

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413 and 422

[HCFA-1685-F, previously BPD-685-F]

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Medicare Program; Payment for Nursing and Allied Health Education

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule sets forth in regulations Medicare policy for the payment of costs of approved nursing and allied health education programs. In addition, the rule clarifies the payment methodology for certified registered nurse anesthetist education programs.

In general, the final rule clarifies and restates payment policies previously established in the Provider Reimbursement Manual and other documents, but never specifically addressed in regulations. The final rule carries out a directive made in the Omnibus Budget Reconciliation Act of 1989 and addresses changes required by the Omnibus Budget Reconciliation Act of 1990.

DATES: These regulations are effective on March 13, 2001.

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SUPPLEMENTARY INFORMATION: The sections contained within this document have been constructed according to the framework outlined in the table of contents that follows. We have summarized pertinent material from our proposed rule followed by public comments and our responses, along with explanations of the provisions of the final rule. Other tools to assist the reader in navigating the document include a crosswalk of reorganized text for § 413.85 and a list of frequently used acronyms.

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Alphabetical List of Acronyms Appearing in the Final Rule

- AMA American Medical Association
 APTA American Physical Therapy Association
 CAHEA Committee on Allied Health Education and Accreditation
 CAAHEP Commission on Accreditation of Allied Health Education Programs
 CRNA Certified Registered Nurse Anesthetist
 EMT-P Emergency Medical Technician and Paramedic Programs
 GME Graduate Medical Education
 HHA Home Health Agency
 MSA Metropolitan Statistical Area
 NAACLS National Accrediting Agency for Clinical Laboratory Sciences
 SNF Skilled Nursing Facility
 OBRA Omnibus Budget Reconciliation Act
 OMB Office of Management and Budget

RFA Regulatory Flexibility Act
 WAIS Wide Area Information Server

I. Background

In 1992, we issued a proposed rule in the **Federal Register** (57 FR 43659) that addressed Medicare payment for costs of approved nursing and allied health education programs, including the requirements imposed by the provisions of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239) and the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).

- Since the inception of Medicare in 1965, we have recognized an obligation to share in the costs of educational activities sponsored by participating providers until the community at large chose to bear them in some other manner. Medicare has historically reimbursed providers for the program's share of costs associated with approved educational activities. The activities may be broken down into three general categories, each with distinct payment policies:

- Approved graduate medical education (GME) programs in medicine, osteopathy, dentistry, and podiatry. Medicare makes direct and indirect GME payment to hospitals for the training of interns and residents. The existing rules for direct GME payment policy are found at 42 CFR 413.86; the rules for indirect GME payment policy are found at 42 CFR 412.105.

- Approved nursing and allied health (paramedical) education programs operated by the provider. (In this document, we use the term "allied health" rather than "paramedical," since Medicare currently allows the costs of approved training programs for medical records librarians, medical technologists, and other disciplines for which the term "allied health" is more appropriate. "Allied health" is the term most commonly used to refer to these health care profession specialties.) Costs for these programs are excluded from inpatient operating cost definitions, payment rate calculations under the prospective payment system, and target amount calculations subject to rate-of-increase ceilings for hospitals and hospital units excluded from the prospective payment system. These costs are separately identified and "passed through" (that is, paid separately on a reasonable cost basis).

- Other educational programs and activities. All other costs that can be categorized as educational programs and activities are considered to be part of normal operating costs and are covered on a per-case basis for hospitals subject to the inpatient prospective payment system, or on a reasonable cost basis

subject to the rate-of-increase limits for hospitals and hospital units excluded from the prospective payment system.

A. Legislative Summary

The following milestones offer a brief historical perspective of the regulations, Congressional actions, court decisions, and manual revisions that have led to our current policy concerning the costs of nursing and allied health education:

- The first regulation to address HCFA's obligation to share in the costs of nursing and allied health education was published in the **Federal Register** on November 22, 1966 (31 FR 14814) at 20 CFR 405.421 (redesignated as 42 CFR 405.421 on September 30, 1977, and further redesignated as 42 CFR 413.85 on September 30, 1986). In that regulation, the net cost of approved educational programs was defined as "the cost of approved educational activities (including stipends of trainees, compensation of teachers, and other costs), less any reimbursement from grants, tuition, and specific donations." The regulation also defined approved educational activities as "formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution" (20 CFR 405.421(b)(1)).

- The types of costs that were allowable as costs of approved educational activities were set forth in both the regulations and the Provider Reimbursement Manual (Chapter 4). Both the regulations and the manual repeated the Congressional Committee Report language from the Social Security Amendments of 1965 (Public Law 89-97) that Medicare would share in the costs of educational activities until communities bore them in some other way (S. Rep. No. 404, 89th Cong., 1st Sess., 36 (1965) and H.R. Rept. No. 213, 89th Cong., 1st Sess., 32 (1965)). In addition, both sources clearly stated that it was not intended that Medicare should pay for increased costs resulting from a redistribution of costs from educational institutions to providers (20 CFR 405.421(c) and section 404.2 of the manual).

- The Social Security Amendments of 1972 (Public Law 92-603) authorized the Secretary to set prospective limits on the costs reimbursed by Medicare. At that time, the costs of approved educational activities were not excluded from costs subject to the limits. Instead, the regulations allowed a provider to apply for an exception to the limits for costs attributable to the operation of an approved medical education program (20 CFR 405.460(f)(2)).

- Section 404.2 of the Provider Reimbursement Manual was revised in November 1975 to specify that in order for costs to be allowable for approved educational activities, an approved nursing or allied health education program had to be operated by a provider.

- Over the next several years, attempts by intermediaries to apply this policy were consistently overruled by the Provider Reimbursement Review Board. These Board decisions were consistently reversed by the Administrator of HCFA. Several of these cases were then litigated in the Federal courts, and in each case that went to a decision on the merits, the courts upheld the Board.

- The most significant of these cases was generally considered to be *St. John's Hickey Memorial Hospital, Inc. v. Califano*, 599 F.2d 803 (7th Cir. 1979). In that case, the U.S. Court of Appeals for the Seventh Circuit sustained the decision of the Provider Reimbursement Review Board that § 405.421(c), as it existed at that time, did not require the provider to be the operator of the associate degree nursing program, but only required the provider to engage in such activity. On October 1, 1979, Medicare policy was amended to correspond with the ruling of the court in the HCFA Administrator's decision on Provider Reimbursement Review Board Decision No. 79-D50.

- A final **Federal Register** notice (44 FR 31806) issued on June 1, 1979, established the schedule of limits on hospital inpatient general routine operating costs, effective for cost reporting periods beginning on or after July 1, 1979. In that notice, the costs of "approved medical education programs" were excluded from the costs subject to the limits.

- The Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) was enacted on September 3, 1982. Section 101 of that law replaced the existing cost limits with an expanded overall limit on hospital inpatient operating costs and a limit on the rate of increase of these costs for cost reporting periods beginning on or after October 1, 1982. Section 1886(a)(2)(A) of the Social Security Act (the Act), as added by section 101 of Public Law 97-248, requires the Secretary to provide for such exemptions from, and exceptions and adjustments to, the hospital cost limits as the Secretary deems appropriate to take into account "medical and paramedical education costs" in implementing these limits.

- HCFA revised Chapter 4 of the Provider Reimbursement Manual in

January 1983 to reflect policy changes resulting from the *St. John's Hickey* decision. Revised § 404.2 specified that provider costs incurred for clinical training associated with an approved program operated by an entity other than a provider could be allowable. Further, it specified that costs incurred by a provider associated with the classroom portion of the program could be allowable if they did not constitute a redistribution of nonprovider costs to the provider, the provider received a benefit for the support furnished, and the cost of the provider's support was less than the cost the provider would incur in operating its own program.

- The Social Security Amendments of 1983 (Public Law 98-21) provided for Medicare payment for the operating costs of hospital inpatient services under a prospective payment system rather than on a reasonable cost basis. Section 601(a)(2) of that law amended section 1886(a)(4) of the Act to specify that costs of approved educational activities were excluded from the definition of inpatient hospital operating costs under the prospective payment system and the target amount for hospitals excluded from that system. Instead, these costs were to be separately identified and "passed through."

- In the September 1, 1983 interim final rule that implemented the prospective payment system (48 FR 39752), § 405.421(d) was amended to provide that costs relating to six types of activities were outside the scope of the pass-through provision. Included among those costs were those related to "other activities which do not involve the actual operation or support (except through tuition or similar payments) of an approved education program." Thus, effective with cost reporting periods beginning on or after October 1, 1983, the costs of only those programs operated directly by the hospital were excluded from the prospective payment system and the target amount for excluded hospitals and paid on a reasonable cost basis.

- The January 3, 1984 prospective payment system final rule (49 FR 234) clarified that only the costs of programs operated directly by providers were excluded from the prospective payment system and eligible for payment on a pass-through basis and that the cost of clinical training for students enrolled in programs operated outside the provider were normal operating costs.

B. The Omnibus Budget Reconciliation Act of 1989

The Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239)

contained three provisions concerning nursing and allied health education. Section 6205(a) created a temporary category of "hospital-based nursing schools." Costs incurred by hospitals for training nursing students in these schools are to be paid on the basis of reasonable cost as though the hospital met the criteria set forth at § 413.85, "Cost of educational activities." This provision was effective for cost reporting periods beginning on or after December 19, 1989, and before the issuance of a final rule as required by section 6205(b)(2) of Public Law 101-239. We implemented this provision in a final rule with comment period published in the **Federal Register** on April 20, 1990 (55 FR 15159) and made further revisions in the final rule that implemented changes to the hospital inpatient prospective payment system for fiscal year 1991, which was published on September 4, 1990 (55 FR 35998).

Under this provision, a hospital may claim as pass-through costs the costs incurred in training students from a nursing school if all of the following criteria are met:

- The hospital incurs at least 50 percent of the net costs, that is, the costs after deduction of tuition revenues incurred for classroom and clinical training provided to students enrolled in an approved nursing education program at the hospital-based nursing school.
- At least 50 percent of the board of directors of either the hospital or the nursing school, whichever board has the fewer members, are also members of the board of the other entity. If application of this criterion requires either board to have more than four common board members, the hospital will meet this criterion by having at least four common board members.
- All instruction is provided at the hospital, or on the immediate grounds.
- The preceding three criteria were met on June 15, 1989, and have been met continuously since that date.

Section 6205(b)(1) of Public Law 101-239 imposed a moratorium for the period on or after December 19, 1989, and before October 1, 1990, on the recoupment of overpayments attributable to a determination by a provider's intermediary that costs claimed by a provider for the operation of a school of nursing or allied health are not eligible for payment on a reasonable cost basis. The basis for this determination is generally that a neighboring or related college or university, not the hospital, is the operator of the program. We announced the provisions of the moratorium in a

program memorandum issued to our fiscal intermediaries (Transmittal No. A-90-9, June 1990).

Section 6205(b)(2) of Public Law 101-239 directed the Secretary to publish regulations clarifying the rules governing which costs of approved educational activities are allowable and when those costs are eligible for pass-through under the prospective payment system, including—

- The relationship required between an approved nursing or allied health education program and a hospital in order for the program's costs to be attributed to the hospital;
- The types of costs related to nursing or allied health education programs that are allowable by Medicare;
- The distinction between costs of approved educational activities as recognized under section 1886(a)(4) of the Act and educational costs treated as operating costs of inpatient hospital services; and
- The treatment of other funding sources for the program.

C. The Omnibus Budget Reconciliation Act of 1990

On November 5, 1990, before the issuance of the proposed regulations required by section 6205(b)(2) of Public Law 101-239, Congress enacted the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). Section 4004(b) of Public Law 101-508 contained several provisions addressing Medicare payment for nursing and allied health education costs on a reasonable cost basis under Medicare Part A. Section 4159(b) of Public Law 101-508 set forth parallel provisions concerning payment on a reasonable cost basis under Medicare Part B for these costs. (The language in section 4159(b) is identical to the language in section 4004(b), except that section 4004(b) applies to Part A and section 4159(b) applies to Part B. For ease of reference in this document, we refer solely to the provisions of section 4004(b); however, each of these references is deemed to be a reference to the corresponding provision of section 4159(b)).

Section 4004(b)(1) provides that, effective with 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) sets forth the following conditions that a hospital must meet to receive payment on a reasonable cost basis under this provision:

- The hospital must have claimed and have been paid for clinical training costs as described in section 4004(b)(1) during its latest cost reporting period that ended on or before October 1, 1989.
- The proportion of the hospital's total allowable costs attributable to the clinical training costs of the approved program and allowable under section 4004(b)(1) during a cost reporting period does not exceed the proportion of total allowable costs that were attributable to the clinical training costs during the hospital's latest cost reporting period that ended on or before October 1, 1989.
- The hospital receives a benefit for the support it furnishes to the education program through the provision of clinical services by nursing and allied health students participating in the program.
- The costs incurred by the hospital for the program do not exceed the costs that would have been incurred by the hospital if it had operated the program.

We published a proposed rule in the **Federal Register** on September 22, 1992, which set forth proposed regulations to satisfy the requirements of section 6205(b)(2) of Public Law 101-239, as well as the provisions of sections 4004(b)(1) and (2) of Public Law 101-508 (57 FR 43659).

In addition to the new payment provision under sections 4004(b)(1) and (b)(2) of Public Law 101-508, section 4004(b)(3) prohibited recoupment of Medicare overpayments made to hospitals for pass-through costs related to approved nursing and allied health education programs for cost reporting periods beginning on or after October 1, 1983 and before October 1, 1990. This section also required us to refund previously recouped overpayments for these costs. We issued a program memorandum (Transmittal No. A-91-3, May 1991) and amended section 404.2 of the Provider Reimbursement Manual (Transmittal No. 368, September 1992) to instruct our fiscal intermediaries on implementing the provisions of section 4004(b)(3) of Public Law 101-508.

II. Provisions of the Proposed Rule and Responses to Public Comments

In accordance with the mandate of section 6205(b)(2) of Public Law 101-239, the September 22, 1992 proposed rule addressed the Medicare rules governing which costs of nursing and allied health educational programs are allowable and when these costs are

eligible for the pass-through payment to a hospital paid under the prospective payment system.

In general, we proposed to continue our existing policies with respect to payment to providers for provider-operated approved nursing and allied health education programs on a reasonable cost basis. That is, we proposed to retain the provisions in existing regulations under § 413.85 that Medicare payments be determined on a reasonable cost basis for a provider's net costs of approved nursing and allied health educational programs and proposed the conditions under which we would make these payments. We proposed to amend § 413.85 to explicitly set forth criteria that define approved nursing and allied health educational programs considered provider-operated, and rules for determining the net costs of provider-operated nursing and allied health educational programs. We also proposed to allow reasonable cost payment for the clinical training costs of certain nonprovider-operated programs to comply with the requirements of section 4004(b) of Public Law 101-508, and addressed the conditions for payment for the net costs of approved certified registered nurse anesthetist (CRNA) educational programs. Finally, we proposed to clarify our policy on the nursing and allied health educational activities we consider as normal operating costs.

We received 31 timely items of correspondence from the public and other interested parties in response to the proposed rule. The specific comments and our responses are set forth below following each section describing the specific provisions of the proposed rule.

A. Determining Provider-Operated Programs

We proposed to revise § 413.85 ("Cost of educational activities.") to clarify our policies on paying providers for the costs incurred for nursing and allied health education activities. We proposed to retain the general rule specified under existing § 413.85 that payment for a provider's net cost of approved educational activities is made on a reasonable cost basis. We also proposed to set forth at § 413.85(e) criteria we would use to identify programs operated by a provider. The proposed regulations reflected that, except as provided in section 4004(b) of Public Law 101-508, the key factor to be considered in determining whether the classroom instruction and clinical training costs of approved nursing and allied health educational programs are

eligible to be passed through is the degree to which the provider controls all aspects of the program. For example, we proposed that if a clear separation of function exists, such as when a college or university directs and operates the classroom portion of the program and the provider furnishes only the setting for clinical training, then the educational program costs would not be eligible to be paid on a pass-through basis. In these cases, clinical training would flow from the part of the program conducted by the institution other than the provider. Thus, the majority of the training costs would be borne by the college or university and not by the provider. While the provider may incur some costs associated with its provision of clinical training to students enrolled in a nearby institution, the provider would also gain in return. For example, it would obtain the services of the trainee, often at no direct cost to itself.

In addition to the value of the services of students in an approved program, providers would receive a number of other benefits from participation in a nursing and allied health educational program operated by another entity. One benefit is the fact that a significant percentage of the graduates of these programs become employees of the provider at which they trained. This would allow the provider to avoid costs it would otherwise have to incur for recruitment.

We proposed that, for purposes of determining the operator of an approved nursing or allied health education program, the fact that a provider and a college or university are considered related organizations under § 413.17 ("Cost to related organizations.") would *not* be sufficient to allow a university-operated program to be considered provider operated. As we explain in section II.C. of this preamble, our policy concerning related organizations was established to avoid program recognition of costs of a provider for goods or services furnished by a related organization in excess of the costs incurred by the related organization.

We proposed that all of the following criteria must be met to be considered the operator of a nursing or allied health education program:

- The provider must incur the costs associated with both the clinical training and classroom instruction portions of the programs, where the classroom instruction is a requirement for completion of the program. For example, the provider must incur the costs for books, supplies, and faculty salaries, where such costs are applicable.

- The provider must directly control the program curriculum, that is, the provider must determine the requirements to be met for graduation. In meeting this requirement, a provider may enter into an agreement with a college or university to provide the basic academic course requirements leading to a degree, diploma, or other certificate, while the provider is directly responsible for providing the courses relating to the theory and practice of the nursing or allied health profession that are required for the degree, diploma, or certificate awarded at completion of the program.

- The provider must control the administrative duties relating to the program. These duties include the collection of tuition (where applicable), maintaining payroll records of the teaching staff or students, or both (where applicable), and being responsible for the day-to-day operation of the entire training program.

- The provider must employ the faculty.

- The provider must provide and control both classroom instruction and clinical training, (where the classroom instruction is a requirement for the completion of the program), subject to the provision in the second criterion of provider-operated programs above that a provider may enter into an agreement with a college or university to provide the basic academic course requirements leading to a degree, diploma, or other certificate, while the provider is directly responsible for providing the courses relating to the theory and practice of the nursing or allied health profession that are required for the degree, diploma, or certificate awarded at completion of the program.

We note that proposed § 413.85(e)(2) (§ 413.85(f)(2) in this final rule) reflected a special rule that a provider that is licensed or accredited to (1) operate the program and (2) issue degrees, diplomas, or certificates to its students upon graduation is assumed, absent evidence to the contrary, to meet the criteria listed above and to be the operator of the program.

In certain situations, providers are entering into arrangements with colleges and universities that, in many cases, have involved provider representation on a joint committee with certain oversight responsibilities. Under these provider/college educational arrangements the provider might not have direct responsibility for the curriculum and control of day-to-day operation of the training programs. We proposed that unless the provider can demonstrate that it meets the requirements enumerated above, the

costs incurred by the provider in connection with such joint programs would not be paid as separate pass-through costs.

There are other situations, however, that involve sequential operation of a program by an educational institution and a provider. These situations frequently involve providers that are changing from offering a certificate or diploma program to offering an associate or baccalaureate degree. The provider may create a program leading to a degree in which instruction in general academic requirements is provided by a college or university and subsequent specialized classroom instruction and clinical training are given by the provider. We proposed that if the provider establishes and controls the curriculum and requirements for graduation, the provider would be considered to be the operator of the program for purposes of receiving pass-through payment under § 413.85. However, no costs incurred by the college may be claimed as provider costs.

As stated above, we proposed that a provider must provide and control both clinical training and classroom instruction in order to meet the criteria of provider-operated under proposed § 413.85(e). Since publication of the proposed rule, it has come to our attention that some nursing and allied health education specialties do not have classroom instruction components. We are therefore clarifying in this final rule that, in such instances, the provider must only provide and control the clinical training, subject to the other conditions specified in redesignated § 413.85(d)(1). Thus, the language at § 413.85(f)(1) of this final rule accounts for situations where the nursing and allied health program does not have a classroom instruction as part of the program. For example, at § 413.85(f)(1)(v), instead of indicating that the provider is required to provide both clinical training and classroom instruction as we had specified in the proposed rule, we now state that the provider must "provide and control both classroom instruction and clinical training (where the classroom instruction is a requirement for the completion of the program)." Where the nursing and allied health program has a classroom instruction component in addition to a clinical training component, the provider must provide and control both components in order to receive pass-through payment. In addition, as discussed below, we note that we are further clarifying in this final rule proposed § 413.85(e)(1)(v) in order to address a public comment on

sequentially operated nursing and allied health education programs by specifying at § 413.85(f)(1)(v) of this final rule that this paragraph is subject to the parenthetical sentence in the second criterion of the provider-operated criteria (§ 413.85(f)(1)(ii) of this final rule) which states that a provider may enter into an agreement with a college or university to provide the basic academic course requirements leading to a degree, diploma, or other certificate, while the provider is directly responsible for providing all of the courses relating to the theory and practice of the nursing or allied health profession that are required for the degree, diploma, or certificate awarded at completion of the program.

In proposed § 413.85(c)(3) and (4), we proposed separate specific definitions of clinical training and classroom instruction costs to allow providers and intermediaries to differentiate between clinical training and classroom instruction. These definitions (as modified slightly for purely editorial changes in this final rule) are as follows:

- *Clinical training costs* involves costs associated with the acquisition and use of the skills of a nursing or allied health profession or trade in the actual environment in which these skills will be used by the student upon graduation. While clinical training may involve occasional or periodic meetings to discuss or analyze cases, critique performance, or discuss specific skills or techniques, it involves no classroom instruction.

- *Classroom instruction costs* are costs associated with the formal, didactic instruction on a specific topic or subject provided in a class that meets at regular, scheduled intervals over a specific time period (for example, semester or quarter) and for which a student receives a grade.

We received many comments on our proposed criteria for provider-operated programs. The majority of the commenters believed the criteria are too restrictive and would result in the exclusion of many nursing and allied health education programs from receiving pass-through payment.

Comment: The majority of those who commented on this provision were concerned that the criteria do not appear to allow reasonable cost payment to programs operated by both a provider and an educational institution. These arrangements, which have become common as the industry moves away from provider-operated education programs to those based at colleges and universities, would not meet the proposed criteria. The commenters indicated that providers have often been

forced to create these arrangements because accrediting agencies would not approve programs operated solely under the control of the provider. They believed that, in some cases, HCFA has been providing payment under the pass-through for these programs based at educational institutions under the theory that the provider controls and wholly owns the subsidiary college. In other cases, hospitals have entered into joint programs with already established educational institutions. The commenters requested that the final rule clearly delineate which of these programs would be considered to be operated by the provider and, thus, eligible for the pass-through, and which would not be eligible.

One commenter stated that, although the proposed rule is intended to be a codification in regulations of current policy, we did not include a current list of hospital-based nursing programs that meet the criteria set forth in section 6205(b)(2) of Public Law 101-239. The commenter believed that, to be consistent, the final regulations need to provide that these programs meet the definition of provider-operated.

Response: Except as provided in OBRA 1990, we do not make pass-through payments to a hospital for the costs of a nursing and allied health education program not operated by a hospital because the costs are considered normal operating costs and the hospital receives payment for those costs through the inpatient prospective payment system payments. We believe that, in the case of programs that are not operated by a hospital, the majority of the training costs of the program are incurred by an entity (the college or university) other than the hospital; to the extent that a hospital incurs costs for a nonprovider-operated program, the inpatient PPS payment encompasses payment for those costs.

In addition, as indicated in the proposed rule, the hospital benefits in a number of ways from its participating in a nonprovider-operated educational program: the hospital obtains services of the trainee during the training; the hospital might receive payments from the college or university for the costs incurred by the hospital; and the hospital might save staffing costs, as well as recruiting costs (many of the trainees ultimately become employees of the hospital). Furthermore, the distinction between provider-operated programs and nonprovider-operated programs is consistent with the provisions of OBRA 1989 and OBRA 1990.

In the case where a hospital enters into a joint program with an educational

institution, the distinction between provider-operated and nonprovider-operated programs also reflects the community support principle, because the program has moved away from the provider-operated mode and into the community assumption of costs. The House and Senate Committee reports accompanying Public Law 89-97 reflect that Congress contemplated that Medicare would share the costs of educational activities *until* the community assumed the costs. If the university undertakes the classroom education of the students, including the collection of the tuition, the employment of the faculty, the control of the curriculum, and the awarding of the degree, the community has undertaken the responsibility for training nurses and allied health personnel and relieved the hospital of this cost. Again, to the extent that the hospital incurs costs for the nonprovider-operated program, the hospital receives payment for these costs through the inpatient PPS payments.

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 training portions of the program, the costs would continue to be paid on a reasonable cost basis. An independent college would not meet these criteria.

An example of a program that could be considered provider-operated would be one in which the hospital is the sole corporate member of the college, elects the board of trustees, has board members in common, employs the faculty and pays the salaries, controls the administration of the program and the curriculum, and provides the site for the clinical and classroom training on the premises of the hospital. We believe that, in these situations, the community has not undertaken to finance the training of health professionals; the provider has merely restructured its provider-operated program to meet certain State or accrediting requirements. In most cases, providers have aligned themselves with already established educational institutions. We note that a program operated by an educational institution that is related to the provider through common ownership or control would not be

considered to meet the criteria for provider operated.

In response to the commenter who was concerned that the proposed regulations did not incorporate those programs receiving reasonable cost payment under the provisions of section 6205(a)(1) of Public Law 101-239, we note that Congress clearly recognized this provision to be temporary. The provision is to expire 30 days after publication of the final rule required by section 6205(b)(2), that is, this final rule.

Comment: One commenter stated that HCFA should not treat provider-operated and nonprovider-operated programs differently. Providers that are providing support to another institution by providing clinical training are incurring costs and these costs should be eligible to be paid under the pass-through payment. The commenter believed that it is highly unlikely that a university would allow a hospital to have sole control of the curriculum or graduation requirements or to employ the faculty. Thus, it would be impossible for these programs to meet the provider-operated criteria. However, HCFA should allow the clinical training costs in all situations.

Response: Please see our response to the previous comment. The proposed criteria set forth in § 413.85(e) (§ 413.85(f)(1) in the final rule) are those to be used in identifying those nursing and allied health programs operated by providers. The commenter appears to be describing programs that are operated by educational institutions for which a provider offers support in clinical training. As discussed in detail above, we believe that Congress intended to support nursing and allied health education programs operated by hospitals only until the community undertakes the costs of the programs itself. Nursing and allied health education programs operated by colleges and universities are considered to be programs in which the costs are borne by the community, since much of the costs of operating the programs are incurred by the colleges and universities. Therefore, we believe it is contrary to Congressional intent for Medicare to provide pass-through payments to providers, in addition to inpatient PPS payments, for the costs of non-provider operated programs (that do not meet the criteria under OBRA 1990).

Comment: One commenter described a CRNA program in which the hospital is allowed to grant a certificate to a student upon completion of the program. This may occur when an affiliated university also grants a degree to the same student. According to the

commenter, the Council on Accreditation of Nurse Anesthetist Programs does not prohibit the awarding of an "anesthesia certificate" in addition to the award of the master's degree for a hospital-based program. The commenter believed that this could be interpreted as the hospital meeting the criteria to be the operator of the program since the hospital awards a certificate, and requested that we clarify this in the final rule.

Response: The program described above where the hospital awards a certificate and an affiliated university confers a degree upon the same student appears to be a university-controlled nursing or allied health program. The certificate awarded by the hospital seems to be an adjunct to the actual degree awarded by the educational institution. In fact, as indicated by the commenter, the certificate is awarded "in addition" to the master's degree awarded by the university. This indicates the program is under the control of the university and the hospital has merely provided support to that program. We note, however, that if the hospital described by the commenter can show that it, in fact, meets the criteria of § 413.85(e) (§ 413.85(f) in this final rule) of operating the program, it may receive pass-through payment.

Comment: One commenter requested that we include the language concerning sequentially conducted education programs in the regulation text. Also, the commenter believed that we need to expand on this discussion. For example, the commenter asked whether a program would be considered provider-operated if a hospital employs only the faculty for the clinical portion of the program.

Response: As noted above, and also in the preamble to the proposed rule, sequential operation of a nursing and allied health education program involves providers that enter into agreements with a college or university in which instruction in general academic requirements leading to a degree is provided by the educational institution, and subsequent specialized didactic and clinical training is given by the provider. The provider may receive pass-through payment for the costs of the program that the provider incurs if the provider meets all of the criteria for operating the program, including the requirement at proposed § 413.85(e)(1)(ii) (§ 413.85(f)(1)(ii) of this final rule) that the provider must directly control the curriculum. We note that under this section of the regulations, there is a provision (also cited at § 413.85(f)(1)(v) of this final

rule) which states that 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 related 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. No costs incurred by the college or university may be claimed as provider costs.

In regard to the commenter's question about employment of the teaching faculty, providers that employ faculty only for the clinical training portion of the program, where there is a classroom component relating to the theory and practice of the nursing and allied health profession involved, would not be considered as a provider operating the program.

Comment: One commenter argued that, through these regulations, the Federal Government is encouraging the provision of nursing and allied health education through provider-operated programs, which is contrary to the movement of these training programs to academic settings. The commenter believed that Medicare costs would be reduced if hospitals provided only clinical training and allowed educational institutions to provide the classroom instruction. Another commenter stated that very few nurses currently graduate from provider-operated programs and that the proposed regulations do not reflect the current state of nursing and allied health education. Rather than erect barriers to receiving funding, the rules should be revised to allow hospitals to claim clinical training costs as a pass-through regardless of operation. Finally, one commenter stated that the clinical training for all programs should be eligible for the pass-through without a corresponding reduction in the prospective payment system standardized amounts.

Response: Our payment policies are designed to make appropriate payments for provider-operated programs and nonprovider-operated programs, not to encourage one type of program over another. We recognize the impact of the current policy of paying on a pass-through basis only for provider-operated nursing and allied health programs (except the narrowly defined nonprovider-operated programs specified at § 413.85(g) of this final rule) when there is a movement of these training programs towards academic settings. We accept the comments that Medicare will provide pass-through

payment to hospitals for the classroom and clinical costs of programs only when the programs are provider-operated, while nursing education has been increasingly occurring in baccalaureate and advanced-level nurse training programs in colleges and universities. However, as explained above, we believe hospitals should only receive pass-through Medicare payments for training students in *provider-operated* programs. We note Congress' implicit acceptance of our longstanding provider-operated policy via its enactment of a narrow exception to the provider-operated policy as set forth by section 4004(b)(2) of Public Law 101-508 of the nonprovider-operated nursing and allied health education programs.

The commenters encouraged HCFA to allow for pass-through payments for the clinical portion of all nursing and allied health education programs, even all of those programs that are nonprovider-operated programs in addition to those that meet the criteria under section 4004(b) of Public Law 101-508. However, under the current inpatient hospital prospective payment system, costs incurred by hospitals for clinical training in nonprovider-operated programs are paid within the prospective payment system per discharge payments. If a legislative change provided for pass-through payment for a hospital's clinical training in all nonprovider-operated programs, we believe an adjustment would be necessary to carve out those costs from the Federal rate.

Comment: Two commenters were concerned that no hospitals control their own curriculum and, therefore, no hospitals could meet the criterion set forth in the proposed regulations. One commenter stated that the accrediting agencies dictate which courses a student must complete in order to obtain a degree or certificate. Another commenter stated that, in today's educational programs, the curriculum is determined by the institution of higher learning.

Response: We understand that a teaching hospital must provide certain required courses and training in order to be accredited. This does not mean that these requirements prohibit a provider from directly controlling the curriculum. Although many courses are required by the accrediting agencies, there are other courses generally provided by the providers. Also, the provider determines in what manner its students will accomplish the course work that will allow them to be accredited. In addition, control of the curriculum also means the provider

actually provides all the courses or arranges for an outside organization to provide those academic courses necessary to complete the course work.

Comment: One commenter believed that the definitions of "clinical training costs" and "classroom costs" are too inflexible and do not account for the classroom time needed to review and discuss clinical assignments and engage in group learning. Classroom activity related to clinical experience should not be separated from clinical training.

Response: We believe that the definitions of classroom instruction and clinical training costs are necessary so that they can be differentiated in relation to the payment policies that apply to them. For example, hospitals that operate nursing or allied health education programs would be eligible to receive pass-through payment for both the clinical training and classroom instruction costs of the program. However, under OBRA 1990, certain nonprovider-operated programs are eligible to receive pass-through payment for only the clinical training costs of the programs. Clinical training does encompass some occasional or periodic meetings that relate to the acquisition of clinical training skills. However, these meetings are not formal, didactic classroom instruction. Classroom instruction consists of classes that meet at regularly scheduled intervals over a specific period of time and the students' participation is graded by the instructor. Costs incurred in meetings or discussions held between students' and clinical trainers are covered costs to the extent they meet the definition of incremental costs incurred because of the provider's participation in the clinical training program.

B. Nursing and Allied Health Education Specialties and Accrediting Bodies

Under existing regulations, one condition that must be met in order for a provider to receive reasonable cost payment for the net costs of its nursing or allied health educational program is that the program must be recognized by a national approving body or State licensing organization. A nursing and allied health education program that wanted to be paid on a reasonable cost basis, in addition to being a provider-operated program, either needed to be included on the list of approved programs under existing § 413.85(e) or needed to qualify to be an approved program under existing § 413.85(f). Recently, it has come to our attention that the list of approved programs contained in existing § 413.85(e) is inaccurate to the extent some of the names of the specialties, as well as their

respective accrediting bodies, have changed. In addition, some specialties listed at existing § 413.85(e), while previously meeting the criteria of programs that are provider operated, may no longer meet these criteria. Because we find that nursing and allied health education is a constantly evolving field, we are clarifying our policy on approved nursing and allied health education programs by removing the current specific list of approved nursing and allied health programs and, instead, framing the issue in general terms by considering a nursing or allied health education program eligible for pass-through payment if the program is recognized by a national approving body or State licensing authority and it meets the other criteria under § 413.85(d) of this final rule. By requiring the nursing and allied health education activity to be recognized by either of these bodies, we ensure that the programs we pay for under Medicare meet at least a minimum standard of accreditation.

We note that this requirement that the nursing and allied health program be accredited by one of these approving bodies is simply *one* of the requirements under the general payment rule under § 413.85(d) of this final rule for a provider to receive reasonable cost payment for the net cost of nursing and allied health education activities. That is, accreditation by a national approving body or State licensing organization for a particular nursing and allied health education activity does not mean that the activity qualifies for pass-through payments; in order to qualify for pass-through payments, the provider must meet the other general payment rule requirements (including the provider-operated criteria). In addition to requiring the program to be recognized by a national approving body or State licensing authority, we also give examples under § 413.85(f) of this final rule of national nursing and allied health approving bodies. The examples we list are: the Commission on Accreditation of Allied Health Education Programs; the National League of Nursing Accrediting Commission; the Association for Clinical Pastoral Education, Inc.; and the American Dietetic Association. In addition, our research has shown that there are currently other national approving bodies of nursing and allied health programs that also meet at least a minimum standard of accreditation. They are: the American Society of Hospital Pharmacists; the National Accrediting Agency for Clinical Laboratory Sciences; the Council on

Accreditation of Nurse Anesthesia Educational Programs; the American College of Nurse-Midwives; the Joint Review Committee for Education of Radiologic Technology; the Joint Review Committee on Nuclear Technology; and the American Physical Therapy Association.

In the September 1992 proposed rule, we proposed to update the listing of approved nursing and allied health programs. We solicited and received many comments about additions and deletions to the list. Because in this final rule we are deleting the specific list of programs and replacing it with a general requirement that the program must be recognized by a national or State licensing approving body, our responses to the comments on the specialties note whether or not we consider the specialty as an approved nursing and allied program, and do not address whether we should add the specialty to or delete the specialty from a list of approved programs.

We also proposed that only those nursing and allied health education programs listed in the regulations may be paid as approved educational activities. We proposed to add a redesignated provision to the regulations (proposed § 413.85(d)) that would provide for other national approving bodies or State licensing authorities to apply to HCFA for inclusion on our list of approved programs. Because we are clarifying our policy in § 413.85(e) of this final rule by eliminating the list of accrediting organizations from our regulations, this proposed provision is no longer necessary. In addition, we proposed to revise the list of approved programs to include the specific title or titles used by the appropriate accrediting organization. The Committee on Allied Health Education and Accreditation (CAHEA), now called the Commission on Accreditation of Allied Health Education Programs (CAAHEP), cooperates with many committees and collaborates with academies, associations, boards, and societies in its accreditation process. In the interest of brevity, and for the convenience of those entities seeking approval for those programs accredited by CAAHEP in collaboration with other organizations, we listed only CAAHEP in the proposed regulations.

Some of the programs that had been previously accredited by CAAHEP are now accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), the Joint Review Committee for Education of Nuclear Medicine Technology, the Joint Review Committee for Education

of Radiologic Technology, and the American Occupational Therapy Association. For the convenience of those programs seeking accreditation, we also note that the name of the accrediting organization, the Commission on Accreditation in Physical Therapy Education (CAPTE), has been changed by the organization to the American Physical Therapy Association (APTA). Lastly, we will acknowledge the American College of Nurse Midwives as a national approving body, for reasons that are explained below.

Comment: We received several comments requesting that we expand our list of approved programs to include nonprovider-operated programs that do not qualify for pass-through payment.

Response: As stated above, we are clarifying our policy of not paying on a pass-through basis for nonprovider-operated programs in this final rule and, to avoid confusion as to which programs are currently being paid for, we have eliminated the specific listing and replaced it with a general requirement for accreditation or State licensure.

Comment: One commenter asserted that the proposed rule clearly allows nonprovider-operated programs to receive payment under the OBRA 1990 pass-through; therefore, restricting the list to programs operated by providers is inconsistent. Another commenter believed that this requirement unnecessarily restricts new programs at nonprovider sites.

Response: As noted above, we have eliminated the specific listing and replaced it with a general requirement for accreditation or State licensure; therefore, comments regarding additions to or the nature of the approved list of programs are no longer relevant. However, as reflected in 42 CFR 413.85(g) of this final rule, any nonprovider-operated programs that meet the requirements under OBRA 1990 and also meet accreditation requirements, may be eligible to receive pass-through payments.

Comment: One commenter stated that the Higher Education Act Amendments of 1992 (Public Law 102-235) require that the American Medical Association (AMA) separate itself from the CAHEA. As a result, that organization may cease to exist. The final regulations should provide for the successor organization. Another commenter stated that since the AMA may withdraw support from the CAHEA, the regulations should list the actual accrediting agencies.

Response: In late October 1992, the AMA announced that the CAHEA would be phased out at the close of 1994 and that it would support the

establishment of a successor agency. By May 1994, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) was established to assume the accreditation programs previously associated with CAHEA. This final rule reflects this change; we list CAAHEP as an example of a national approving body under § 413.85(e). Since an actual successor agency has been established, we do not believe that it is necessary to list the individual agencies that cooperate with this new organization.

Comment: The American College of Nurse-Midwives and the American Academy of Physicians Assistants formally requested that their allied health education programs be included in our list of approved programs.

Response: These comments are no longer applicable because we are clarifying our policy in this final rule by stating a general requirement rather than including a specific listing.

Comment: We received several comments protesting our proposal to exclude emergency medical technician and paramedic programs (EMT-P) from the list of approved education programs. These commenters disagree with our conclusion that there is a tenuous relationship between the care provided by these individuals and the quality of patient care in a hospital. All of the commenters urged that we pay for these programs because the care and services provided by these personnel prior to admission are often vital in determining the patient's condition and prognosis and, thus, there is an essential link between these personnel and inpatient care. One commenter believed that the preadmission services provided by paramedics are crucial to patient outcomes through early intervention and delivery to the appropriate hospital. Another commenter stated that the care provided en route to the hospital has a direct result on the condition of the patient's condition when admitted, which has an impact on the amount and intensity of inpatient services required. Also, hospital emergency room care is a coordinated effort. The emergency medical technicians and paramedics are in communication with and often receive direction from the emergency room physician while en route to the hospital. Several commenters indicated that emergency medical technicians and paramedics often provide services in the emergency room and are used elsewhere in the hospital in areas such as the operating room, the intensive care units, and labor and delivery. Therefore, they do contribute to patient care. Finally, one commenter stated that, since HCFA provides payment for EMT-P under the

existing regulations, excluding them from the list as proposed is contrary to the statement in the proposed rule that HCFA is merely codifying existing policy into regulations.

Response: As we indicated earlier, we are deleting the listing of approved programs in the final regulations. However, after consideration of these comments and other information we have learned about EMT-P education programs since publication of the proposed rule, we are persuaded that there is a sufficient relationship between the services of EMT-P education programs and the quality of inpatient care. As the commenters indicated, EMT-P trainees provide essential preadmission services to (potential) hospital inpatients, and the trainees work in several inpatient care areas of the hospital. We note that there may be some EMT-P education programs that might meet the provider-operated criteria and thus would qualify for pass-through payment under the nursing and allied health education provider-operated provisions. We also note that the accrediting organization is the Joint Review Committee on Educational Programs for the EMT-Paramedic in collaboration with the CAAHEP.

Comment: One commenter disagreed with our inclusion of clinical pastoral counseling in the list of approved programs. The commenter believed that this policy violates the separation of church and state. In addition, the commenter asserted that such a major use of the Medicare Trust Fund should occur only after notice and public comment as provided in the Administrative Procedure Act. Finally, the commenter did not believe that pastoral counseling qualifies as direct patient care since these services are not medical services and Medicare does not pay directly for the care provided by pastoral counselors.

Response: The existing regulations at § 413.85(e) list several approved nursing and allied health education programs that are eligible for the pass-through payment. Paragraph (f) of that section states that the fiscal intermediary and HCFA will give appropriate consideration to programs not listed in paragraph (e) that a provider conducts that come within the purview of the principle of the regulations. Thus, the regulation in effect when these programs were approved was subject to appropriate notice and public comment. Over the years, we have approved many types of allied health education programs under the authority of this section.

Although there is no direct payment by Medicare for the services of pastoral counselors, the services they provide to hospital inpatients are included in the hospital's allowable costs under the Medicare program. The costs are included in the administrative and general (A&G) cost center. As early as the mid-1970s, Medicare recognized pastoral care as having a beneficial and therapeutic effect on the medical condition of a patient, and, therefore, the costs a provider incurs to furnish such care to its patients are considered patient care related costs. Therefore, we do not agree with the commenter that these programs should be excluded from receiving education payments.

Comment: We received requests from several commenters to expand our list of approved programs. These programs include: nurse practitioners, nurse-midwives, clinical nurse specialists, physician assistants, phlebotomists, central supply technicians, social workers, and biomedical engineering.

Response: In the proposed regulations, we stated that national approving bodies or State licensing authorities may apply to HCFA for inclusion in the list of approved programs. As discussed above, we are no longer including a list of approved programs in our regulations. We note, however, that hospitals with programs approved by national approving bodies or State licensing organizations may submit a request to receive Medicare payments on a reasonable cost basis, and the fiscal intermediary will determine whether the program meets the definition as an approved program.

Comment: One commenter requested that we add the phrase "operated by providers" to proposed § 413.85(d) (§ 413.85(e) in this final rule) to make it clear that we will approve programs only if they are the type operated by providers.

Response: This comment is no longer applicable since we are clarifying our policy under § 413.85(e) in this final rule to provide that a program must be approved by the appropriate accrediting body in order to receive Medicare payment for nursing and allied health education activities on a reasonable cost basis. We note that it is no longer necessary to address the issue of other programs not listed in the regulation (which was previously addressed by proposed § 413.85(d)) because we are now stating that all programs must be recognized, or continue to be recognized by the appropriate accrediting body, in addition to meeting the other general payment requirements listed under § 413.85(d) of this final rule in order to

receive Medicare payment on a reasonable cost basis.

C. Determination of Net Costs

We proposed to revise our policy for determining the net costs of approved nursing and allied health education programs in proposed § 413.85(c)(1) (§ 413.85(d)(2) of this final rule). The formula for determining the net costs at existing § 413.85(g) states that "Net costs of approved educational activities are determined by deducting, from a provider's total costs of these activities, revenues it receives from tuition."

When the existing regulation was drafted, we assumed that the tuition paid by students enrolled in approved nursing and allied health educational programs was intended to cover all facilities and services for which a provider would incur costs. It was not our intention to imply that costs for which a provider charges a separate fee, in addition to tuition, were not to be considered as part of the cost of the approved nursing and allied health educational activity. Two examples of these costs are the purchase of textbooks for resale to students and the provision of housing or room and board in exchange for an additional fee.

We clarified in the proposed regulations that the term "tuition" includes these additional charges and fees and specified a proposed formula for determining the net costs to indicate that "total costs" includes only direct and indirect costs incurred by a provider that are directly attributable to the operation of an approved educational activity. These costs do not include usual patient care costs that would be incurred in the absence of the educational activity, such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses. Moreover, these costs do not include costs incurred by a related organization.

The existing regulation concerning related organizations set forth at § 413.17 was established to avoid program recognition of artificially inflated costs that might be generated from less than arm's length transaction. This policy was not intended to expand the range of items and services for which a provider could claim payment. With respect to educational costs (with the limited exception for certain graduate medical education costs incurred by a related medical school as provided in Intermediary Letter 78-7) our policy has been that the provider, rather than the related organization, must directly incur the costs on its books and records before the costs will be recognized for Medicare payment

purposes. Otherwise, the principle that Medicare payment for medical education costs should not result in a redistribution of costs from the educational institution to the provider would be violated.

Whereas providers that operate their own programs may receive reasonable cost reimbursement for both the classroom instruction and the clinical training costs, but no reimbursement for costs incurred by a related educational institution, providers that would qualify under section 4004(b) of Public Law 101-508 may receive reasonable cost reimbursement for the clinical training costs only, and for the clinical training costs incurred by a related educational institution. We believe that the language included in the Committee Report that accompanied Public Law 101-508 supports this distinction between total allowable costs for provider-operated and nonprovider-operated programs. In that report, the conferees noted that—

"in the case of hospital-operated nursing and allied health education programs, the Secretary does not recognize costs incurred by a related educational organization as allowable educational costs since such costs are a redistribution of costs from the educational institution to the hospital. Although [section 4004 of Public Law 101-508] provides for recognition of the costs incurred by a related educational organization for clinical training on the hospital's premises in the case of a hospital-supported program, the conferees intend that nothing in [section 4004 of Public Law 101-508] should be construed as requiring the Secretary to modify his current policy in regard to the determination of reasonable costs for a hospital-operated program" (H.R. Rept. No. 964, 101st Cong., 2d Sess. 719 (1990)).

We note that this clear statement of Congressional intent is also consistent with our policy on provider-operated programs stated above of not recognizing the costs of related organizations in determining a provider's total costs of approved educational programs.

In the January 3, 1984 final rule, the definition of net costs (proposed § 413.85(g)) was revised by eliminating grants and donations from revenues that were to be offset against the cost of approved educational activities. This revision was made in response to a public comment to ensure that the policy on net costs of educational activity would be consistent with the policy that deals with the treatment of grants, gifts, and income from endowments under reasonable cost payment under § 413.5(c)(3). However, in the proposed rule, we stated that we were reconsidering our position on this issue. As a result, we requested public

comment on whether the net costs of approved educational activities should be defined as the costs determined by deducting the revenues that a provider receives from tuition, student fees, and the allocable amounts from any donations and grants from the provider's total allowable costs that are directly related to approved educational activities.

Also, in our discussion in the preamble of the September 1992 proposed rule relating to what types of revenues a provider receives that should be deducted from the provider's total allowable costs to determine the net cost of approved educational activities, we inadvertently included "non-Medicare public funding". This inclusion erroneously implied that Medicare's policy has been to consider State appropriations as grants or donations that are not offset from a provider's allowable costs. Our response to a comment in a final regulation concerning Medicare GME policy, published on September 22, 1989 (54 FR 40302), also had been mistakenly interpreted as including State appropriations in the definition of grants. In the response to a comment about whether there is a redistribution of GME costs when State appropriations or other funding sources are sufficient to cover the cost of operating, we explained our policy and section 1134 of the Act as it relates to offsets from allowable costs of gifts, grants, and donations. Our response was intended to describe private philanthropy and other grants but not to include State appropriations in the definition of grants. In administrative, legal, and policy matters, we have consistently maintained that State appropriations for the cost of medical education activities constitute community support that is to be offset from a provider's allowable costs.

We note that several courts have upheld Medicare's policy of including State appropriations in the definition of community support. On May 3, 1991, the U.S. District Court for the Southern District of Mississippi ruled that the Secretary's offset of nursing and allied health costs of State appropriations was appropriate. Additionally, the U.S. District Court for the Eastern District of Pennsylvania in *Thomas Jefferson University* (993 F.2d. 879 (1993)) in a decision affirmed by a U.S. Appeals Court stated that the Secretary's definition of community support, which includes "State-funded support," is reasonable. This decision was upheld by the U.S. Supreme Court on the redistribution principle discussed

elsewhere in this preamble (114 S. Ct. 2381 (1994)).

We note that the proposed revisions in the proposed rule inadvertently did not include community support as the basis for an offset from the allowed cost of a GME or nursing and allied health program. In this final rule, we restate our longstanding policy that Medicare will only share in the costs of educational activities of providers where communities have not assumed responsibility for financing these programs. Medicare's policy is to offset from otherwise allowable education costs, community funding for these activities.

Comment: We received all unfavorable comments on our reconsideration of existing policy that excludes grants and donations from the revenues that are used to offset the cost of approved educational activities. One commenter stated that it seeks outside support in the form of grants for the purpose of recruiting students. The commenter indicated that these monies, which are used to help alleviate current shortages of trained professionals, should not be deducted in determining net costs. Another commenter stated that we did not provide any rationale for changing our policy on grants and donations. An additional commenter believed that if we adopted the revised policy, only those grants and donations that are specifically restricted to supporting education programs should be deducted.

Response: We are persuaded by the commenters that, in this time of shrinking revenues, hospitals should not be discouraged from seeking additional support through grants and donations. Therefore, we are not adopting the proposed revision in this final rule. We will retain the existing policy.

Comment: One commenter requested that student fees that are used to cover costs that are not included in Medicare allowable costs should not be deducted from a provider's total costs. Another commenter believed that since the revenues a provider obtains for housing costs and textbook purchase for resale are not used to offset clinical instruction costs, they should not be included in the definition of tuition and used to offset total costs.

Response: We believe that the total amount of payments made to a provider on behalf of a student it is training should be deducted from the allowable costs the provider is claiming. If the provider operates the program, it is claiming the cost of student stipends, student housing, and the purchase of books and materials for student use. If

the provider receives revenues in exchange for the provision of these services, those revenues should be deducted from total costs, regardless of the name given to the fee. If the provider collects a fee from students that does not involve any allowable cost, such as monies used for recreational activities for which the provider does not seek Medicare payment, these revenues need not be deducted. However, any general fund for student activities would probably be required to be deducted. A provider that does not operate the nursing or allied health education program and is claiming only clinical costs would not be including housing fees in that cost. Any housing fees should be the responsibility of the educational institution.

Comment: One commenter disagreed with the proposed policy that providers that do not operate their own education programs but receive reasonable cost payments under the provisions of section 4004(b) of Public Law 101-508 may include costs of the educational institution related to the provider. These costs are excluded from the total costs of a provider that operates its own programs. The commenter believed that it is unfair to make this distinction.

Response: As we explained in the proposed rule (57 FR 43668), when Congress included a provision in Public Law 101-508 that the costs of a related educational institution should be allowed as part of total costs for those providers that are eligible to receive reasonable cost payment for education programs they do not operate, specific language in the Conference Report made clear that this provision did not prohibit the Secretary from continuing to consider these costs as redistribution costs and excluding them from allowable costs of provider-operated programs.

D. Payment for Certain Nonprovider-Operated Programs Under Public Law 101-508

In accordance with the provisions of sections 4004(b)(1) and (b)(2) of Public Law 101-508, proposed § 413.85(f) (§ 413.85(g)(1) and (2) of this final rule) provided that the net costs incurred by a provider, or by an educational institution that is related to the provider by common ownership or control (that is, a related organization as defined in § 413.17(b)), for the clinical training of students enrolled in an approved nursing or allied health program that is not operated by the provider would be paid on a reasonable cost basis if the following conditions are met:

- The clinical training must occur on the premises of the provider.

- The provider must have claimed and been *paid* for clinical training costs on a reasonable cost basis during its most recent cost reporting period that ended on or before October 1, 1989. (We proposed that, in this context, we would consider a provider to be "paid" for clinical training costs if, for its most recent cost reporting period ending on or before October 1, 1989, the provider's intermediary included the clinical training costs in the allowable costs used to determine the interim payment rate for that cost reporting period, and the provider subsequently claimed the clinical training costs as a pass-through cost on its initially submitted cost report for that period.)

- In any cost reporting period, the percentage of total allowable provider cost attributable to allowable clinical training cost cannot exceed the percentage of total allowable cost attributable to clinical training in the provider's most recent cost reporting period ending on or before October 1, 1989.

- The students in the educational program must provide a benefit to the provider through the provision of clinical services to patients of the provider.

- The clinical training costs must be incurred by the provider or by an educational institution related to the provider by common control on ownership as defined in § 413.17(b). Costs incurred by a third party, regardless of its relationship to either the provider or the educational institution, would not be allowed.

- The costs incurred by a provider do not exceed the costs the provider would incur if it operated the program itself.

Section 4004(b)(1) of Public Law 101-508 also required that we define allowable clinical training costs under this provision for payment for certain nonprovider-operated programs. At 57 FR 43667 in the September 22, 1992 proposed rule, we proposed to define these costs as the incremental costs that, in the absence of the students, would not be incurred by the provider. These incremental costs would include the costs of clinical instructors and administrative and clerical support staff whose function is to coordinate rotations with a nursing school and to schedule clinical rotation for each student nurse. They would not, however, include the costs of a charge or floor supervisor nurse who may spend a portion of his or her time supervising student nurses but who, in the absence of the students, would still have to be employed by the provider. In general, these costs are payroll and related salary costs. Although some

provider-incurred overhead costs directly related to the cost of the students would be allowable, overhead costs incurred by the related organization generally would not be considered allowable.

In the proposed rule, we stated that, if, after implementation of the provisions of sections 4004(b)(1) and (b)(2) of Public Law 101-508, we found a wide variation in the clinical cost per student among different hospitals' nursing and allied health programs, we would consider methods to narrow that variation under the definition of reasonable cost as set forth in section 1861(v)(1) of the Act. We specifically requested public comment on how we could best evaluate the reasonable cost of these programs. We received the following comments on our proposed implementation of the provisions of Public Law 101-508.

Comment: Many commenters objected to the retroactive nature of the special exception for providers to receive pass-through payment for the clinical training they provide in support of nonprovider-operated programs. These commenters believed that allowing ongoing payment only for those programs for which providers claimed and were paid costs for cost reporting periods that ended on or before October 1, 1989, discriminates against newer programs. They believed this criterion unjustly penalizes those providers that did not claim pass-through costs in the past due to lack of clear guidelines or because they were following the direction provided by HCFA in the preamble of the January 3, 1984 final rule. One commenter requested that the rule should be based on cost reports filed after the effective date of the final rule or allow providers to reopen their fiscal year 1989 cost reports to include nursing and allied health education costs. Another commenter suggested that hospitals be allowed to claim clinical training costs in future years if they had claimed them in their capital base year cost report.

Response: The October 1, 1989 cost reporting period date set forth in the proposed rule was mandated by section 4004(b)(2)(A) of Public Law 101-508. The practical effect of this provision is that providers may receive payment on a reasonable cost basis under this provision for the clinical training of students enrolled in a nonprovider-operated program only if they had claimed and received payment for periods prior to the enactment of the statute. This protects those providers that were relying on the payments.

Comment: Other commenters disagreed with the requirement that, for

cost reporting periods ending after October 1, 1989, the percentage of allowable clinical training costs is limited to the percentage allowable for the provider's previous cost reporting period. Again, commenters view this provision as a limitation on the development of new programs and as a disincentive to hospitals' participation as clinical training sites.

Response: The proposed regulations incorporated the provisions of section 4004(b)(2)(A) of Public Law 101-508 concerning which providers can claim pass-through payment for clinical training and how much they may claim. The commenters are correct in their assessment that, under these rules, providers that expand the magnitude of the support they provide to educational institutions would not receive a corresponding increase in Medicare pass-through payment. However, the rules merely limit the percentage of the costs, so if a provider expands some programs and decreases others, then there might be no adverse Medicare payment impact. Again, we believe that the Congressional intent was to protect providers who had come to rely on Medicare payments for nonprovider-operated education programs without increasing Medicare expenditures.

Comment: One commenter believed that the language at proposed § 413.85(f)(1) (§ 413.85(g)(2)(i) of this final rule) implies that in order for clinical training to be eligible for the pass-through, all training must take place at the provider. The commenter believed that providers should be limited to claiming the costs for training that takes place solely on the premises of the provider, but that the students should be allowed to spend time in training in other settings as long as the costs are not claimed by the provider.

Response: The language set forth at proposed paragraph (f)(1) is intended to limit providers to claiming as clinical training pass-through costs only those costs associated with training that takes place on the premises of the provider. It is not our intention to prevent students enrolled in educational institutions from obtaining clinical training at more than one provider setting. However, if that off-site training is part of the education program, it would be subject to the rules specified earlier defining a provider-operated program.

Comment: Several commenters objected to our proposal that clinical training costs would be allowable only if they were costs that the provider would not have incurred in the absence of the students. That is, only incremental costs would be recognized

under the pass through. The commenters believed this to be inequitable. For example, even if the floor charge nurse directs the training of the students as part of the nurse's usual duties, it may be necessary for the hospital to hire additional support personnel to perform duties previously provided by the floor nurse or there may be an increase in overtime to compensate for time devoted to students. One commenter believed that this restriction will encourage providers to increase their allowable costs through the hiring of additional staff dedicated to clinical training instead of allocating a portion of existing staff time. The commenters recommended that the final rule allow providers to claim the portion of the employee's salary or related costs associated with the time devoted to clinical training.

Response: We believe that allowable clinical training costs should be limited to those incremental costs that the provider actually incurs in the course of training nursing or allied health students. If a provider must hire additional staff or increase the salaried hours of existing staff to accomplish the clinical training, the costs of the staff time for providing the training would be considered allowable costs. These staff could include clinical training instructors and administrative and clerical support. However, if the provider merely adds the supervision of students to a floor nurse's list of duties and this is accomplished without the provider incurring additional costs, there is no incremental cost to be claimed.

Comment: Several commenters objected to our statement in the preamble to the proposed rule that, in the future, we might consider methods to narrow variation in the clinical cost per student among hospital programs. The commenters stated that the complexity of care in different programs and the mandates imposed by States may contribute to a great deal of variation. Thus, they believed that it would be extremely difficult to determine an appropriate limit on the per student costs. One commenter requested that, before such a limit is imposed, HCFA should define a list of components for cost per student. These elements should be separately assigned a cost and then averaged to create a range of reasonable cost. The commenter encouraged us to include adjustments for type of facility, region, and type of facility ownership to make the range as accurate as possible.

Response: We agree with the commenters that determining an appropriate limit on per student costs

would be a difficult undertaking and it is not a policy that we will pursue at this time. If, in the future, we decide that it is necessary, we will not implement any change in policy without first publishing it under the notice and public comment procedure.

Comment: One commenter was concerned that the proposal does not allow a hospital to claim costs incurred by a third party. The commenter's hospital sends its CRNA students to other hospitals to receive training that the commenter's hospital cannot provide. These other hospitals employ a CRNA clinical coordinator. The commenter requested clarification on whether the other hospitals can claim reasonable cost payment for the coordinator.

Response: The pass-through payment can be made to any provider that trains students in a nursing and allied health program as long as the program is operated by the provider, whether the provider is the originator of the program or whether the provider is one to which the students are rotated. However, the original provider of the program (or any other provider) may not claim the costs of training the students in the program while the students are rotating to another provider—only the provider actually training the students and incurring the clinical training costs may be paid on a reasonable cost basis. That is, a provider may not claim the costs of a third party provider.

Comment: One commenter requested that we clarify our policy that clinical training must be provided on "the premises of the provider."

Response: We will consider that the training is on the hospital's premises if it is in the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings. This clarification would encompass not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets. We are clarifying § 413.85(f)(1) (§ 413.85(g)(2)(i) in this final rule) accordingly.

E. Costs of Educational Activities Considered To Be Normal Operating Costs

As we have previously discussed, the final hospital inpatient prospective payment system rule published January 3, 1984, attempted to clarify the Medicare policy on the classification of

training costs incurred by providers as costs of approved educational activities paid on a reasonable cost basis. Since that time, questions have arisen about some types of training programs that are neither listed as approved programs under existing § 413.85(e) nor readily identifiable under existing § 413.85(d) as activities not within the scope of approved educational activities.

The programs that had been included in our list of approved programs were generally 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. 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 prospective payment system, as costs subject to the target rate-of-increase limits. In proposed § 413.85(g)(3) (§ 413.85(h)(3) of this final rule), we proposed to revise the regulations to include continuing educational programs in the same category as "educational seminars and workshops that increase the quality of medical care or operating efficiency of the provider."

Proposed § 413.85(g), like existing § 413.85(d), stated that the costs of certain activities are recognized as normal operating costs and are paid in accordance with applicable principles.

Comment: One commenter questioned the language in proposed § 413.85(g)(6) which describes the allowable costs of the clinical training and classroom instruction of students enrolled in an approved educational program that is not operated by the provider. The commenter requested clarification as to whether these costs are allowable as normal operating costs or as pass-through costs.

Response: The title of proposed paragraph (g) is "Activities treated as normal operating costs." All costs listed in this paragraph (paragraph (h) in this final rule) are costs that are recognized as normal operating costs and, as such, are not eligible to be paid under the pass-through. Although we believe that the language in the proposed rule is clear, we are revising paragraph (h)(6) in this final rule for better comprehension.

Comment: In the existing regulations, the costs of residents in anesthesiology who are employed to replace anesthesiologists are specifically included in normal operating costs and excluded from the pass-through. One commenter was concerned that this language was deleted from the proposed regulations.

Response: The language concerning residents working in a hospital and not participating in a medical education program was added as a part of the original hospital inpatient prospective payment system regulations in order to ensure that hospitals that hired residents to replace anesthesiologists in an attempt to circumvent the rebundling provision did not attempt to include the costs of those residents as education costs. Since that time, revised regulations governing Medicare payment for the direct medical education of residents have been published. These regulations are set forth in § 413.86. Those regulations clearly exclude residents not in an approved program from receiving payment under the medical education provisions. We believe that it is no longer necessary to include this language in the regulations governing nursing and allied health education programs, and therefore proposed to delete it from the regulations. We are adopting this deletion in this final rule. We note that this action does not signify a change in our policy.

Comment: One commenter stated that HCFA should consider allowing outpatient, nonacute care clinical training as eligible for the reasonable cost payment. Many of these auxiliary service sites are operated by a Medicare provider or under an agreement with such a provider. The commenter urged HCFA to consider the advantages to Medicare beneficiaries, health system costs, and future health professionals in allowing as reasonable costs the clinical training costs occurring outside the inpatient, acute care facility.

Response: Based on this comment and others we received, we believe that there is a fair amount of confusion surrounding Medicare payment for medical education, which we will attempt to clarify. The following is a brief overview of Medicare payment for

graduate medical education and payment for nursing and allied health education.

- Payment for Graduate Medical Education (GME)

Regulations governing Medicare payment for the direct cost of GME programs are set forth in § 413.86. In general, Medicare payment for the direct costs of GME is based on the hospital's historical per resident costs in a base year (fiscal year 1984), updated for inflation. Payment to the hospital in the current year is determined based on the product of the hospital's updated per resident amount, the actual number of residents (capped by the number of allopathic and osteopathic residents in a hospital's most recent cost reporting period ending on or before December 31, 1996), and Medicare's inpatient utilization in that year.

Under regulations at § 409.26(a), the Medicare Skilled nursing facility (SNF) benefit includes coverage of medical services that are furnished by an intern or resident (who is training in a hospital teaching program approved in accordance with the provisions of § 409.15), if the resident is in a participating hospital with which the SNF has in effect a transfer agreement. Payment for these services is included in the SNF prospective payment system per diem global payment. In addition, under regulations at § 409.45(g), the Medicare home health benefit includes services provided by interns and residents. To the extent that these services were paid on a reasonable cost basis and covered under the home health benefit, there cannot be separate payment for these services under the home health prospective payment system. These services will be subject to the consolidated billing requirements. However, the home health prospective payment system rates and consolidated billing requirements do not affect Medicare payments to hospitals for graduate medical education or physician billing requirements under the fee schedule.

- Payment for Other Medical Education (Nursing and Allied Health Education)

The direct costs of all other medical education in which providers engage are covered by the regulations at § 413.85. Hospitals may receive payment for nursing and allied health education programs they operate on a reasonable cost basis. For hospitals subject to the prospective payment system, these costs are paid on a reasonable cost basis. For hospitals excluded from that system and paid on a reasonable cost basis subject to cost limits, the medical education costs are excluded from application of

the limits. Hospitals that participate in a nursing and allied health program that is a nonprovider-operated program may receive pass-through payment if they meet the criteria set forth at § 413.85(g)(2) in this final rule.

- Provider-Operated Requirement for Nursing and Allied Health Education

One of the main distinctions between payment for GME and nursing and allied health education is that, generally, a facility can only receive separate payment for nursing and allied health education if the program is provider-operated. Hospitals, however, can receive payment for residents participating in approved programs regardless of whether the program is operated by a provider. We have consistently applied this policy since the inception of the Medicare program.

The January 3, 1984 prospective payment system final rule (49 FR 267) states that only the costs of provider-operated approved medical education programs are excluded from the prospective payment system and paid on a reasonable cost basis. This language only applied to nursing and allied health education. That final rule states the following:

“If a program is operated by another institution, such as a nearby college or university, it must be noted that by far the majority of the costs of that program are borne by that other institution, and not by the hospital. While it is true that the hospital may incur some costs associated with the provision of clinical training to *students* enrolled in a nearby institution, the hospital also gains in return.” (*Emphasis added.*)

The reference to students and not residents indicates our intention to apply this language only to nursing and allied health education. Furthermore, we believe hospitals do incur significant costs associated with providing a clinical setting for training residents even when they do not operate an approved program. Thus, the statement that the majority of costs are borne by that other institution reflects our views only with respect to nursing and allied health education.

We have always recognized costs associated with GME programs regardless of whether or not they are provider operated. The September 29, 1989 (54 FR 40286) regulations implemented a GME payment system based on per resident amounts, provided that the hospital's per resident amount would be based on its GME costs divided by the number of full-time equivalent residents working in all areas of the hospital complex. We provided a specific example of how to determine the hospital's per resident amount when the approved program is operated by

another institution. In addition, we noted that, in accordance with section 1886(h)(5)(A) of the Act, the definition of an approved medical residency program at § 413.86(b) does not provide that the program must be provider-operated. In contrast, § 413.85, which set forth regulations governing payment of nursing and allied health education, included a definition of “approved educational activities” which refers to programs that “can be operated by providers.”

Concerning the commenters' more specific comment that providers be allowed to claim the costs incurred when students receive clinical training in outpatient, nonacute care or nonhospital settings, we believe that the issue regarding allowing pass-through payment for the costs of training nursing and allied health students in these settings does not revolve around whether the hospital operates the program and incurs the costs, but, rather, whether training in these settings enhances the quality of inpatient care. Current nursing and allied health policy at § 413.85(2)(b) defines “approved educational activities”, in part, as enhancing the quality of patient care in an institution. We have further clarified this definition as a requirement under the general payment rule at § 413.85(d)(1)(i)(C) of this final rule; that is, a program must “enhance the quality of inpatient care” to be considered an approved educational activity. This phrase refers only to training while providing care directly to hospital inpatients. Thus, we feel it is inappropriate to allow pass-through payment for the time students train in outpatient departments, nonacute care, or nonhospital settings.

F. Net Costs of Approved Certified Registered Nurse Anesthetist (CRNA) Educational Programs

On January 26, 1989, we published a proposed rule (54 FR 3803) to implement section 9320 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509). That rule proposed to change the classification of patient care services of CRNAs to permit payment under the Medicare Part B fee schedule for such services furnished on or after January 1, 1989. This policy created difficulties in distinguishing between the training and patient care activities of teaching CRNAs. To minimize the possibility of duplicate payments, we proposed to modify the regulations at § 413.85(b)(3) (§ 413.85(d)(2)(iii) of this final rule) to recognize the special circumstances that exist with regard to the costs of approved CRNA training programs. While, for the most part, the

costs of these programs would continue to be paid under the generally applicable rules set forth at § 413.85, we proposed to exclude from allowable costs the costs providers incur in connection with compensating teaching CRNAs for the time spent with student anesthetists in clinical training during surgical procedures. These activities involve the provision of patient care services that are payable under Medicare Part B under the CRNA fee schedule.

In developing the proposed rule, we considered requiring that all teaching CRNAs complete allocation agreements, similar to those completed for provider-compensated physicians, detailing how the CRNAs spend their time at the provider. In the interest of administrative simplicity and reducing provider recordkeeping burden, we proposed that it would be sufficient that providers present auditable documentation to intermediaries justifying CRNA faculty compensation costs related to hours spent in classroom instruction or in administrative activities related to the approved program. No other compensation costs for CRNA faculty members would be allowable. Compensation costs for faculty members who are not CRNAs would continue to be allowable since the duplicate payment potential would not exist for these personnel. We specifically sought comments on whether the proposal was an equitable way to deal with the problems arising from the change in the payment method for the services of CRNAs. We received a number of comments regarding this proposal.

Comment: In general, commenters did not believe that it would be equitable to have different rules for CRNA clinical training costs. One commenter stated that CRNAs are providing double service when they supervise students in anesthesia procedures and deserve the additional Part B payment. Other commenters stated that CRNAs are not always allowed to bill under Part B for the services they provide. One commenter pointed out that CRNAs who work under the direction of a physician cannot bill under Part B unless the physician is directing two or more cases. Another commenter noted that CRNAs can bill under Part B only when they are supervising no more than one student. The hospital at which the commenter provides services generally requires CRNAs to supervise two or more students and the CRNA cannot bill under Part B under these circumstances. These latter two commenters, as well as others, indicated support for allowing the clinical costs of CRNAs supervising

students to be included in the pass-through payment as long as the CRNA cannot bill under Part B.

Response: Under the provisions of the existing regulation that implemented the CRNA fee schedule, a CRNA who is supervising student anesthetists cannot receive payment under Part B when supervising more than one student because supervision of more than one student is considered to be a teaching activity (42 CFR 414.46). In addition, this regulation also stated that if an anesthesiologist and a CRNA are involved in a single procedure, the procedure is considered to be personally performed by the physician. However, this policy was revised in the December 8, 1995 **Federal Register** (60 FR 63152), (as implemented in § 414.46), effective for services furnished on or after January 1, 1998, to specify that the "medical direction payment" rules apply if an anesthesiologist and a CRNA are both involved in a single anesthesia case. The payment for both the CRNA service and the physician medical direction service are paid at 50 percent of the fee otherwise recognized for the anesthesiologist who performs the case alone.

We are revising the regulations at § 413.85(d)(2)(iii) (previously proposed § 413.85(b)(3)) to state that the clinical training costs of a CRNA who is continuously supervising one student anesthetist are not allowable under the pass-through because the CRNA may bill for this service under the Medicare Part B fee schedule. The clinical training costs of a CRNA are also not allowable under the pass-through when the CRNA may bill for fifty percent of a service under the Part B fee schedule. We expect that the fiscal intermediaries will be careful to review the documentation the hospital maintains to support its request for payment under the pass-through for CRNA clinical training. In general, the teaching portion of the pass-through is not allowed in situations where any practitioner (including CRNAs) can bill for the service under the Medicare Part B fee schedule.

Comment: Three commenters stated that CRNAs should be required to complete allocation agreements, like those completed by provider-compensated physicians, that detail the way the physicians spend their time at the provider. This would allow a consistent set of rules under Medicare. Another commenter, who believed that the requirements for physicians are more precise, requested that the final rule present examples of what we would consider to be "adequate documentation."

Response: We do not agree with the commenters' suggestion that we impose elaborate recordkeeping requirements on providers concerning the allocation of a CRNA's time spent in the clinical training of students. A provider is free to require that the CRNAs that it employs complete allocation agreements or similar documents that detail the CRNAs services. However, we believe that there are less burdensome ways in which the provider can keep track of a CRNA's time in order to support the costs that the provider is claiming under the Medicare Part A pass-through. Examples of documentation may include operating room assignments, schedules, or any other information indicating the portion of time the CRNA spends in activities which are billable under Medicare Part B. We do not believe we need to include these examples as part of the regulation text.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions of approved nursing and allied health education activities as proposed with the following changes to § 413.85. For the sake of clarity, we are reorganizing the text of § 413.85. For ease of reference, a crosswalk appears below:

Proposed	Final
Paragraph (a)	Paragraph (d)
Paragraph (b)(1)	Paragraph (b)(2)
Paragraph (b)(2)	Paragraph (b)(3)
Paragraph (b)(3)	Paragraph (d)(2)(iii)
Paragraph (c)(1)	Paragraph (d)(2)(i), (ii) and (iv)
Paragraph (c)(2)	Paragraph (c), defini- tion
Paragraph (c)(3)	Paragraph (c), defini- tion
Paragraph (c)(4)	Paragraph (c), defini- tion
Paragraph (c)(5)	Paragraphs (c) defini- tion, and (e)
Paragraph (d)	Paragraph (e)
Paragraph (e)(1)	Paragraph (f)(1)
Paragraph (e)(2)	Paragraph (f)(2)
Paragraph (f)	Paragraph (g)
Paragraph (g)	Paragraph (h)

All substantive revisions made to the section are summarized below.

- We are renaming § 413.85 to read "Cost of approved nursing and allied health education activities," instead of "Cost of approved educational activities," and generally refer to "approved educational activities" as "approved nursing and allied health education activities" under this section. We are using the phrase "nursing and allied health education activities" in connection with "approved educational activities" because it clarifies that this section addresses only nursing and

allied health education activities, and no other types of educational activities, such as graduate medical education.

- We are revising paragraphs (c) and (e) to reflect our clarification in policy that, as part of a provider's requirements for receiving Medicare payment on a reasonable cost basis for the net costs of its nursing and allied health education activities, the activities must be recognized by a national approving body or State licensing organization.

- We are revising and reorganizing proposed § 413.85, and are making editorial revisions where necessary, to clarify our policy on approved nursing and allied health education activities. The reorganized editorial revisions do not reflect a change from the proposed policy on approved nursing and allied health education programs.

- We are redesignating the existing paragraph (h) of § 413.85 as § 422.270 (with appropriate revision of the paragraph codes) because paragraph (h) more properly belongs in the Medicare+Choice sections of the Medicare regulation.

- We are revising paragraph (a) to include the statutory basis for implementing this policy on nursing and allied health education programs.

- We are revising redesignated paragraph (g)(2)(i) to clarify the meaning of "on the premises of the provider."

- We are revising redesignated paragraph (d)(2)(iii) to provide that the clinical training costs of CRNAs who are medically directing student anesthetists are not allowable under the pass through if the CRNA may bill for the services under the Part B fee schedule.

- We are revising redesignated paragraph (h) to clarify those costs that are allowable as normal operating costs.

- We are revising one of the criteria for identifying programs operated by a provider to indicate that the provider must provide and control both classroom instruction and clinical training "where the classroom instruction is a requirement for program completion." In addition, we are further revising this criterion that it is subject to the parenthetical sentence in paragraph (f)(1)(ii) of this final rule.

IV. Regulatory Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually).

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless we certify that a final rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, all providers are treated as small entities.

In general, the provisions that are set forth in this final rule conform the regulations to the statute and to our existing policy as set forth in the Provider Reimbursement Manual and other instructions. These provisions have no impact on those providers that operate their own nursing and allied health education program. We note, however that section 6205(b)(1) of Public Law 101-239 imposed a moratorium for the period on or after December 19, 1989, and before October 1, 1990, on the recoupment of overpayments attributable to a determination by a provider's intermediary that costs claimed by a provider for the operation of a school of nursing or allied health are not eligible for payment on a reasonable cost basis. The basis for this determination is generally that a neighboring or related college or university, not the hospital, is the operator of the program.

As discussed earlier in this preamble, some hospitals that do not operate their own nursing and allied health education programs received overpayments for nursing and allied health education costs for cost reporting periods beginning on or after October 1, 1983 and ending before October 1, 1990. However, we were prohibited from collecting these overpayments and were required to refund previously collected overpayments under section 4004(b)(3) of Public Law 101-508. The statute did not substantially alter payments to hospitals that did not operate their own programs prior to Public Law 101-508. Sections 4004(b)(1) and (2) of Public Law 101-508 required the Secretary to continue making pass-through payments to these hospitals for the clinical training costs of nursing and allied health education programs. Funding for nursing and allied health education for these hospitals has only been affected to the extent that prior overpayments included payment for classroom education which are not provided for under Public Law 101-508. If Medicare had not made pass-through payments hospitals prior to Public Law 101-508 for programs they do not operate, there

would have been no subsequent pass-through payment under OBRA 1990 for any of these nursing and allied health programs. Thus, relative to Medicare's policy prior to enactment of Public Law 101-508, Public Law 101-508 substantially benefited a small number of hospitals that do not operate their own programs.

Although we have data on Medicare's expenditures for nursing and allied health education both before and after enactment of Public Law 101-508, we do not have data broken down on the respective shares accounted for by provider and nonprovider-operated programs. For this reason, we cannot make an accurate estimate of the impact of Public Law 101-508 and this final rule on payment for nursing and allied health education. However, we note that this provision only affected a small number of hospitals with existing nonprovider-operated programs.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a final rule will have significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 50 beds. We are not preparing a rural impact statement, since we have determined, and certify, that this final rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that the final rule will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million. This final rule does not mandate any requirements for State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

V. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and

solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this final rule, § 413.85(e) requires that, in order for an activity to be considered an approved nursing and allied health education activity, the activity must be recognized by a national approving body or State licensing authority (in addition to meeting the other requirements listed in paragraph (d)(1) of this section). For example, such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for Clinical Pastoral Education, Inc., and the American Dietetic Association. The burden associated with this requirement is the time necessary for the provider to maintain documentation demonstrating that this requirement has been met. We estimate that 1,400 providers will be required to maintain documentation and that it will take each organization 5 minutes on an annual basis to maintain the documentation, for a total burden of 117 hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirement in § 413.85(e). Compliance with this requirement is not required until it has been approved by OMB.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and record-keeping requirements.

42 CFR Part 422

Health maintenance organizations (HMO), Medicare+Choice, Provider sponsored organizations (PSO).

42 CFR Chapter IV is amended as set forth below:

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

A. Part 413 is amended as follows:
1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 1395l, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.85, the section heading is revised, paragraph (h) is redesignated as a new § 422.270, and the remainder of the section is revised to read as follows:

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

(a) *Statutory basis.* This section implements section 1861(v)(1)(A) of the Act and section 4004(b) of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) by establishing the methodology for Medicare payment of the costs of approved nursing and allied health education activities.

(b) *Scope.* (1) This section sets forth the rules for determining Medicare payments to hospitals for the costs of nursing and allied health education activities.

(2) This section does not address Medicare payments for the direct and indirect costs of graduate medical education (that is, approved residency programs in medicine, osteopathy, dentistry, and podiatry). Medicare payment for these costs is determined as provided in § 412.105 of this subchapter and § 413.86.

(3) The rules under this section do not apply to activities that are specified in paragraph (h) of this section and identified as normal operating costs.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Approved educational activities means formally organized or planned programs of study of the type that:

- (1) Are operated by providers as specified in paragraph (f) of this section;
- (2) Enhance the quality of inpatient care at the provider; and
- (3) Meet the requirements of paragraph (e) of this section for State licensure or accreditation.

Classroom instruction costs are those costs associated with formal, didactic instruction on a specific topic or subject in a class that meets at regular, scheduled intervals over a specific time period (for example, semester or

quarter), and for which a student receives a grade.

Clinical training costs means costs of training for the acquisition and use of the skills of a nursing or allied health profession or trade in the actual environment in which these skills will be used by the student upon graduation. Clinical training may involve occasional or periodic meetings to discuss or analyze cases, critique performance, or discuss specific skills or techniques; it involves no classroom instruction.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

Redistribution of costs means an attempt by a provider to increase the amount, or to expand the types, of the costs of educational activities that are allowed for Medicare payment purposes by claiming costs that previously were not claimed by the provider and were considered costs of an educational institution. For example, costs for a school of nursing or allied health education or a medical school that were incurred by an educational institution and were not allowable to the provider in its prospective payment or rate-of-increase limit base year cost report, or graduate medical education per resident amount calculated under § 413.86, are not allowable costs in subsequent fiscal years.

(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:

(i) An approved educational activity—
(A) Is recognized by a national approving body or State licensing authority as specified in paragraph (e) of this section;

(B) Meets the criteria specified in paragraph (f) of this section for identification as an operator of an approved education program.

(C) Enhances the quality of inpatient care at the provider.

(ii) The cost for certain nonprovider-operated programs are reimbursable on a reasonable cost basis if the programs meet the criteria specified in paragraph (g)(2) of this section.

(2) *Determination of net cost.* (i) Subject to the provisions of paragraph (d)(2)(iii) of this section, the net cost of approved educational activities is

determined by deducting the revenues that a provider receives from tuition and student fees from the provider's total allowable educational costs that are directly related to approved educational activities.

(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.

(iii) The net costs of approved certified registered nurse anesthetist (CRNA) education programs that are determined on a reasonable cost basis are subject to the additional condition that allowable compensation costs for faculty members who are CRNAs are limited to the compensation costs for administrative activities related to the educational program, the compensation costs directly related to hours spent in classroom instruction, and the costs related to the clinical training of students for which the CRNA may not receive payment under the CRNA fee schedule. No pass-through compensation costs are allowable for the time a CRNA spends in the clinical training of a student anesthetist during a surgical procedure in the operating room for which the CRNA may receive payment under the CRNA fee schedule. As specified at § 414.46 of this chapter, if the CRNA continuously supervises the services of a single student nurse anesthetist, or where the medical direction rules allow a CRNA to bill for the service, payment can be made under the CRNA fee schedule.

(iv) Net costs are subject to apportionment for Medicare utilization as described in § 413.50.

(e) *Approved nursing and allied health education programs.* HCFA will consider an activity an approved nursing and allied health education program if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. Such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for

Clinical Pastoral Education Inc., and the American Dietetic Association.

(f) *Criteria for identifying programs operated by a provider.* (1) Except as provided in paragraph (f)(2) of this section, for cost reporting periods beginning on or after October 1, 1983, in order to be considered the operator of an approved nursing or allied health education program, a provider must meet all of the following requirements:

(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.

(2) Absent 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 paragraph (f)(1) of this section and to be the operator of the program.

(g) *Payment for certain nonprovider-operated programs.* (1) *Payment rule.* Costs incurred by a provider, or by an educational institution that is related to the provider by common ownership or control (that is, a related organization as defined in § 413.17(b)), for the clinical training of students enrolled in an approved nursing or allied health education program that is not operated by the provider, are paid on a reasonable cost basis if the conditions specified in paragraph (g)(2) of this section are met.

(2) *Criteria for identification of nonprovider-operated education programs.* Payment for the incurred costs of educational activities identified

in paragraph (g)(1) of this section will be made if the following conditions are met:

(i) The clinical training must occur on the premises of the provider, that is, in the hospital itself or in the physical area immediately adjacent to the provider's main buildings, or in other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.

(ii) The provider must have claimed and been paid for clinical training costs on a reasonable cost basis during the most recent cost reporting period that ended on or before October 1, 1989. This condition is met if a notice of program reimbursement (NPR) was issued for that cost reporting period by November 5, 1990, and the clinical training costs were included as pass-through costs. If an NPR was not issued by that date, or an NPR was issued but did not treat the clinical training costs as pass-through costs, the condition is met if—

(A) The intermediary included the clinical training costs in the allowable costs used to determine the interim rate for the most recent cost reporting period ending on or before October 1, 1989; or

(B) The provider claimed the clinical training costs as pass-through costs when the cost report for the most recent cost reporting period ending on or before October 1, 1989, was initially submitted.

(iii) In any cost reporting period, the percentage of total allowable provider cost attributable to allowable clinical training cost does not exceed the percentage of total cost for clinical training in the provider's most recent cost reporting period ending on or before October 1, 1989.

(iv) The students in the educational program must provide a benefit to the provider through the provision of clinical services to patients of the provider.

(v) The clinical training costs must be incurred by the provider or by an educational institution related to the provider by common control or ownership as defined in § 413.17(b) ("*Cost to related organizations.*") Costs incurred by a third-party, regardless of its relationship to either the provider or the educational institution, are not allowed.

(vi) The costs incurred by a provider does not exceed the costs the provider would have incurred if it was the sole operator of the program.

(h) *Cost of educational 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:

(1) Orientation and on-the-job training.

(2) Part-time education for bona fide full-time employees at properly accredited academic or technical institutions (including other providers) devoted to undergraduate or graduate work.

(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.

(4) Maintenance of a medical library.

(5) Training of a patient or patient's family in the use of medical appliances or other treatments.

(6) Except as provided in paragraph (g) of this section, clinical training and classroom instruction of students enrolled in an educational program that is not operated by the provider. The following are clinical training and classroom instruction costs that are allowable as normal operating costs:

(i) Costs incurred in the clinical training of students, including the clinical training or clerkship of undergraduate medical school students that takes place in a provider.

(ii) Classroom instruction costs incurred by a provider that meet the following criteria:

(A) The provider's support does not constitute a redistribution of nonprovider costs to the provider. The support must be in addition to the costs already being incurred by the nonprovider-operated program. If the nonprovider entity reduces its costs due to receiving provider support, this reduction constitutes a redistribution of costs from an educational institution to a patient care institution and is a nonallowable provider cost.

(B) The provider receives a benefit for the support it furnishes.

(C) The cost of the provider's support is less than the cost the provider would incur were it to operate the program.

(7) Other activities that do not involve the actual operation of an approved educational program.

PART 422—MEDICARE+CHOICE PROGRAM

B. Part 422 is amended as follows:

1. The authority citation for part 422 is revised to read as follows:

Authority: Secs. 1851 and 1855 of the Social Security Act (42 U.S.C. 1395w-21 and 1395w-25).

2. Newly designated § 422.270 is revised to read as follows:

§ 422.270 Payments to M+C organizations for graduate medical education costs.

(a) Effective January 1, 1999, Medicare+Choice organizations may receive direct graduate medical education payments for the time that residents spend in nonhospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) Medicare+Choice organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The Medicare+Choice organization incurs "all or substantially all" of the costs for the training program in the nonhospital setting as defined in § 413.86(b) of this subchapter.

(3) There is a written agreement between the Medicare+Choice organization and the nonhospital site that indicates the Medicare+Choice organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the nonhospital site for teaching activities.

(c) A Medicare+Choice organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this subchapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the nonhospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The Medicare+Choice organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the Medicare+Choice organization.

(e) Direct graduate medical education payments made to Medicare+Choice organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance and Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: January 5, 2001.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: January 5, 2001.

Donna E. Shalala,

Secretary.

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