hours of training leads to board certification in chaplaincy, and, as we understand it, most JCAHO-accredited hospitals generally only employ board-certified chaplains. In consideration of these facts, the costs of CPE 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 generally a requirement for employment in a particular specialty, may be eligible for Medicare reasonable cost pass-through payment.

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 to 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" 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 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 the ability to practice and begin employment in a nursing or allied health specialty."

Our view of a "specialty" in the nursing and allied health education context is based on what the industry views as the standard of practice in a specific area within a profession. The training required to allow a person to serve in the "specialty" is tailored to the

skill level and context that an individual is expected to use in that "specialty."

Consistent with what we stated in the proposed rule, Medicare reasonable cost pass-through payments are only provided for programs that, according to industry norms, qualify an individual to be employed in a specialty in which the individual could not have been employed before completing a particular education program. Given the confusion expressed by commenters, we recognize the need to specify how we will determine whether completion of a particular education program enables an individual to be employed in a specialty. We will use "industry norms" as the standard to determine whether participation in a specialty enables an individual to be employed in a capacity that he or she could not have been employed without having first completed a particular education program. 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 a case, if appropriate, we would consider excluding hospitals with less than 100 beds, which would still retain over 75 percent of all hospitals in the universe).

Based on comments received, we believe that it is the "industry norm" to require a CPE residency and board certification for employment as a hospital chaplain. Since it is currently the "industry norm" for hospitals to employ only board-certified chaplains, and since completion of approximately 1,600 hours of CPE training is a requirement to practice and begin employment in hospital chaplaincy, we view hospital chaplaincy as a "specialty" of pastoral counseling. Consequently, a hospital that operates a CPE residency may be eligible for reasonable cost pass-through payment.

Specifically, assuming all requirements under § 413.85 are met, Medicare reasonable cost pass-through payments may only be made to hospitals for CPE hours that are *not* prerequisites for *any* academic degree, *and* are provided to students in order to obtain board certification in hospital chaplaincy. A hospital may not receive reasonable cost payment for any costs

incurred in connection with providing CPE that is undertaken to meet the requirements of an academic degree. In addition, since generally a minimum of approximately 1,600 hours of CPE is required to become a board-certified chaplain, any costs incurred for an individual participating in CPE training that exceeds the minimum number of hours required to obtain board certification would not be eligible to be paid on a reasonable cost basis.

However, we note that we do not completely defer to the information provided by industry representatives in order to determine the "industry norm." Rather, if at any time we obtain information that calls our view of industry norms into question, we may make our own determination based on a random sample of hospitals. Therefore, assuming all other requirements under § 413.85 are met, a hospital may receive reasonable cost pass-through payment for the hours of CPE for which academic credit is *not* granted (since *those* CPE hours are not generally provider-operated), and for the hours of CPE that may be used to satisfy training requirements for board certification. We will continue to allow reasonable cost payment for CPE that leads to board certification as long as we do *not* have evidence indicating that, based on a statistically valid, random sample, the "industry norm" is *not* to require board certification for chaplains that are employed by hospitals.

We also recognize that industry norms are susceptible to change over time. Therefore, although it may not currently be the "industry norm" to require completion of a particular nursing or allied health education program in order to practice and begin employment in a particular specialty, it may become the "industry norm" in the future. If we find that it has become the "industry norm," we may allow the hospitals operating those programs (and meeting the requirements at § 413.85) to be paid for the costs of those programs on a reasonable cost basis.

In relation to the commenters' recommendation that reasonable cost reimbursement should be provided for CPE supervisory training, we understand that, essentially, the purpose of the supervisory training is to prepare a chaplain to develop CPE programs and to teach interns and residents. We believe that CPE supervisors are practicing in the teaching profession, not within a nursing or allied health discipline. Furthermore, we do not believe that Congress intended to provide for reasonable cost pass-through payments for programs that are intended to

produce instructors or teachers. While we recognize that CPE supervisors are necessary to train and prepare individuals for hospital chaplaincy, we believe that it is appropriate for the costs of supervisory programs in general to be treated as normal operating costs and paid accordingly.

Comment: One commenter stated that our proposed definition of provider-operated programs intended to exclude programs "that do not lead to certification required to practice or begin employment in a nursing or allied health specialty * * *" is not appropriate in light of the growing number of skills that require intensive clinical experiences. Another commenter stated that this proposal will seriously hinder reversal of the nursing shortage across the nation and, as a result, will have an adverse impact on the quality and safety of care provided in hospitals. The commenters used the example of nurse residencies, which a number of hospitals across the country are hosting for registered nurses. The commenters explained that these residencies, which are postgraduate and typically last 1 year, are designed to equip the newly licensed nurse with the skills to care for patients who require the most complex and sophisticated diagnostic and therapeutic services, and to prepare the nurses for leadership roles earlier in their careers and give them the tools to improve the quality of care and reduce medical errors. The commenters claimed that the Federal Government has thus far provided minimal funding to help ameliorate the nursing shortage and, therefore, the proposed rule is particularly distressing. They urged CMS to include criteria in the final rule for pass-through payment of nurse residencies.

Response: First, we do not believe that nurse residencies, which are intended to help integrate newly licensed nurses into complex acute care environments by enhancing their competencies and skills, are programs that qualify these nurses to be employed in a new specialty. Accordingly, it is more appropriate to treat such activities as normal operating costs. As we stated above, Medicare reasonable cost pass-through payment will only be provided for programs that, according to industry norms, qualify an individual to be employed in a specialty in which the individual could not have been employed prior to completing a particular education program. Second, we note that nurse residencies do not qualify for reasonable cost payment because they also do not meet the requirement for accreditation by a national approving body under

§ 413.85(d)(1)(i)(A). Therefore, while we are sympathetic to the commenters' concerns, we do not believe that it is appropriate at the present time to allow for pass-through payment to be made under the Medicare program for nurse residencies.

Comment: Some commenters stated that CMS was "entirely correct" in identifying CPE as continuing education and concurred with our proposal to discontinue pass-through payments for CPE. One commenter contended that ACPE-accredited training is not primarily used to prepare students to be health care chaplains. Rather, CPE is primarily ministry training, and there are various ways that one can choose to use CPE. One commenter added that very few individuals who train in CPE, including those individuals in 1-year residencies, become employed as health care chaplains. The commenter further stated that CPE is "properly a funding responsibility of the church rather than the government". The commenters argued that Medicare should not be supporting continuing education for religious care providers whose primary base and certifying group is their denomination or faith group.

Another commenter presented a similar argument concerning pharmacy residencies and questioned why Medicare (that is, taxpayers) should subsidize these residency programs. The commenter claimed that hospitals "use government monies in order to hire these 'residents,' utilize them in 'clinical' positions under the guise of postgraduate training, thereby bypassing having to use FTEs in the hospital pharmacy budget." The commentator believed that if hospitals and pharmacists were truly concerned with improving patient care, hospital pharmacy departments would train their own staff pharmacists to perform the clinical aspects themselves, rather than having taxpayers provide the funding.

Response: We are sympathetic to the commenters' concerns. However, we understand that many CPE programs do occur in hospitals, and that, while there may be various kinds of CPE training, generally, completion of approximately 1,600 hours of CPE training is required for board certification and employment by a hospital. Therefore, we believe that CPE residencies that lead to board certification generally would not be considered continuing education.

In response to the commenters' concerns about the taxpayers, through the Medicare program, providing support for CPE and pharmacy residencies, we note Medicare payment for these and other similar programs are made in accordance with the Medicare

statute. Under section 1861(v) of the Act, Congress provides for Medicare payments to be made in support of certain medical education activities. Currently, if a program meets the regulatory requirements under § 413.85, which were specified earlier in this preamble, a hospital operating that program may qualify for Medicare reasonable cost pass-through payment.

Comment: One commenter explained that a dietetic internship is a post-baccalaureate program that is one of the requirements for practicing as a registered dietitian. The commenter pointed out that the Commission on Accreditation of Dietetic Education (CADE) of the American Dietetic Association accredits these internships and the interns contribute directly to patient care in a hospital. The commenter urged us to continue to pay health care organizations for dietetic internships.

Response: We appreciate the comment and note that, as long as a dietetic internship meets the requirements under § 413.85 (and we do not find that it is not the industry norm to require this training to be employed as a registered dietitian), the hospital operating the internship may qualify for Medicare reasonable cost pass-through payment.

Comment: A large number of commenters responded to our proposal to clarify that, effective October 1, 2003, training that does not lead to certification required to practice or begin employment in a nursing or allied health specialty would be treated as educational activities (continuing education) that are part of normal operating costs, and not as approved programs that are eligible for reasonable cost pass-through payments. Many commenters strongly disagreed with our proposal that included pharmacy residencies in the type of training that is considered continuing education and claimed that the proposed rule reflected a fundamental misunderstanding of pharmacy education. The commenters stated that educational seminars, workshops, and continuing education programs are generally performed outside the provider setting, and in most instances do not exceed 40 hours per year, whereas a pharmacy residency is a full-time commitment that lasts for 1 year. The commenters emphasized that the pharmacy residencies are structured, intensive programs that incorporate direct patient care experience where residents work as part of a clinical team and are required to complete a comprehensive project. The commenters contended that residency experience provides focused, invaluable training

that yields proven positive clinical and financial outcomes. The commenters also noted that, while residencies are not a requirement for all hospital pharmacy positions, they are a requirement for most clinical specialist positions. The commenters maintained that residencies would be a more universal hiring requirement were it not for the current shortage of pharmacists and residency programs. The commenters stressed the benefits of clinical pharmacist involvement in patient care and cautioned that CMS' attempt at short-term cost savings will result in significant long-term cost of care increases. The commenters urged CMS to ensure continuing reasonable cost pass-through payments for pharmacy residencies.

Response: As we stated above in response to the comments received from the clinical pastoral counseling community, in the May 19, 2003 proposed rule (68 FR 27210), we explained what constitutes "continuing education" for the purpose of determining whether a nursing or allied health education activity would or would not qualify for Medicare reasonable cost pass-through payments. We acknowledge that the definition of "continuing education" for Medicare payment purposes may differ from the academic view of what, in general, constitutes such activities. As we stated earlier, we believe that provider-operated programs that do not lead to any specific certification, or the ability to perform in the specialty, would be classified as "continuing education."

Our intent is to ensure that Medicare reasonable cost pass-through payments are only provided for programs that enable an individual to be employed in a capacity that he or she could not have been employed without having first completed a particular education program. We believe that, *for Medicare purposes*, training that enhances an individual's competencies, but does not permit that individual to be employed in a new specialty in which he or she could not have been employed without completing the additional training, would not qualify for Medicare reasonable cost pass-through payment. Medicare provides payment for such educational activities, but only under the methodology applicable to payments for normal operating costs. Our intent was to provide clarification for the purpose of distinguishing between those educational programs that qualify for reasonable cost pass-through payment (that is, programs that enable an individual to begin employment in a specialty), and those programs that should be paid as normal operating

costs (that is, activities that are intended to enhance the current skill set of an individual for a profession or advance an individual's professional career).

Since publication of the proposed rule, we have learned from information provided by the commenters that there are two categories of pharmacy residencies—pharmacy practice residencies and specialized pharmacy residencies, both of which are accredited by the American Society of Health-System Pharmacists (ASHP). If a pharmacist chooses to participate in residency training, he or she would generally do so after completion of an undergraduate bachelor of science degree or a doctor of pharmacy degree. (In some cases, residencies are offered as a part of a postgraduate degree (a master of science or a doctor of pharmacy). However, these programs would *not* meet our provider-operated criteria.) A pharmacy practice residency is typically a 1-year, organized, directed, postgraduate training program in a defined area of pharmacy practice that may take place in a variety of settings, including hospitals. For those seeking additional skills in a focused area of pharmacy practice (for example, oncology), an individual may choose to complete a second year of specialized pharmacy residency. Currently, ASHP, in partnerships with other professional organizations, accredits 17 second-year pharmacy residencies, in areas such as cardiology, geriatrics, infectious diseases, and oncology.

Of the 17 second-year pharmacy residencies, only 5 of these residencies currently lead to board certification. The Board of Pharmaceutical Specialties (BPS) is the organization that administers the certifying examinations after completion of each of these five residencies. Upon completion of a residency in 1 of the other 12 second-year residencies, the hospital in which the resident has trained issues a certificate to the pharmacist.

We understand that many employers, including hospitals, increasingly are requiring completion of an ASHP-accredited first year pharmacy practice residency as a condition for employment as a clinical ("on the floor") or direct patient care pharmacist. While a licensed pharmacist who has not completed a pharmacy practice residency might be hired by a hospital as a staff or distribution pharmacist, a hospital typically would only hire an individual who has completed at least a 1-year pharmacy practice residency to fill a position that requires direct work with hospital patients. Some hospitals may even require their pharmacists to have completed a second-year

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 to 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

■ 11. Section 412.278 is amended by revising paragraph (f)(2)(i) to read as follows:

§ 412.278 Administrator's review.

* * * * *

(f) * * *

(2) The Administrator issues a decision in writing to the party with a copy to CMS—

(i) Not later than 90 days following receipt of the party's request for review, except the Administrator may, at his or her discretion, for good cause shown, toll such 90 days; or

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

■ 2. Section 413.70 is amended by revising paragraph (b)(2)(iii), introductory text, to read as follows:

§ 413.70 Payment for services of a CAH.

* * * * *

(b) *Payment for outpatient services furnished by CAH.* * * *

(2) *Reasonable costs for facility services.* * * *

(iii) Payment for outpatient clinical diagnostic laboratory tests is not subject to the Medicare Part B deductible and coinsurance amounts. Payment to a CAH for clinical diagnostic laboratory tests will be made on a reasonable cost basis under this section only if the individuals are outpatients of the CAH, as defined in § 410.2 of this chapter, and are physically present in the CAH, at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present in the CAH when the specimens are collected will be made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act.

* * * * *

■ 3. Section 413.85 is amended by—

■ A. Republishing the introductory text of paragraph (d)(1) and adding a new paragraph (d)(1)(iii).

■ B. Adding a new paragraph (g)(3).

■ C. Republishing the introductory text of paragraph (h) and revising paragraph (h)(3).

The addition and revision read as follows.

§ 413.85 Cost of approved nursing and allied health education activities.

* * * * *

(d) *General payment rules.* (1) Payment for a provider's net cost of nursing and allied health education activities is determined on a reasonable cost basis, subject to the following conditions and limitations:

* * * * *

(iii) The costs of certain nonprovider-operated programs at wholly owned subsidiary educational institutions are reimbursable on a reasonable cost basis if the provisions of paragraph (g)(3) of this section are met.

* * * * *

(g) *Payments for certain nonprovider-operated programs.* * * *

(3) *Special rule: Payment for certain nonprovider-operated programs at wholly owned subsidiary educational institutions.*

(i) Effective for portions of cost reporting periods occurring on or after October 1, 2003, a provider that incurs costs for a nursing or allied health education program(s) where those program(s) had originally been provider-operated according to the criteria at paragraph (f) of this section, and then operation of the program(s) was transferred to a wholly owned subsidiary educational institution in order to meet accreditation standards prior to October 1, 2003, and where the provider has continuously incurred the costs of both the classroom and clinical training portions of the program(s) at the educational institution, may receive reasonable cost payment for such a program(s) according to the specifications under paragraphs (g)(3)(ii) and (g)(3)(iii) of this section.

(ii) Payment for the incurred costs of educational activities identified in paragraph (g)(3)(i) of this section will be made on a reasonable cost basis if a provider, as described in paragraph (g)(3)(i) of this section, received Medicare reasonable cost payment for those nursing and allied health education program(s) both prior and subsequent to the date the provider transferred operation of the program(s) to its wholly owned subsidiary educational institution (and ceased to be a provider-operated program(s) according to the criteria under paragraph (f) of this section).

(iii) The provider that meets the requirements in paragraphs (g)(3)(i) and (g)(3)(ii) of this section will be eligible

to receive payment under this paragraph for: (A) the clinical training costs incurred for the program(s) as described in paragraph (g)(3)(i) of this section; and (B) classroom costs, but only those costs incurred by the provider for the courses that were included in the programs.

(h) *Activities treated as normal operating costs.* The costs of the following educational activities incurred by a provider but not operated by that provider are recognized only as normal operating costs and paid in accordance with the reimbursement principles specified in part 412 of this subchapter. They include:

* * * * *

(3) 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.

* * * * *

■ 4. Section 413.86 is amended by—

■ A. Under paragraph (b)—

■ (1) Removing the definitions of "Affiliated group" and "Affiliation agreement".

■ (2) Adding definitions of "Community support", "Medicare GME affiliated agreement", "Medicare GME affiliated group", and "Redistribution of costs" in alphabetical order.

■ (3) Under the definition of "Rural track FTE limitation", revising the phrase "paragraph (g)(11)" to read "paragraph (g)(12)".

■ B. Revising the introductory text of paragraph (f).

■ C. Adding a new paragraph (f)(4)(iv).

■ D. In paragraph (g)(1)(i), revising the reference "paragraphs (g)(1)(ii) and (g)(1)(iii)" to read "paragraphs (g)(1)(ii) through (g)(1)(iv)".

■ E. Revising the introductory text of paragraph (g)(4).

■ F. Revising paragraph (g)(4)(iv).

■ G. Revising the introductory text of paragraph (g)(5).

■ H. Adding a new paragraph (g)(5)(vii).

■ I. Revising paragraphs (g)(6)(i)(D) and (g)(6)(i)(E).

■ J. Revising paragraph (g)(7).

■ K. Revising the introductory text of paragraph (g)(12).

■ L. Revising paragraph (g)(12)(i).

■ M. Revising paragraph (g)(12)(ii), introductory text.

■ N. Revising paragraph (g)(12)(ii)(A).

■ O. Revising paragraph

(g)(12)(ii)(B)(1)(i).

■ P. Revising paragraph (g)(12)(iii).

■ Q. Revising paragraph (g)(12)(iv), introductory text.