

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

Subpart A—Introduction and General Rules

Sec.

- 413.1 Introduction.
- 413.5 Cost reimbursement: General.
- 413.9 Cost related to patient care.
- 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.
- 413.17 Cost to related organizations.

Subpart B—Accounting Records and Reports

- 413.20 Financial data and reports.
- 413.24 Adequate cost data and cost finding.

Subpart C—Limits on Cost Reimbursement

- 413.30 Limitations on payable costs.
- 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.
- 413.40 Ceiling on the rate of increase in hospital inpatient costs.

Subpart D—Apportionment

- 413.50 Apportionment of allowable costs.
- 413.53 Determination of cost of services to beneficiaries.
- 413.56 [Reserved]

Subpart E—Payments to Providers

- 413.60 Payments to providers: General.
- 413.64 Payments to providers: Specific rules.
- 413.65 Requirements for a determination that a facility or an organization has provider-based status.
- 413.70 Payment for services of a CAH.
- 413.74 Payment to a foreign hospital.

Subpart F—Specific Categories of Costs

- 413.75 Direct GME payments: General requirements.
- 413.76 Direct GME payments: Calculation of payments for GME costs.
- 413.77 Direct GME payments: Determination of per resident amounts.
- 413.78 Direct GME payments: Determination of the total number of FTE residents.
- 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

413.85 Cost of approved nursing and allied health education activities.

413.87 Payments for Medicare + Choice nursing and allied health education programs.

413.88 Incentive payments under plans for voluntary reduction in number of medical residents.

413.89 Bad debts, charity, and courtesy allowances.

413.90 Research costs.

413.92 Costs of surety bonds.

413.94 Value of services of nonpaid workers.

413.98 Purchase discounts and allowances, and refunds of expenses.

413.99 Qualified and Non-Qualified Deferred Compensation Plans.

413.100 Special treatment of certain accrued costs.

413.102 Compensation of owners.

413.106 Reasonable cost of physical and other therapy services furnished under arrangements.

413.114 Payment for posthospital SNF care furnished by a swing-bed hospital.

413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

413.124 Reduction to hospital outpatient operating costs.

413.125 Payment for home health agency services.

Subpart G—Capital-Related Costs

413.130 Introduction to capital-related costs.

413.134 Depreciation: Allowance for depreciation based on asset costs.

413.139 Depreciation: Optional allowance for depreciation based on a percentage of operating costs.

413.144 Depreciation: Allowance for depreciation on fully depreciated or partially depreciated assets.

- 413.149 Depreciation: Allowance for depreciation on assets financed with Federal or public funds.
- 413.153 Interest expense.
- 413.157 Return on equity capital of proprietary providers.

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

- 413.170 Scope.
- 413.171 Definitions.
- 413.172 Principles of prospective payment.
- 413.174 Prospective rates for hospital-based and independent ESRD facilities.
- 413.176 Amount of payments.
- 413.177 Quality incentive program payment.
- 413.178 ESRD quality incentive program.
- 413.180 Procedures for requesting exceptions to payment rates.
- 413.182 Criteria for approval of exception requests.
- 413.184 Payment exception: Pediatric patient mix.
- 413.186 Payment exception: Self-dialysis training costs.
- 413.194 Appeals.
- 413.195 Limitation on review.
- 413.196 Notification of changes in rate-setting methodologies and payment rates.
- 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.
- 413.200 [Reserved]
- 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.
- 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.
- 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.
- 413.215 Basis of payment.
- 413.217 Items and services included in the ESRD prospective payment system.
- 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.
- 413.230 Determining the per treatment payment amount.
- 413.231 Adjustment for wages.
- 413.232 Low-volume adjustment.
- 413.233 Rural facility adjustment.
- 413.234 Drug designation process.
- 413.235 Patient-level adjustments.
- 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.
- 413.237 Outliers.
- 413.239 Transition period.

- 413.241 Pharmacy arrangements.

Subpart I—Prospectively Determined Payment Rates for Low-Volume Skilled Nursing Facilities, for Cost Reporting Periods Beginning Prior to July 1, 1998

- 413.300 Basis and scope.
- 413.302 Definitions.
- 413.304 Eligibility for prospectively determined payment rates.
- 413.308 Rules governing election of prospectively determined payment rates.
- 413.310 Basis of payment.
- 413.312 Methodology for calculating rates.
- 413.314 Determining payment amounts: Routine per diem rate.
- 413.316 Determining payment amounts: Ancillary services.
- 413.320 Publication of prospectively determined payment rates or amounts.
- 413.321 Simplified cost reports for SNFs.

Subpart J—Prospective Payment for Skilled Nursing Facilities

- 413.330 Basis and scope.
- 413.333 Definitions.
- 413.335 Basis of payment.
- 413.337 Methodology for calculating the prospective payment rates.
- 413.338 Skilled nursing facility value-based purchasing program.
- 413.340 Transition period.
- 413.343 Resident assessment data.
- 413.345 Publication of Federal prospective payment rates.
- 413.348 Limitation on review.
- 413.350 Periodic interim payments for skilled nursing facilities receiving payment under the skilled nursing facility prospective payment system for Part A services.
- 413.355 Additional payment: QIO reimbursement for cost of sending records electronically or by photocopy and mailing.
- 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

- 413.370 Scope.
- 413.371 Definition.
- 413.372 AKI dialysis payment rate.
- 413.373 Other adjustments to the AKI dialysis payment rate.
- 413.374 Renal dialysis services included in the AKI dialysis payment rate.

§ 413.1

42 CFR Ch. IV (10–1–24 Edition)

413.375 Notification of changes in rate-setting methodologies and payment rates.

Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals, Organ Procurement Organizations, and Histocompatibility Laboratories

- 413.400 Definitions.
- 413.402 Organ acquisition costs.
- 413.404 Standard acquisition charge.
- 413.406 Acquisition of pancreata for islet cell transplant.
- 413.408 [Reserved]
- 413.410 [Reserved]
- 413.412 Intent to transplant, intent for research, counting en bloc, and unusable organs.
- 413.414 Medicare secondary payer and organ acquisition costs.
- 413.416 Organ acquisition charges for kidney-paired exchanges.
- 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.
- 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

AUTHORITY: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

SOURCE: 51 FR 34793, Sept. 30, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 413 appear at 76 FR 50537, August 22, 2014.

Subpart A—Introduction and General Rules

§ 413.1 Introduction.

(a) *Basis, scope, and applicability*—(1) *Statutory basis*—(i) *Basic provisions*. (A) Section 1815 of the Act requires that the Secretary make interim payments to providers and periodically determine the amount that should be paid under Part A of Medicare to each provider for the services it furnishes.

(B) Section 1814(b) of the Act (for Part A) and section 1833(a) (for Part B) provide for payment on the basis of the lesser of a provider's reasonable costs or customary charges.

(C) Section 1861(v) of the Act defines “reasonable cost”.

(ii) *Additional provisions*. (A) Section 1138(b) of the Act specifies the conditions for Medicare payment for organ procurement costs.

(B) Section 1814(j) of the Act provides for exceptions to the “lower of costs or charges” provisions.

(C) Sections 1815(a) and 1833(e) of the Act provide the Secretary with authority to request information from providers to determine the amount of Medicare payment due providers.

(D) Section 1833(a)(4) and (i)(3) of the Act provide for payment of a blended amount for certain surgical services furnished in a hospital's outpatient department.

(E) Section 1833(n) of the Act provides for payment of a blended amount for outpatient hospital diagnostic procedures such as radiology.

(F) Section 1834(c)(1)(C) of the Act establishes the method for determining Medicare payment for screening mammograms performed by hospitals.

(G) Section 1834(g) of the Act provides that payment for critical access hospital (CAH) outpatient services is the reasonable costs of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter.

(H) Section 1881 of the Act authorizes payment for services furnished to ESRD patients.

(I) Section 1883 of the Act provides for payment for post-hospital SNF care furnished by a rural hospital that has swing-bed approval.

(J) Sections 1886(a) and (b) of the Act impose a ceiling on the rate of increase in hospital inpatient costs.

(K) Section 1886(h) of the Act provides for payment to a hospital for the services of interns and residents in approved teaching programs on the basis of a “per resident” amount.

(L) Section 1834(x) of the Act authorizes payment for services furnished by rural emergency hospitals (REHs) and establishes the payment methodology.

(2) *Scope*. This part sets forth regulations governing Medicare payment for services furnished to beneficiaries by—

(i) Hospitals, critical access hospitals (CAHs), and rural emergency hospitals (REHs);

(ii) Skilled nursing facilities (SNFs);

(iii) Home health agencies (HHAs);

(iv) End-stage renal disease (ESRD) facilities;

(v) Organ procurement organizations (OPOs) and histocompatibility laboratories.

(3) *Applicability.* The payment principles and related policies set forth in this part are binding on CMS and its fiscal contractors, on the Provider Reimbursement Review Board, and on the entities listed in paragraph (a)(2) of this section.

(b) *Reasonable cost reimbursement.* Except as provided under paragraphs (c) through (h) of this section, Medicare is generally required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Regulations implementing section 1861(v) are found generally in this part beginning at §413.5.

(c) *Outpatient maintenance dialysis and related services.* Section 1881 of the Act authorizes special rules for the coverage of and payment for services furnished to ESRD patients. Sections 413.170 and 413.174 implement various provisions of section 1881. In particular, §413.170 establishes a prospective payment method for outpatient maintenance dialysis services that applies both to hospital-based and independent ESRD facilities, and under which Medicare pays for both home and infacility dialysis services furnished on or after August 1, 1983.

(d) *Payment for inpatient hospital services.* (1) For cost reporting periods beginning before October 1, 1983, the amount paid for inpatient hospital services is determined on a reasonable cost basis.

(2) Payment to short-term general hospitals located in the 50 States and the District of Columbia for the operating costs of hospital inpatient services for cost reporting periods beginning on or after October 1, 1983, and for the capital-related costs of inpatient services for cost reporting periods beginning on or after October 1, 1991, are determined prospectively on a per discharge basis under part 412 of this chapter except as follows:

(i) Payment for the following is described in §412.113 of this chapter:

(A) Capital related costs for cost reporting periods beginning before October 1991.

(B) Medical education costs.

(C) Organ acquisition costs as specified in part 413, subpart L.

(D) The costs of certain anesthesia services.

(ii) Payment to children's hospitals that are excluded from the prospective payment systems under subpart B of part 412 of this chapter, and hospitals outside the 50 States and the District of Columbia is on a reasonable cost basis, subject to the provisions of §413.40.

(iii) Payment to hospitals subject to a State reimbursement control system is described in paragraph (e) of this section.

(iv) For cost reporting periods beginning before January 1, 2005, payment to psychiatric hospitals (as well as separate psychiatric units (distinct parts) of short-term general hospitals) that are excluded under subpart B of part 412 of this chapter from the prospective payment system is on a reasonable cost basis, subject to the provisions of §413.40.

(v) For cost reporting periods beginning on or after January 1, 2005, payment to inpatient psychiatric facilities that meet the conditions of §412.404 of this chapter, is made under the prospective payment system described in subpart N of part 412 of this chapter.

(vi) For cost reporting periods beginning before January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals), that are excluded under subpart B of part 412 of this subchapter from the prospective payment systems is made on a reasonable cost basis, subject to the provisions of §413.40.

(vii) For cost reporting periods beginning on or after January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals) that meet the conditions of §412.604 of this chapter is based on prospectively determined rates under subpart P of part 412 of this subchapter.

§ 413.5

42 CFR Ch. IV (10–1–24 Edition)

(viii) For cost reporting periods beginning before October 1, 2002, payment to long-term care hospitals that are excluded under subpart B of Part 412 of this subchapter from the prospective payment systems is on a reasonable cost basis, subject to the provisions of § 413.40.

(ix) For cost reporting periods beginning on or after October 1, 2002, payment to the long-term hospitals that meet the condition for payment of §§ 412.505 through 412.511 of this subchapter is based on prospectively determined rates under subpart O of Part 412 of this subchapter.

(e) *State reimbursement control systems.* Beginning October 1, 1983, Medicare reimbursement for inpatient hospital services may be made in accordance with a State reimbursement control system rather than under the Medicare reimbursement principles set forth in this part, if the State system is approved by CMS. Regulations implementing this alternative reimbursement authority are set forth in subpart C of part 403 of this chapter.

(f) *Services of qualified nonphysician anesthetists.* For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, costs incurred for the services of qualified nonphysician anesthetists are not paid on a reasonable cost basis unless the provisions of § 412.113(c)(2) of this chapter apply. These services are paid under the special rules set forth in § 405.553 of this chapter.

(g) *Payment for services furnished in SNFs.* (1) Except as specified in paragraph (g)(2)(ii) of this section, the amount paid for services furnished in cost reporting periods beginning before July 1, 1998, is determined on a reasonable cost basis or, where applicable, in accordance with the prospectively determined payment rates for low-volume SNFs established under section 1888(d) of the Act, as set forth in subpart I of this part.

(2) The amount paid for services (other than those described in § 411.15(p)(2) of this chapter)—

(i) That are furnished in cost reporting periods beginning on or after July 1, 1998, to a resident who is in a covered Part A stay, is determined in accordance with the prospectively determined

payment rates for SNFs established under section 1888(e) of the Act, as set forth in subpart J of this part.

(ii) That are furnished on or after July 1, 1998, to a resident who is not in a covered Part A stay, is determined in accordance with any applicable Part B fee schedule or, for a particular item or service to which no fee schedule applies, by using the existing payment methodology utilized under Part B for such item or service.

(h) *Payment for services furnished by HHAs.* The amount paid for home health services as defined in section 1861(m) of the Act (except durable medical equipment and the covered osteoporosis drug as provided for in that section) that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter.

[51 FR 34793, Sept. 30, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 413.5 Cost reimbursement: General.

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services furnished Medicare beneficiaries

are subject to the provisions of §§413.13 and 413.30.

(b) Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.

(5) That the principles should result in the equitable treatment of both non-profit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

(c) As formulated herein, the principles given recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and an allowance for a reasonable return on equity capital (in the case of certain proprietary providers). With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) [Reserved]

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although "fringe benefit" allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

(9) Reasonable cost of physicians' direct medical and surgical services (including supervision of interns and residents in the care of individual patients) furnished in a teaching hospital may be reimbursed as a provider cost (as described in §415.162 of this chapter) if elected as provided for in §415.160 of this chapter.

(d) In developing these principles of reimbursement for the Medicare program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for Medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. Although funding of depreciation is not required,

there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

(e) A return on the equity capital of proprietary facilities, as described in § 413.157, is an allowance in addition to the reasonable cost of covered services furnished to beneficiaries.

(f) Renal dialysis items and services furnished under the ESRD provision are reimbursed and reported under §§ 413.170 and 413.174 respectively. For special rules concerning health maintenance organizations (HMOs), and providers of services and other health care facilities that are owned or operated by an HMO, or related to an HMO by common ownership or control, see §§ 417.242(b)(14) and 417.250(c) of this chapter.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 57 FR 39829, Sept. 1, 1992; 60 FR 63189, Dec. 8, 1995; 61 FR 63748, Dec. 2, 1996]

§ 413.9 Cost related to patient care.

(a) *Principle.* All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost. However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in § 413.13.

(b) *Definitions*—(1) *Reasonable cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals

not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

(c) *Application.* (1) It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution's costs are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of Medicare beneficiaries. Reasonable cost includes all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, if the provider's operating costs include amounts not related to patient care, specifically not reimbursable under the program, or flowing from the provision

of luxury items or services (that is, those items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services), such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

[51 FR 34795, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

(a) *Definitions.* As used in this section—

Customary charges means the regular rates that providers charge both beneficiaries and other paying patients for the services furnished to them.

Fair compensation means the reasonable cost of covered services.

Nominal charge means a charge equal to 60 percent or less of the reasonable cost of a service.

Public provider means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

Reasonable cost means cost actually incurred, to the extent that cost is necessary for the efficient delivery of the service, and subject to the exclusions specified in paragraph (d) of this section.

(b) *Application of the lesser of costs or charges (LCC) principle*—(1) *General rule.* Except as provided in paragraph (c) of this section, CMS pays providers the lesser of the reasonable cost or the customary charges for services furnished to Medicare beneficiaries. Reasonable cost and customary charges are compared separately for Part A services and Part B services.

(2) *Example.* (i) A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is \$125,000.

(ii) The provider's customary charges for those services is \$110,000.

(iii) CMS pays the provider \$110,000 less the deductible and coinsurance amounts for which the beneficiaries are responsible.

(c) *Exceptions to the LCC principle*—(1) *Providers not subject to the LCC principle.* CMS pays the following providers the fair compensation for the services they furnish:

(i) CORFs.

(ii) Public providers that furnish services free of charge or at a nominal charge.

(iii) Any provider that requests payment of fair compensation and can demonstrate to its contractor that a significant portion of its patients are low income and that its charges are less than costs because its customary practice is to charge patients on the basis of their ability to pay.

(2) *Services not subject to the LCC principle.* The following services are not subject to the LCC principle:

(i) *Part A inpatient hospital services.* Inpatient hospital services are not subject to the LCC principle if they are subject to either of the following:

(A) The prospective payment system under part 412 of this chapter.

(B) The rate of increase limits set forth in § 413.40.

(ii) *Facility services related to ambulatory surgical procedures performed in outpatient hospital departments.* Facility services related to ambulatory surgical procedures performed in hospital outpatient departments are subject to the payment methodology set forth in § 413.118.

(iii) *Services furnished by a critical access hospital (CAH).* Inpatient and outpatient services furnished by a CAH are subject to the payment methodology set forth in § 413.70.

(iv) *Hospital outpatient radiology services.* Hospital outpatient radiology services are subject to the payment methodology set forth in § 413.122.

(v) *Other diagnostic procedures performed by a hospital on an outpatient basis.* Other outpatient diagnostic procedures are subject to the payment methodology set forth in § 413.122.

(vi) *Skilled nursing facility services.* Skilled nursing facility services subject to the payment methodology set forth in §§ 413.330 et seq.

(vii) Services furnished by a rural emergency hospital (REH). Services furnished by a rural emergency hospital are subject to the payment methodology set forth in part 419, subpart J, of this chapter.

(d) *Exclusions from reasonable cost.* For purposes of comparison with customary charges under this section, reasonable cost does not include the following:

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts, as provided in § 413.89.

(2) Amounts that represent the recovery of excess depreciation resulting from termination from the Medicare program or a decrease in Medicare utilization applicable to prior cost reporting periods, as provided in § 413.134.

(3) Amounts that result from disposition of depreciable assets, applicable to prior cost reporting periods, as provided in § 413.134.

(4) Payments to funds for the donated services of teaching physicians, as provided in § 413.85.

(5) Except as provided in paragraph (f)(2)(iii) of this section for making nominal charge determinations in special situations, graduate medical education costs.

(e) *Reductions in customary charges.* Customary charges are reduced in proportion to the ratio of the aggregate amount actually collected from charge-paying non-Medicare patients to the amount that would have been realized had customary charges been paid, if the provider—

(1) Did not actually impose charges on most of the patients liable for payment for its services on a charge basis; or

(2) Failed to make a reasonable effort to collect those charges.

(f) *Nominal charge determinations.* In determining whether a provider's customary charges equal 60 percent or less of its reasonable costs, the following rules apply:

(1) *General rule.* The determination is based on charges actually billed to charge-paying, non-Medicare patients, and (except for clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act) is made separately for Part A services and Part B services.

(2) *Determination in special situations.*

(i) *Charges based on ability to pay.* For providers that have a sliding scale or discounted charges based on patients' ability to pay, the determination—

(A) Is based on charges billed to all charge-paying patients;

(B) Uses the ratio of the sliding scale charges to the provider's full customary charges; and

(C) Applies the ratio to the discounted charges to equate those charges to customary charges.

(ii) *HHA services.* In determining nominal charges for HHAs, all Part A and Part B services, with the exception of DME, are considered together.

(iii) *Graduate medical education.* When making the nominal charge determination, graduate medical education payments (or the provider's reasonable costs for that education, if supported by appropriate data) are included in reasonable costs.

[65 FR 8661, Feb. 22, 2000, as amended at 70 FR 47487, Aug. 12, 2005; 87 FR 72287, Nov. 23, 2022]

§ 413.17 Cost to related organizations.

(a) *Principle.* Except as provided in paragraph (d) of this section, costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

(b) *Definitions*—(1) *Related to the provider.* Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) *Common ownership.* Common ownership exists if an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) *Control.* Control exists if an individual or an organization has the

power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(c) *Application.* (1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

(d) *Exception.* (1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the contractor, that—

(i) The supplying organization is a bona fide separate organization;

(ii) A substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization;

(iii) The services, facilities, or supplies are those that commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and

(iv) The charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies.

(2) In such cases, the charge by the supplier to the provider for such services, facilities, or supplies is allowable as cost.

[51 FR 34793, Sept. 30, 1986, as amended at 81 FR 57270, Aug. 22, 2016]

Subpart B—Accounting Records and Reports

§ 413.20 Financial data and reports.

(a) *General.* The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

(b) *Frequency of cost reports.* Cost reports are required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal contractors will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

(c) *Recordkeeping requirements for new providers.* A newly participating provider of services (as defined in § 400.202 of this chapter) must make available to its selected contractor for examination

§ 413.24

42 CFR Ch. IV (10–1–24 Edition)

its fiscal and other records for the purpose of determining such provider's ongoing recordkeeping capability and inform the contractor of the date its initial Medicare cost reporting period ends. This examination is intended to assure that—

(1) The provider has an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors and adequate for cost reporting purposes under section 1815 of the Act; and

(2) No financial arrangements exist that will thwart the commitment of the Medicare program to reimburse providers the reasonable cost of services furnished beneficiaries. The data and information to be examined include cost, revenue, statistical, and other information pertinent to reimbursement including, but not limited to, that described in paragraph (d) of this section and in § 413.24.

(d) *Continuing provider recordkeeping requirements.* (1) The provider must furnish such information to the contractor as may be necessary to—

(i) Assure proper payment by the program, including the extent to which there is any common ownership or control (as described in § 413.17(b)(2) and (3)) between providers or other organizations, and as may be needed to identify the parties responsible for submitting program cost reports;

(ii) Receive program payments; and

(iii) Satisfy program overpayment determinations.

(2) The provider must permit the contractor to examine such records and documents as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due. These records include, but are not limited to, matters pertaining to—

(i) Provider ownership, organization, and operation;

(ii) Fiscal, medical, and other recordkeeping systems;

(iii) Federal income tax status;

(iv) Asset acquisition, lease, sale, or other action;

(v) Franchise or management arrangements;

(vi) Patient service charge schedules;

(vii) Costs of operation;

(viii) Amounts of income received by source and purpose; and

(ix) Flow of funds and working capital.

(3)(i) The provider must furnish the contractor, upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

(e) *Suspension of program payments to a provider.* If an contractor determines that a provider does not maintain or no longer maintains adequate records for the determination of reasonable cost under the Medicare program, payments to such provider will be suspended until the contractor is assured that adequate records are maintained. Before suspending payments to a provider, the contractor will, in accordance with the provisions in § 405.372(a) of this chapter, send written notice to such provider of its intent to suspend payments. The notice will explain the basis for the contractor's determination with respect to the provider's records and will identify the provider's recordkeeping deficiencies. The provider must be given the opportunity, in accordance with § 405.372(b) of this chapter, to submit a statement (including any pertinent evidence) as to why the suspension must not be put into effect.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63749, Dec. 2, 1996; 85 FR 59023, Sept. 18, 2020; 86 FR 45521, Aug. 13, 2021]

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting, except for—

(1) Governmental institutions which operate on a cash basis method of accounting. Cost data based on such basis

of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(2) Costs of qualified defined benefit pension plans shall be reported on a cash basis method of accounting, as described at § 413.100(c)(2)(vii)(D) for cost reporting periods beginning on or after October 1, 2011.

(b) *Definitions*—(1) *Cost finding*. Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) *Accrual basis of accounting*. As used in this part, the term *accrual basis of accounting* means that revenue is reported in the period in which it is earned, regardless of when it is collected; and an expense is reported in the period in which it is incurred, regardless of when it is paid. (See § 413.100 regarding limitations on allowable accrued costs in situations in which the related liabilities are not liquidated timely.)

(c) *Adequacy of cost information*. Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

(d) *Cost finding methods*. After the close of the accounting period, providers must use one of the following methods of cost finding to determine

the actual costs of services furnished during that period. (These provisions do not apply to SNFs that elect and qualify for prospectively determined payment rates under subpart I of this part for cost reporting periods beginning on or after October 1, 1986. For the special rules that are applicable to those SNFs, see § 413.321.) For cost reporting periods beginning after December 31, 1971, providers using the departmental method of cost apportionment must use the step-down method described in paragraph (d)(1) of this section or an "other method" described in paragraph (d)(2) of this section. For cost reporting periods beginning after December 31, 1971, providers using the combination method of cost apportionment must use the modified cost finding method described in paragraph (d)(3) of this section. Effective for cost reporting periods beginning on or after October 1, 1980, HHAs not based in hospitals or SNFs must use the step-down method described in paragraph (d)(1) of this section. (HHAs based in hospitals or SNFs must use the method applicable to the parent institution.) However, an HHA not based in a hospital or SNF that received less than \$35,000 in Medicare payment for the immediately preceding cost reporting period, and for whom this payment represented less than 50 percent of the total operating cost of the agency, may use a simplified version of the step-down method, as specified in instructions for the cost report issued by CMS.

(1) *Step-down method*. This method recognizes that services furnished by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers that they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered "closed" and no further costs are apportioned to that center. This applies even though it may have

received some service from a center whose cost is apportioned later. Generally, if two centers furnish services to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) *Other methods*—(i) *The double-apportionment method.* The double-apportionment method may be used by a provider upon approval of the contractor. This method also recognizes that the nonrevenue-producing departments or centers furnish services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of non-revenue-producing centers is made. These centers or departments are not “closed” after this preliminary allocation. Instead, they remain “open,” accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) *More sophisticated methods.* A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the contractor. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the contractor. Written request for the approval must be made on a prospective basis and must be submitted before the end of the fourth month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) *Modified cost finding for providers using the Combination Method for reporting periods beginning after December 31, 1971.* This method differs from the step-down method in that services furnished by nonrevenue-producing departments

or centers are allocated directly to revenue-producing departments or centers even though these services may be utilized by other nonrevenue-producing departments or centers. In the application of this method the cost of nonrevenue-producing centers having a common basis of allocation are combined and the total distributed to revenue-producing centers. All nonrevenue-producing centers having significant percentages of cost in relation to total costs will be allocated this way. The combined total costs of remaining nonrevenue-producing costs centers will be allocated to revenue-producing cost centers in the proportion that each bears to total costs, direct and indirect, already allocated. The bases which are to be used and the centers which are to be combined for allocation are not optional but are identified and incorporated in the cost report forms developed for this method. Providers using this method must use the program cost report forms devised for it. Alternative forms may not be used without prior approval by CMS based upon a written request by the provider submitted through the contractor.

(4) *Temporary method for initial period.* If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the contractor for permission to use some other acceptable method that would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

(5) *Simplified optional reimbursement method for small, rural hospitals with distinct parts for cost reporting periods beginning on or after July 20, 1982.* (i) A rural hospital with a Medicare-certified distinct part SNF may elect to be reimbursed for services furnished in its hospital general routine service area and distinct part SNF using the reimbursement method specified in § 413.53 for swing-bed hospitals, if it meets the following conditions:

(A) The institution is located in a rural area as defined in § 482.58 of this chapter.

(B) On the first day of the cost reporting period, the hospital and distinct part SNF have fewer than 50 beds in total (with the exception of beds for newborns and beds in intensive care type inpatient units).

(ii) In applying the optional reimbursement method, only those beds located in the hospital general routine service area and in the distinct part SNF certified by Medicare are combined into a single cost center for purposes of cost finding.

(iii) The reasonable cost of the routine extended care services is determined in accordance with §413.114(c). The reasonable cost of the hospital general routine services is determined in accordance with §413.53(a)(2).

(iv) The hospital must make its election to use the optional swing-bed reimbursement method in writing to the contractor before the beginning of the hospital's cost reporting year. The hospital must make any request to revoke the election in writing before the beginning of the affected cost reporting period.

(v) The contractor must approve requests to terminate use of the optional swing-bed reimbursement method. If a hospital terminates use of this optional method, no further elections may be made by the facility to use the optional method.

(6) *Provider-based entities and departments: Preventing duplication of cost.* In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general

service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form CMS 2552-96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.

(7) *Costs of services furnished to free-standing entities.* The costs that a provider incurs to furnish services to free-standing entities with which it is associated are not allowable costs of that provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in

an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

(e) *Accounting basis.* The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

(f) *Cost reports.* For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by CMS.

(1) *Cost reports—Terminated providers and changes of ownership.* A provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership must file a cost report for that period under the program beginning with the first day not included in a previous cost reporting period and ending with the effective date of termination of its provider agreement or change of ownership.

(2) *Due dates for cost reports.* (i) Cost reports are due on or before the last day of the fifth month following the close of the period covered by the report. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period.

(ii) Extensions of the due date for filing a cost report may be granted by the contractor only when a provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire.

(3) *Changes in cost reporting periods.* A provider may change its cost reporting

period if a change in ownership is experienced or if the—

(i) Provider requests the change in writing from its contractor;

(ii) Contractor receives the request at least 120 days before the close of the new reporting period requested by the provider; and

(iii) Contractor determines that good cause for the change exists. Good cause would not be found to exist if the effect is to change the initial date that a hospital would be affected by the rate of increase ceiling (see § 413.40), or be paid under the prospective payment systems (see part 412 of this chapter).

(4) *Electronic submission of cost reports.*

(i) As used in this paragraph (f)(4), “provider” means a hospital, rural emergency hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989, for hospitals; cost reporting periods ending on or after February 1, 1997, for skilled nursing facilities and home health agencies; cost reporting periods ending on or after December 31, 2004, for hospices, and end-stage renal disease facilities; cost reporting periods ending on or after March 31, 2005, for organ procurement organizations, histocompatibility laboratories, rural health clinics, federally qualified health centers, and community mental health centers; and cost reporting periods beginning on or after January 1, 2023, for rural emergency hospitals, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

(iii) The contractor stores the provider's as-filed electronic cost report and may not alter that file for any reason. The contractor makes a “working

copy” of the as-filed electronic cost report to be used, as necessary, throughout the settlement process (that is, desk review, processing audit adjustments, and final settlement). The provider’s electronic program must be able to disclose if any changes have been made to the as-filed electronic cost report after acceptance by the contractor. If the as-filed electronic cost report does not pass all specified edits, the contractor must return it to the provider for correction. For purposes of the requirements in paragraph (f)(2) of this section concerning due dates, an electronic cost report is not considered to be filed until it is accepted by the contractor.

(iv)(A) Effective as specified in paragraphs (f)(4)(iv)(A)(1) through (5) of this section and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(1) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(2) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997;

(3) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004;

(4) For organ procurement organizations, histocompatibility laboratories, rural health clinics, federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005; and

(5) For rural emergency hospitals, effective for cost reporting periods beginning on or after January 1, 2023.

(B) The following certification statement must immediately precede the dated original signature, or electronic signature as set forth in paragraph (f)(4)(iv)(C)(I) of this section, of the

provider’s administrator or chief financial officer:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by ____ (Provider Name(s) and Number(s)) for the cost reporting period beginning ____ and ending ____ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(C) Effective for cost reporting periods ending on or after December 31, 2017—(I) A provider that is required to file an electronic cost report may elect to electronically submit the settlement summary, if applicable, and the certification statement with an electronic signature of the provider’s administrator or chief financial officer. The following checkbox for electronic signature and submission will immediately follow the certification statement as set forth in paragraph (f)(4)(iv)(B) of this section and must be checked if electronic signature and submission is elected.

☐ I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be

the legally binding equivalent of my original signature.

(2) A provider that is required to file an electronic cost report but does not elect to electronically submit the certification statement with an electronic signature, must submit a hard copy of the settlement summary, if applicable, and a certification statement with an original signature of the provider's administrator or chief financial officer as set forth in paragraphs (f)(4)(iv)(A) and (B) of this section.

(v) A provider may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship or if the provider qualifies as a low or no Medicare utilization provider. The provider must submit a written request for delay or waiver with necessary supporting documentation to its contractor no later than 30 days after the end of its cost reporting period. The contractor reviews the request and forwards it, with a recommendation for approval or denial, to CMS central office within 30 days of receipt of the request. CMS central office either approves or denies the request and notifies the contractor within 60 days of receipt of the request.

(5) An acceptable cost report submission is defined as follows:

(i) The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. For providers claiming costs on their cost reports that are allocated from a home office or chain organization, the Home Office Cost statement must be submitted by the home office or chain organization as set forth in paragraph (f)(5)(i)(E) of this section. A cost report is rejected for lack of supporting documentation if it does not include the following, except as provided in paragraphs (f)(5)(i)(A)(2)(ii) and (f)(5)(i)(E) of this section:

(A) *Teaching hospitals.* For teaching hospitals, the Intern and Resident Information System (IRIS) data.

(1) *Data format.* For cost reporting periods beginning on or after October 1, 2021, the IRIS data must be in the new XML IRIS format.

(2) *Resident counts.* (i) Effective for cost reporting periods beginning on or

after October 1, 2021, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

(ii) For cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022, the cost report is not rejected if the requirement in paragraph (f)(5)(i)(A)(2)(i) of this section is not met.

(B) *Bad debt*—Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a detailed bad debt listing that corresponds to the amount of bad debt claimed in the provider's cost report.

(C) *DSH eligible hospitals*—Effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share hospital payment adjustment, a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, the hospital must submit an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report.

(D) *Charity care and uninsured discounts*—Effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the DSH eligible hospital's cost report.

(E) *Home office cost allocation.* (1) *Same fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with the same fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to the amounts allocated

from the home office or chain organization to the provider's cost report.

(2) *Differing fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with a different fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to some portion of the amounts allocated from the home office or chain organization to the provider's cost report.

(ii) For providers that are required to file electronic cost reports—In addition to the requirements of paragraphs (f)(4) and (f)(5)(i) of this section, the provider must submit its cost reports in an electronic cost report format in conformance with the requirements contained in the Electronic Cost Report (ECR) Specifications Manual (unless the provider has received an exemption from CMS).

(iii) The contractor makes a determination of acceptability within 30 days of receipt of the provider's cost report. If the cost report is considered unacceptable, the contractor returns the cost report with a letter explaining the reasons for the rejection. When the cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.

(g) *Exception from full cost reporting for lack of program utilization.* If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period, it is not required to submit a full cost report. It must, however, submit an abbreviated cost report, as prescribed by CMS.

(h) *Waiver of full or simplified cost reporting for low program utilization.* (1) If the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the contractor) and has received correspondingly low interim payments for the cost reporting period, the contractor may waive a full cost report or the simplified cost report described in § 413.321 if it decides that it can determine, without a full or simplified report, the reasonable cost of covered services provided during that period.

(2) If a full or simplified cost report is waived, the provider must submit within the same time period required for full or simplified cost reports:

- (i) The cost reporting forms prescribed by CMS for this situation; and
- (ii) Any other financial and statistical data the contractor requires.

(i) [Reserved]

(j) *Substantive reimbursement requirement of an appropriate cost report claim—*

(1) *General requirement.* In order for a provider to receive or potentially qualify for reimbursement for a specific item for its cost reporting period, the provider's cost report, whether determined on an as submitted, as amended, or as adjusted basis (as prescribed in paragraph (j)(3) of this section), must include an appropriate claim for the specific item, by either—

(i) Claiming full reimbursement in the provider's cost report for the specific item in accordance with Medicare policy, if the provider seeks payment for the item that it believes comports with program policy; or

(ii) Self-disallowing the specific item in the provider's cost report, if the provider seeks payment that it believes may not be allowable or may not comport with Medicare policy (for example, if the provider believes the contractor lacks the authority or discretion to award the reimbursement the provider seeks for the item), by following the procedures (set forth in paragraph (j)(2) of this section) for properly self-disallowing the specific item in the provider's cost report as a protested amount.

(2) *Self-disallowance procedures.* In order to properly self-disallow a specific item, the provider must—

(i) Include an estimated reimbursement amount for each specific self-disallowed item in the protested amount line (or lines) of the provider's cost report; and

(ii) Attach a separate work sheet to the provider's cost report for each specific self-disallowed item, explaining why the provider self-disallowed each specific item (instead of claiming full reimbursement in its cost report for the specific item) and describing how the provider calculated the estimated reimbursement amount for each specific self-disallowed item.

(3) *Procedures for determining whether there is an appropriate cost report claim.* Whether the provider's cost report for its cost reporting period includes an appropriate claim for a specific item (as prescribed in paragraph (j)(1) of this section) must be determined by reference to the cost report that the provider submits originally to, and was accepted by, the contractor for such period, provided that none of the following exceptions applies:

(i) If the provider submits an amended cost report for its cost reporting period and such amended cost report is accepted by the contractor, then whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, provided that neither of the exceptions set forth in paragraphs (j)(3)(ii) and (iii) of this section applies;

(ii) If the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the final contractor determination (as defined in § 405.1801(a) of this chapter) for the provider's cost reporting period, provided that the exception set forth in paragraph (j)(3)(iii) of this section does not apply;

(iii) If the contractor reopens either the final contractor determination for the provider's cost reporting period (pursuant to § 405.1885 of this chapter) or a revised final contractor determination for such period (issued pursuant to § 405.1889 of this chapter) and the contractor adjusts the provider's cost report with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the most recent revised final contractor determination for such period.

(4) *Reimbursement effects of contractor's determination of whether there is an appropriate cost report claim.* If the contractor determines that the provider's cost report included an appropriate claim for a specific item (as specified in paragraphs (j)(1), (2), and (3) of this section) and that all the other substantive reimbursement requirements for the specific item are also satisfied, the final contractor determination (as defined in § 405.1801(a) of this chapter) must include reimbursement for the specific item to the extent permitted by Medicare policy. If the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the specific item, the contractor must make appropriate adjustments to the provider's cost report and include reimbursement for the specific item in the final contractor determination in accordance with such cost report adjustments and to the extent permitted by program policy. If the contractor determines that the provider did not make an appropriate cost report claim for a specific item, the final contractor determination must not include any reimbursement for the specific item, regardless of whether the other substantive reimbursement requirements for the specific item are or are not satisfied.

(5) *Administrative review of whether there is an appropriate cost report claim.* If the provider files an administrative appeal (pursuant to Part 405, Subpart R of this chapter) seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in paragraphs (j)(1), (2), (3), and (4) of this section), the reviewing entity (as defined in § 405.1801(a) of this chapter) must follow the procedures prescribed in § 405.1873 of this chapter (if the appeal was filed originally with the Board), or the procedures set forth in § 405.1832 of this chapter (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item under appeal is satisfied. The reviewing

entity must follow the procedures set forth in paragraph (j)(3) of this section in determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The reviewing entity may permit reimbursement for the specific item under appeal solely to the extent authorized by § 405.1873(f) of this chapter (if the appeal was filed originally with the Board) or by § 405.1832(f) of this chapter (if the appeal was filed initially with the contractor).

[51 FR 34793, Sept. 30, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.24, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on payable costs.

(a) *Introduction*—(1) *Scope*. This section implements section 1861(v)(1)(A) of the Act by setting forth the general rules under which CMS may establish limits on SNF and HHA costs recognized as reasonable in determining Medicare program payments. It also sets forth rules governing exemptions and exceptions to limits established under this section that CMS may make as appropriate in considering special needs or situations of particular providers.

(2) *General principle*. Reimbursable provider costs may not exceed the costs CMS estimates to be necessary for the efficient delivery of needed health care services. CMS may establish estimated cost limits for direct or indirect overall costs or for costs of specific services or groups of services. CMS imposes these limits prospectively and may calculate them on a per admission, per discharge, per diem, per visit, or other basis.

(b) *Procedure for establishing limits*. (1) In establishing limits under this section, CMS may classify SNFs and HHAs by factors that CMS finds appropriate and practical, including the following:

- (i) Type of services furnished.
- (ii) Geographical area where services are furnished, allowing for grouping of

noncontiguous areas having similar demographic and economic characteristics.

(iii) Size of institution.

(iv) Nature and mix of services furnished.

(v) Type and mix of patients treated.

(2) CMS bases its estimates of the costs necessary for efficient delivery of health services on cost reports or other data providing indicators of current costs. CMS adjusts current and past period data to arrive at estimated costs for the prospective periods to which limits are applied.

(3) Before the beginning of a cost period to which revised limits will be applied, CMS publishes a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they are calculated.

(4) In establishing limits under paragraph (b)(1) of this section, CMS may find it inappropriate to apply particular limits to a class of SNFs or HHAs due to the characteristics of the SNF or HHA class, the data on which CMS bases those limits, or the method by which CMS determines the limits. In these cases, CMS may exclude that class of SNFs or HHAs from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Requests regarding applicability of cost limits*. For cost reporting periods beginning before July 1, 1998, a SNF may request an exception or exemption to the cost limits imposed under this section. An HHA may request only an exception to the cost limits. The SNF or HHA must make its request to its contractor within 180 days of the date on the contractor's notice of program reimbursement.

(1) *Home health agencies*. The contractor makes a recommendation on the HHA's request to CMS, which makes the decision. CMS responds to the request within 180 days from the date CMS receives the request from the contractor. The contractor notifies the HHA of CMS's decision. The time required by CMS to review the request is considered good cause for the granting of an extension of the time limit for requesting a contractor hearing or a Provider Reimbursement Review Board (Board) hearing as specified in

§§ 405.1813 and 405.1836 of this chapter, respectively.

(2) *Skilled nursing facility exception.* The contractor makes the final determination on the SNF's exception request and notifies the SNF of its determination within 90 days from the date that the contractor receives the request from the SNF. If the contractor determines that the SNF did not provide adequate documentation from which a proper determination can be made, the contractor notifies the SNF that the request is denied. The contractor also notifies the SNF that it has 45 days from the date on the contractor's denial letter to submit a new exception request with the complete documentation and that otherwise, the denial is the final determination. The time required by the contractor to review the request is considered good cause for the granting of an extension of the time limit for requesting a contractor hearing or a Board hearing as specified in §§ 405.1813 and 405.1836 of this chapter, respectively.

(d) *Exemptions.* Exemptions from the limits imposed under this section may be granted to a new SNF with cost reporting periods beginning before July 1, 1998 as stated in § 413.1(g)(1). The contractor makes a recommendation on the provider's request to CMS, which makes the decision. A new SNF is a provider of inpatient services that has operated as a SNF (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than 3 full years. An exemption granted under this paragraph expires at the end of the SNF's first cost reporting period beginning at least 2 years after the provider accepts its first inpatient.

(e) *Exceptions.* Limits established under this section may be adjusted upward for a SNF or HHA under the circumstances specified in paragraphs (e)(1) through (e)(5) of this section. An adjustment is made only to the extent that the costs are reasonable, attributable to the circumstances specified, separately identified by the SNF or HHA, and verified by the contractor.

(1) *Atypical services.* The SNF or HHA can show that the—

(i) Actual cost of services furnished by a SNF or HHA exceeds the applica-

ble limit because the services are atypical in nature and scope, compared to the services generally furnished by SNFs or HHAs similarly classified; and

(ii) Atypical services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) *Extraordinary circumstances.* The SNF or HHA can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquake, flood, or other unusual occurrences with substantial cost effects.

(3) *Areas with fluctuating populations.* The SNF meets the following conditions:

(i) Is located in an area (for example, a resort area) that has a population that varies significantly during the year.

(ii) Is furnishing similar services in an area for which the appropriate health planning agency has determined does not have a surplus of beds or similar services and has certified that the beds or similar services furnished by the SNF are necessary.

(iii) Meets occupancy or capacity standards established by the Secretary.

(4) *Medical and paramedical education.* The SNF or HHA can demonstrate that, if compared to other SNFs or HHAs in its group, it incurs increased costs for services covered by limits under this section because of its operation of an approved education program specified in § 413.85.

(5) *Unusual labor costs.* The SNF or HHA has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(f) *Operational review.* Any SNF or HHA that applies for an exception to the limits established under paragraph (e) of this section must agree to an operational review at the discretion of CMS. The findings from this review may be the basis for recommendations for improvements in the efficiency and economy of the SNF's or the HHA's operations. If recommendations are

made, any future exceptions are contingent on the SNF's or HHA's implementation of these recommendations.

[64 FR 42612, Aug. 5, 1999; 65 FR 60104, Oct. 10, 2000, as amended at 67 FR 48802, July 26, 2002; 73 FR 30267, May 23, 2008; 73 FR 49357, Aug. 21, 2008]

§ 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 413.30. This charge may be made only if—

(1) The contractor determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) CMS has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf

as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the contractor will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in § 413.30(e), the provider, subject to validation by the contractor, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding two years and published by SSA or CMS. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the contractor a statement indicating the charge for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The contractor may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges—(1) Establishing the charges.* If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds

the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of \$58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, that is, the reporting period starting in calendar year 1973, was \$60 per day, the provider (after first having obtained contractor validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge Medicare Part A beneficiaries up to \$2 per day for general routine services.

(2) *Adjusting cost.* Program reimbursement for the costs to which limits imposed under § 413.30 are applied in any cost reporting period will not exceed the lesser of the provider's actual cost or the limits imposed under § 413.30. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider will be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was \$57,000, the cost limit was \$58,000, and billed charges to Medicare Part A beneficiaries were \$2,000, the provider would receive \$55,000 from the program (\$57,000 actual cost minus the \$2,000 in charges to the beneficiaries).

(d) *Definition of emergency services.* For purposes of paragraph (a)(2) of this section, emergency services are those hospital services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (as determined under § 424.106 of this chapter) available and equipped

to furnish such services. If an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) *Identification of charges to individual.* For purposes of paragraph (a)(5) of this section, a provider must give or send to the individual or his representative, a schedule of all items and services that the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule must specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare and include such other information as CMS considers necessary to protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, must give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

[51 FR 34793, Sept. 30, 1986, as amended at 53 FR 6648, Mar. 20, 1988; 60 FR 45849, Sept. 1, 1995]

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

(a) *Introduction*—(1) *Scope.* This section implements section 1886(b) of the Act, establishing a ceiling on the rate of increase in operating costs per case for hospital inpatient services furnished to Medicare beneficiaries that will be recognized as reasonable for purposes of determining the amount of Medicare payment. This rate-of-increase ceiling applies to hospital cost reporting periods beginning on or after October 1, 1982. This section also sets forth rules governing exemptions from and adjustments to the ceiling.

(2) *Applicability.* (i) This section is not applicable to—

(A) Hospitals reimbursed in accordance with section 1814(b)(3) of the Act or under State reimbursement control systems that have been approved under

section 1886(c) of the Act and subpart C of part 403 of this chapter; or

(B) Hospitals that are paid under the prospective payment systems for inpatient hospital services in accordance with section 1886 (d) and (g) of the Act and part 412 of this chapter.

(C) Psychiatric hospitals and psychiatric units that are paid under the prospective payment system for inpatient psychiatric facilities described in subpart N of part 412 of this chapter for cost reporting periods beginning on or after January 1, 2005.

(D) Rehabilitation hospitals and rehabilitation units that are paid under the prospective payment system for inpatient hospital services in accordance with section 1886(j) of the Act and subpart P of part 412 of this subchapter for cost reporting periods beginning on or after January 1, 2002.

(E) Long-term care hospitals, as defined in section 1886(d)(1)(B)(iv) of the Act, that are paid based on 100 percent of the Federal prospective payment rate for inpatient hospital services in accordance with section 123 of Public Law 106-113 and section 307 of Public Law 106-554 and § 412.533(b) and (c) of subpart O of part 412 of this subchapter for cost reporting periods beginning on or after October 1, 2002.

(ii) For cost reporting periods beginning on or after October 1, 1983, this section applies to—

(A) Hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter;

(B) Psychiatric and rehabilitation units excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter and in accordance with § 412.25 through § 412.30 of this chapter, except as limited by paragraphs (a)(2)(iii) and (a)(2)(iv) of this section with respect to psychiatric and rehabilitation hospitals and psychiatric and rehabilitation units as specified in §§ 412.22, 412.23, 412.25, 412.27, 412.29 and 412.30 of this chapter.

(C) Long-term care hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter and in accordance with § 412.23 of this subchapter, except as limited by paragraph (a)(2)(v) of this section with respect to long-term care

hospitals specified in § 412.23(e) of this subchapter.

(iii) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2005 this section applies to psychiatric hospitals and psychiatric units that are excluded from the prospective payment systems as specified in § 412.1(a)(1) of this chapter and paid under the prospective payment system as specified in § 412.1(a)(2) of this chapter.

(iv) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2002, this section applies to rehabilitation hospitals and rehabilitation units that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter.

(v) For cost reporting periods beginning on or after October 1, 1983 and before October 1, 2002, this section applies to long-term care hospitals that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter. For cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, this section also applies to long-term care hospitals, subject to paragraph (a)(2)(i)(D) of this section.

(3) *Definitions.* As used in this section—

Ceiling is the aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that the program will recognize for payment purposes. For each cost reporting period, the ceiling is determined by multiplying the updated target amount, as defined in this paragraph, for that period by the number of Medicare discharges during that period. For a hospital-within-a-hospital, as described in § 412.22(e) of this chapter, the number of Medicare discharges in a cost reporting period does not include discharges of a patient to another hospital in the same building on or on the same campus, if—

(A) The patient is subsequently readmitted to the hospital-within-a-hospital directly from the other hospital; and

(B) The hospital-within-a-hospital has discharged to the other hospital and subsequently readmitted more than 5 percent (that is, in excess of 5.0

percent) of the total number of Medicare inpatients discharged from the hospital-within-a-hospital in that cost reporting period.

Date of discharge is the earliest of the following dates:

(A) The date the patient has exhausted Medicare Part A hospital inpatient benefits (including the election to use lifetime reserve days) during his or her spell of illness.

(B) The date the patient is formally released as specified in § 412.4(a)(1) of this chapter.

(C) The date the patient is transferred to another facility.

(D) The date the patient dies.

Market basket index is CMS's projection of the annual percentage increase in hospital inpatient operating costs. The market basket index is a wage and price index that incorporates weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of hospital inpatient operating costs subject to the ceiling, as described in paragraph (c)(1) of this section.

Net inpatient operating costs include the costs of certain preadmission services as specified in paragraph (c)(2) of this section, the costs of routine services, ancillary services, and intensive care services (as defined in § 413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in § 413.130, the costs of approved medical education programs as described in §§ 413.75 through 413.83 and 413.85, and organ acquisition costs as specified in subpart L of this part incurred by approved transplant programs. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

Rate-of-increase percentage is the percentage by which each hospital's target amount from the preceding Federal fiscal year is increased.

Target amount is the per discharge (case) limitation, derived from the hospital's allowable net Medicare inpatient operating costs in the hospital's base year, and updated for each subsequent hospital cost reporting period by

the appropriate annual rate-of-increase percentage.

Update adjustment percentage is the percentage by which a hospital's allowable inpatient operating service costs for the 12-month cost reporting period beginning in Federal fiscal year 1990 exceeds the hospital's ceiling for that period.

Update factor is the decimal equivalent of the rate-of-increase percentage. The update factor is the value by which a hospital's target amount for the preceding year is multiplied in order to determine the target amount for the following year. For example, if the rate-of-increase percentage for a year is 2.7 percent, the update factor for that year is 1.027.

(b) *Cost reporting periods subject to the rate-of-increase ceiling*—(1) *Base period*. Each hospital's target amount is based on its allowable net inpatient operating costs per case from the cost reporting period of at least 12 months immediately preceding the first cost reporting period subject to the rate-of-increase ceiling established under this section. If the immediately preceding cost reporting period is a short reporting period (fewer than 12 months), the first period of at least 12 months subsequent to that short period is the base period.

(i) The target amount established under this provision remains applicable to a hospital or excluded hospital unit, as described in §§ 412.25 through 412.30 of this chapter, despite intervening cost reporting periods during which the hospital or excluded hospital unit is not subject to the ceiling as a result of other provisions of the law or regulations, or nonparticipation in the Medicare program, unless the hospital or excluded hospital unit qualifies as a new hospital or excluded part hospital unit under the provisions of paragraph (f) of this section.

(ii) The base period for a newly established excluded unit is the first cost reporting period of at least 12 months following the unit's certification to participate in the Medicare program.

(iii) When the operational structure of a hospital or unit changes (that is, a freestanding hospital becomes an excluded unit or an excluded unit becomes a freestanding hospital, or an

entity of a multicampus hospital becomes a newly created hospital or unit or a hospital or unit becomes a part of a multicampus hospital), the base period for the hospital or unit that changed its operational structure is the first cost reporting period of at least 12 months effective with the revised Medicare certification classification.

(iv) *Request for rebased target amount for the cost reporting period beginning on or after October 1, 1997 and on or before September 30, 1998.* Except for qualified long-term care hospitals as defined in paragraph (b)(1)(v) of this section, each hospital or unit under present or previous ownership that received payment under section 1886(b) of the Act during cost reporting periods beginning before October 1, 1990, may submit a request to its contractor to rebase its target amount. The request must be received by the contractor by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased target amount for the cost reporting period beginning during fiscal year 1998 is determined as follows:

(A) Determine the hospital's inpatient operating costs per case for each of the five most recent settled cost reports as of August 5, 1997.

(B) For each of the five cost reports, update the operating costs per case by the applicable update factors up to the hospital's cost reporting period beginning during FY 1998.

(C) Exclude the highest and lowest of the five updated amounts determined under paragraph (b)(1)(iv)(B) of this section.

(D) Compute the average for the remaining three updated amounts for operating cost per case.

(v) *Request by qualified long-term care hospital.* A qualified long-term care hospital may file a request to its contractor for a rebased FY 1998 target amount. The request must be received by the contractor by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased FY 1998 target amount is the hospital's FY 1996 inpatient operating costs updated to FY 1997. A qualified long-term care hospital means a long-

term care hospital that meets the following two conditions for its two most recent settled cost reports as of August 5, 1997:

(A) Its Medicare inpatient operating costs exceed 115 percent of the ceiling.

(B) The hospital would have had a disproportionate patient percentage (as defined in § 412.106) equal to or greater than 70 percent if it were a prospective payment hospital.

(2) *Periods subject to the ceiling.* The ceiling established under this section applies to all cost reporting periods that—

(i) Begin on or after October 1, 1982; and

(ii) Immediately follow the base period established under paragraph (b)(1) of this section unless the exception in paragraph (b)(3) of this section is applicable.

(3) *Periods of other than 12 months.* The ceiling established under this section does not apply to cost reporting periods of fewer than 12 months that occur in conjunction with a change in operation of the facility, as defined in paragraph (b)(1)(iii) of this section, as a result of changes in ownership, merger, or consolidation. However, the ceiling applies to cost reporting periods of fewer than 12 months that result solely from the approval of a hospital's request for a change in accounting cycle, as specified in § 413.24(f)(3).

(c) *Costs subject to the ceiling—(1) Applicability.* The ceiling established under this section applies to net operating costs incurred by a hospital in furnishing inpatient hospital services to Medicare beneficiaries.

(2) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the calendar day immediately preceding the date of the beneficiary's admission to the hospital that meet the condition specified in paragraph (c)(2)(i) of this section and at least one of the conditions specified in paragraphs (c)(2)(ii) through (c)(2)(iv):

(i) The services are furnished by the hospital or any entity wholly owned or operated by the hospital. An entity is wholly owned by the hospital if the hospital is the sole owner of the entity.

An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.

(ii) For services furnished after January 1, 1991, the services are diagnostic (including clinical diagnostic laboratory tests).

(iii) For services furnished on or after October 1, 1991 through June 24, 2010, the services are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient and are not the following:

(A) Ambulance services.

(B) Maintenance renal dialysis services.

(iv) Nondiagnostic services furnished on or after June 25, 2010, other than ambulance services and maintenance renal dialysis services, that are furnished on the date of the beneficiary's inpatient admission or on the calendar day immediately preceding the date of the beneficiary's inpatient admission and the hospital does not attest that such services are unrelated to the beneficiary's inpatient admission.

(3) *Rate-of-increase percentages and update factors.* The applicable rate-of-increase percentages and update factors are determined as follows:

(i) *Federal fiscal year 1986.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1985 and before September 30, 1986 is five twenty-fourths of one percent, and the update factor is 1.00208333. For purposes of determining the target amount for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase for cost reporting periods beginning during Federal fiscal year 1986 is deemed to have been one-half percent, and the update factor is 1.005.

(ii) *Federal fiscal year 1987.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1986 and before September 30, 1987 is 1.15 percent; the update factor is 1.0115.

(iii) *Federal fiscal year 1988.* The applicable rate-of-increase percentage for cost reporting periods beginning on or

after October 1, 1987 and before October 1, 1988 is 2.3238 percent; the update factor is 1.023238. For purposes of updating the target amount for cost reporting periods beginning on or after October 1, 1988, the rate-of-increase percentage for cost reporting periods beginning during FY 1988 is deemed to have been 2.7 percent; the update factor is deemed to have been 1.027.

(iv) *Federal fiscal year 1989 through Federal fiscal year 1993.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1988, and before October 1, 1993, is the percentage increase projected by the hospital market basket index (as defined in paragraph (a)(3) of this section).

(v) *Federal fiscal year 1994 through Federal fiscal year 1997.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1993, and before October 1, 1998, is the market basket percentage increase minus the lesser of, 1 percentage point, or the percentage point difference between 10 percent and the hospital's "update adjustment percentage" (as defined in paragraph (a)(3) of this section); for hospitals with an "update adjustment percentage" of at least 10 percent, the applicable rate-of-increase percentage is the market basket percentage increase. The "update adjustment percentage" is increased in each Federal fiscal year by the sum of the hospital's applicable reductions applied to the market basket percentage increase for previous Federal fiscal years.

(vi) *Federal fiscal year 1998.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1997 is 0 percent.

(vii) *Federal fiscal year 1999 through Federal fiscal year 2002.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1998, and before October 1, 2002, based on data from the most recent available cost report, is:

(A) The percentage increase in the market basket, if inpatient operating costs are equal to or exceed the ceiling amount by 10 percent or more of the ceiling.

(B) The percentage increase in the market basket minus .25 percentage

points for each percentage point by which inpatient operating costs are less than 10 percent over the ceiling (but not less than 0), if inpatient operating costs exceed the ceiling by less than 10 percent of the ceiling.

(C) The greater of the percentage increase in the market basket minus 2.5 percentage points or 0 percent, if inpatient operating costs are equal to or less than the ceiling but greater than 66.7 percent of the ceiling.

(D) 0 percent, if inpatient operating costs do not exceed 66.7 percent of the ceiling.

(viii) *Federal fiscal year 2003 and following.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 2002, is the percentage increase projected by the hospital market basket index.

(4) *Target amounts.* The contractor will establish a target amount for each hospital. The target amount for a cost reporting period is determined as follows:

(i) Except as provided in paragraph (c)(4)(iv) of this section, and subject to the provisions of paragraph (c)(4)(iii) of this section, for the first cost reporting period to which this ceiling applies, the target amount equals the hospital's allowable net inpatient operating costs per case for the hospital's base period increased by the update factor for the subject period.

(ii) Subject to the provisions of paragraph (c)(4)(iii) of this section, for subsequent cost reporting periods, the target amount equals the hospital's target amount for the previous cost reporting period increased by the update factor for the subject cost reporting period, unless the provisions of paragraph (c)(5)(ii) of this section apply.

(iii) For cost reporting periods beginning on or after October 1, 1997 through September 30, 2002, in the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the target amount is the lower of the amounts specified in paragraph (c)(4)(iii)(A) or paragraph (c)(4)(iii)(B) of this section.

(A) The hospital-specific target amount.

(I) In the case of all hospitals and units, except long-term care hospitals for cost reporting periods beginning

during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors.

(2) In the case of long-term care hospitals, for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

(B) One of the following for the applicable cost reporting period—

(I) For cost reporting periods beginning during fiscal year 1998, the 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1997.

(2) For cost reporting periods beginning during fiscal year 1999, the amount determined under paragraph (c)(4)(iii)(B)(I) of this section, increased by the market basket percentage up through the subject period, subject to the provisions of paragraph (c)(4)(iv) of this section.

(3) For cost reporting periods beginning during fiscal year 2000—

(i) The labor-related portion and the nonlabor-related portion of the wage-neutralized 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, are increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1999.

(ii) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(4)(i) of this section is wage adjusted by multiplying it by the hospital's FY 2000 hospital inpatient prospective payment system wage index.

(iii) The wage-adjusted 75th percentile target amounts for hospitals in the same class is determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph

(c)(4)(iii)(B)(3)(i) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(3)(ii) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(4) For cost reporting periods beginning during fiscal years 2001 and 2002—

(i) The amounts determined under paragraph (c)(4)(iii)(B)(3)(i) of this section are: increased by the market basket percentage up through the subject period; or in the case of a long-term care hospital for cost reporting periods beginning during FY 2001, the amounts determined under paragraph (c)(4)(iii)(B)(3)(i) of this section, increased by the market basket percentage up through the subject period and further increased by 2 percent.

(ii) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(4)(i) of this section is wage-adjusted by multiplying by the hospital's FY 2001 hospital inpatient prospective payment system wage index, for cost reporting periods beginning during fiscal year 2001 and the hospital's FY 2002 hospital inpatient prospective payment system wage index for cost reporting periods beginning during fiscal year 2002.

(iii) The wage-adjusted 75th percentile target amounts for hospitals in the same class are determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(4)(i) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(4)(ii) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(iv) For purposes of the limits on target amounts established under paragraph (c)(4)(iii) of this section, each hospital or unit that qualifies for exclusion as a member of only one class of excluded facility (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) will be subject to the limit applicable to that class. If a hospital or unit qualifies to be classified in more than one way under the exclusion criteria in

subpart B of part 412 of this chapter, the hospital's or unit's target amount may not exceed the lowest applicable limit.

(v) In the case of a hospital that received payments under paragraph (f)(2)(ii) of this section as a newly created hospital or unit, to determine the hospital's target amount for the hospital's third 12-month cost reporting period, the payment amount determined under paragraph (f)(2)(ii)(A) of this section for the preceding cost reporting period is updated to the third cost reporting period.

(5) *Applicable update factor.* (i) The applicable update factor is derived from the prospectively determined rate-of-increase percentage published by CMS. The update factor for each Federal fiscal year is applied prospectively to the target amount for each cost reporting period beginning during the Federal fiscal year.

(ii) In the case of cost reporting periods of less than 12 months, the target amount determined for a hospital's first cost reporting period beginning in a Federal fiscal year applies to subsequent periods beginning in the same Federal fiscal year.

(d) *Application of the target amount in determining the amount of payment—*(1) *General process.* (i) At the end of each cost reporting period subject to this section, the hospital's contractor will compare a hospital's allowable net inpatient operating costs with that hospital's ceiling (as defined in paragraph (a)(3) of this section) for that period.

(ii) The hospital's actual allowable costs will be determined without regard to the lesser of cost or charges provisions of § 413.13, and in accordance with the provisions of paragraphs (d)(2) or (d)(3) of this section, as applicable.

(2) *Net inpatient operating costs are less than or equal to the ceiling.* (i) For cost reporting periods beginning on or after October 1, 1997, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient operating costs plus 2 percent of the ceiling.

(ii) For psychiatric hospitals and units, for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2001, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient costs plus 3 percent of the ceiling.

(3) *Net inpatient operating costs are greater than the ceiling.* For cost reporting periods beginning on or after October 1, 1997—

(i) If a hospital's allowable net inpatient operating costs do not exceed 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable);

(ii) If a hospital's allowable net inpatient operating costs are greater than 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable) plus the lesser of:

(A) 50 percent of the allowable net inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable); or

(B) 10 percent of the ceiling (or the adjusted ceiling, if applicable).

(4) *Continuous improvement bonus payments.* (i) For cost reporting periods beginning on or after October 1, 1997, eligible hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1 percent of the ceiling.

(ii) For cost reporting periods beginning on or after October 1, 2000, and before September 30, 2001, eligible psychiatric hospitals and units and long-term care hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applica-

ble. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1.5 percent of the ceiling.

(iii) For cost reporting periods beginning on or after October 1, 2001, and before September 30, 2002, eligible psychiatric hospitals and units and long-term care hospitals receive payments in addition to those in paragraph (d)(5) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 2 percent of the ceiling.

(5) *Eligibility requirements for continuous improvement bonus payments.* To qualify, a hospital must have been paid as a prospective payment excluded hospital for at least three full cost reporting periods prior to the applicable period, and the hospital's operating costs per discharge for the period must be less than the least of the following:

(i) The hospital's target amount.

(ii) The hospital's trended costs.

(A) For a hospital for which its cost reporting period ending during fiscal year 1996 was its third or subsequent full cost reporting period, trended costs are the lesser of the allowable inpatient operating costs per discharge or the target amount for the cost reporting period ending in fiscal year 1996, increased in a compounded manner for each succeeding fiscal year by the market basket percentage increase;

(B) For all other hospitals, trended costs are the allowable inpatient operating costs per discharge for its third full cost reporting period increased in a compounded manner for each succeeding fiscal year by the market basket increase.

(iii) The hospital's expected costs. The hospital's expected costs are the lesser of its allowable inpatient operating costs per discharge or the target amount for the previous cost reporting period, updated by the market basket percentage increase for the fiscal year.

(e) *Hospital requests regarding adjustments to the payment allowed under the rate-of-increase ceiling—(1) Timing of application.* A hospital may request an adjustment to the rate-of-increase ceiling

imposed under this section. The hospital's request must be received by the hospital's contractor no later than 180 days after the date on the contractor's initial notice of amount of program reimbursement (NPR) for the cost reporting period for which the hospital requests an adjustment.

(2) *Contractor recommendation.* Unless CMS has authorized the contractor to make the decision, the contractor makes a recommendation on the hospital's request to CMS, which makes the decision. CMS issues a decision to the contractor no later than 180 days after receipt of the completed application and the contractor's recommendation.

(3) *Contractor decision.* If CMS has authorized the contractor to make the decision, the contractor issues a decision no later than 180 days after receipt of the completed application.

(4) *Notification and review.* (i) The contractor notifies the hospital of the decision, including a full explanation of the grounds for the decision. A decision issued under paragraph (e)(2) or (e)(3) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the contractor's notice of the decision.

(ii) The final decision is subject to review under the provider reimbursement determination and appeal procedures in subpart R of part 405 of this chapter, provided the hospital has received an NPR for the cost reporting period in question, and the NPR disallows costs for which the hospital had requested an adjustment (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(5) *Extending the time limit for review of NPR.* The time required to review the request is considered good cause for the granting of an extension of the time limit for requesting a contractor hearing or a Board hearing as specified in §§ 405.1813 and 405.1836 of this chapter, respectively.

(6) *Applicability.* The provisions in paragraphs (e)(1) through (e)(5) of this section apply to a hospital's initial request for an adjustment and to a re-

quest for a review of the original decision based on additional data.

(f) *Comparison to the target amount for new hospitals and units—*(1) *New hospitals and units—*(i) *New hospitals.* For purposes of this section, a new hospital is a provider of hospital inpatient services that—

(A) Has operated as the type of hospital for which CMS granted it approval to participate in the Medicare program, under present or previous ownership (or both), for less than 2 full years; and

(B) Has provided the type of hospital inpatient services for which CMS granted it approval to participate in the Medicare program, for less than 2 years.

(ii) *New units.* A newly established unit that is excluded from the prospective payments system under the provisions of §§ 412.25 through 412.30 of this chapter does not qualify for the exemption afforded to a new hospital under paragraph (f)(2)(i) of this section unless the unit is located in an acute care hospital that, if it were subject to the provisions of this section, would qualify as a new hospital under paragraph (f)(1)(i) of this section.

(2) *Comparison—*(i) *Exemptions.* (A) A new children's hospital is exempt from the rate-of-increase ceiling imposed under this section. The exemption begins when the hospital accepts its first patient and ends at the end of the first cost reporting period ending at least 2 years after the hospital accepts its first patient. The first cost reporting period of at least 12 months beginning at least 1 year after the hospital accepts its first patient is the base year, in accordance with paragraph (b) of this section.

(B) Within 180 days of the date a hospital is excluded from the prospective payment system, the contractor determines whether the hospital is exempt from the rate-of-increase ceiling. The contractor notifies the hospital of its determination and the hospital's base period.

(C) A decision issued under paragraph (f)(2)(ii)(B) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the contractor's

notice of the decision. The final decision is subject to review under subpart R of part 405 of this chapter, provided the hospital has received a notice of program reimbursement (NPR) for the cost reporting period in question and the NPR does not reflect an exemption (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(ii) *Median target amount.* (A) For cost reporting periods beginning on or after October 1, 1997, the amount of payment for a new psychiatric hospital or unit, a new rehabilitation hospital or unit, or a new long-term care hospital that was not paid as an excluded hospital prior to October 1, 1997, is the lower of the hospital's net inpatient operating cost per case or 110 percent of the national median of the target amounts for the class of excluded hospitals and units (psychiatric, rehabilitation, long-term care) as adjusted for differences in wage levels and updated to the first cost reporting period in which the hospital receives payment. The second cost reporting period is subject to the same target amount as the first cost reporting period.

(B) The national median of the target amounts is the FY 1996 median target amount—

(1) Adjusted to account for differences in area wage levels;

(2) Updated by the market basket percentage increase to the fiscal year in which the hospital first received payments as an excluded provider.

(3) *Risk-basis HMOs.* Items or services that are furnished to beneficiaries enrolled in an HMO by a hospital that is either owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control are exempt from the rate-of-increase ceiling (see the definition of an entity with a risk sharing contract in § 417.401 of this chapter).

(g) *Adjustments*—(1) *General rules.* (i) CMS adjusts the amount of the operating costs considered in establishing the rate-of-increase ceiling for one or more cost reporting periods, including both periods subject to the ceiling and the hospital's base period, under the circumstances specified in paragraphs (g)(2), (g)(3), and (g)(4) of this section.

(ii) When the hospital requests an adjustment, CMS makes an adjustment only to the extent that the hospital's operating costs are reasonable, attributable to the circumstances specified separately, identified by the hospital, and verified by the contractor.

(iii) When the hospital requests an adjustment, CMS makes an adjustment only if the hospital's operating costs exceed the rate-of-increase ceiling imposed under this section.

(iv) In the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the amount of payment under paragraph (g)(3) of this section may not exceed the payment amount based on the target amount determined under paragraph (c)(4)(iii) of this section.

(v) In the case of a hospital or unit that received a revised FY 1998 target amount under the rebasing provisions of paragraph (b)(1)(iv) of this section, the amount of an adjustment payment for a cost reporting period is based on a comparison of the hospital's operating costs for the cost reporting period to the average costs and statistics for the cost reporting periods used to determine the FY 1998 rebased target amount.

(2) *Extraordinary circumstances.* CMS may make an adjustment to take into account unusual costs (in either a cost reporting period subject to the ceiling or the hospital's base period) due to extraordinary circumstances beyond the hospital's control. These circumstances include, but are not limited to, strikes, fire, earthquakes, floods, or similar unusual occurrences with substantial cost effects.

(3) *Comparability of cost reporting periods*—(i) *Adjustment for distortion.* CMS may make an adjustment to take into account factors that would result in a significant distortion in the operating costs of inpatient hospital services between the base year and the cost reporting period subject to the limits.

(ii) *Factors.* The adjustments described in paragraph (g)(3)(i) of this section, include, but are not limited to, adjustments to take into account:

(A) FICA taxes (if the hospital did not incur costs for FICA taxes in its base period).

(B) Services billed under part B of Medicare during the base period, but paid under part A during the subject cost reporting period.

(C) Malpractice insurance costs (if malpractice costs were not included in the base year operating costs).

(D) Increases in service intensity or length of stay attributable to changes in the type of patient served.

(E) A change in the inpatient hospital services that a hospital provides, and that are customarily provided directly by similar hospitals, such as an addition or discontinuation of services or treatment programs.

(F) The manipulation of discharges to increase reimbursement.

(iii) *Adjusting operating costs.* Without a formal request from a hospital, CMS may adjust the amount of operating costs determined under paragraph (c)(1) of this section to take into account certain adjustments. These adjustments include, but are not limited to, adjustments under paragraphs (g)(3)(ii)(A), (B), (C), (E), and (F) of this section.

(4) *Significant wage increase.* (i) *Criteria.* CMS may make an adjustment to take into account a significant increase in wages occurring between the base period and the cost reporting period subject to the ceiling if there is a significant increase in the average hourly wage for the geographic area in which the hospital is located (determined by reference to the wage index for prospective payment hospitals without regard to geographic reclassifications under sections 1886(d)(8) and (10) of the Act). For this purpose, there is a significant wage increase if the wage index value based on wage survey data collected for the cost reporting period subject to the ceiling is at least 8.0 percent higher than the wage index value based on survey data collected for the base year cost reporting period. If survey data are not available for the cost reporting periods used in the comparison, the wage index value based on the latest available survey data collected prior to that cost reporting period is used.

(ii) *Amount of the adjustment.* The adjustment for a significant wage increase equals the amount by which the lesser of the following calculations ex-

ceeds 108 percent of the increase in the national average hourly earnings for hospital workers:

(A) The rate of increase in the average hourly wage in the geographic area (determined by applying the applicable increase in the area wage index value to the rate of increase in the national average hourly earnings for hospital workers).

(B) The rate of increase in the hospital's average hourly wage.

(5) *Adjustment limitations.* For cost reporting periods beginning on or after October 1, 1993, and before October 1, 2003, the payment reductions under paragraph (c)(3)(v) through (c)(3)(vii) of this section will not be considered when determining adjustments under this paragraph.

(h) [Reserved]

(i) *Assignment of a new base period—*(1) *General rule.* (i) Effective with cost reporting periods beginning on or after April 1, 1990, CMS may assign a new base period to establish a revised ceiling if the new base period is more representative of the reasonable and necessary cost of furnishing inpatient services and all the following conditions apply:

(A) The actual allowable inpatient costs of the hospital in the cost reporting period that would be affected by the revised ceiling exceed the target amount established under paragraph (c) of this section.

(B) The hospital documents that the higher costs are the result of substantial and permanent changes in furnishing patient care services since the base period. In making this determination, CMS takes into consideration the following factors:

(1) Changes in the services provided by the hospital.

(2) Changes in applicable technologies and medical practices.

(3) Differences in the severity of illness among patients or types of patients served.

(C) The adjustments described in paragraph (g) of this section would not result in recognition of the reasonable and necessary costs of providing inpatient services.

(ii) The revised ceiling is based on the necessary and proper costs incurred during the new base period.

(A) Increases in overhead costs (for example, administrative and general costs and housekeeping costs) are not taken into consideration unless the hospital documents that these increases result from substantial and permanent changes in furnishing patient care services.

(B) In determining whether wage increases are necessary and proper, CMS takes into consideration whether increases in wages and wage-related costs for hospitals in the labor market area exceed the national average increase.

(2) *New base period.* The new base period is the first cost reporting period that is 12 months or longer that reflects the substantial and permanent change.

(3) *New applicable rate-of-increase percentages and update factors.* The revised target amount resulting from the assignment of a new base period is increased by the applicable rate-of-increase percentages (update factors) described in paragraph (c)(3) of this section.

(j) *Reduction to capital-related costs.* For psychiatric hospital and units, rehabilitation hospitals and units, and long-term care hospitals, the amount otherwise payable for capital-related costs for hospital inpatient services is reduced by 15 percent for portions of cost reporting periods occurring on or after October 1, 1997 through September 30, 2002.

[58 FR 46340, Sept. 1, 1993]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.40, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

Subpart D—Apportionment

§ 413.50 Apportionment of allowable costs.

(a) Consistent with prevailing practice in which third-party organizations pay for health care on a cost basis, reimbursement under the Medicare program involves a determination of—

(1) Each provider's allowable costs for producing services; and

(2) The share of these costs which is to be borne by Medicare. The provider's costs are to be determined in accordance with the principles reviewed in

the preceding discussion relating to allowable costs. The share to be borne by Medicare is to be determined in accordance with principles relating to apportionment of cost.

(b) In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under Medicare that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to non-beneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

(c) A basic factor bearing upon apportionment of costs is that Medicare beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the Medicare share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients serviced by the provider.

(d) The method of cost reimbursement most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average-per-diem cost, does not take into account, variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

(e) In considering the average-per-diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance

of presently available evidence strongly indicates that the over-age 65 patient is not typical from the standpoint of average-per-diem cost. On the average this patient stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average-per-diem cost for the aged alone, significantly below the average-per-diem for all patients.

(f) Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only for services to beneficiaries.

(g) A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

(h) An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs in which individuals are indemnified for incurred expenses, a form of health insurance widely held throughout the United States. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay “costs or charges, whichever is less” and some of which pay exclusively on the basis of charges. In all of these instances, the provider’s own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a meas-

ure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider’s services.

(i) An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods that utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider’s total charges to all patients is used to determine the proportion of the provider’s total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider’s activities for which the amount of costs and charges are ascertained through a breakdown of data from the provider’s accounting records.

(j) For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by “cost-finding” techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are furnished.

§ 413.53 Determination of cost of services to beneficiaries.

(a) *Principle.* Total allowable costs of a provider will be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. The methods of apportionment are defined as follows:

(1) *Departmental method*—(i) *Methodology.* Except as provided in paragraph (a)(1)(ii) of this section with respect to the treatment of the private room cost differential for cost reporting periods starting on or after October 1, 1982, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas as

defined in paragraph (b) of this section, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units.

(ii) *Exception: Indirect cost of private rooms.* For cost reporting periods starting on or after October 1, 1982, except with respect to a hospital receiving payment under part 412 of this chapter (relating to the prospective payment system), the additional cost of furnishing services in private room accommodations is apportioned to Medicare only if these accommodations are furnished to program beneficiaries, and are medically necessary. To determine routine service cost applicable to beneficiaries—

(A) Multiply the average cost per diem (as defined in paragraph (b) of this section) by the total number of Medicare patient days (including private room days whether or not medically necessary);

(B) Add the product of the average per diem private room cost differential (as defined in paragraph (b) of this section) and the number of medically necessary private room days used by beneficiaries; and

(C) Effective October 1, 1990, do not include private rooms furnished for SNF-type and NF-type services under the swing-bed provision in the number of days in paragraphs (a)(1)(ii)(A) and (B) of this section.

(2) *Carve-out method.* (i) The carve-out method is used to allocate hospital inpatient general routine service costs in a participating swing-bed hospital, as defined in § 413.114(b). Under this method, effective for services furnished on or after October 1, 1990, the reasonable costs attributable to the inpatient routine SNF-type and NF-type services furnished to all classes of patients are subtracted from total inpatient routine service costs before computing the average cost per diem for inpatient routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services covered by Medicare is based on the regional Medicare swing-bed SNF rate in effect for a given calendar year, as described in § 413.114(c). The Medicare SNF rate applies only to days covered and paid

as Medicare days. When Medicare coverage runs out, the Medicare rate no longer applies.

(iii) The cost per diem attributable to all non-Medicare swing-bed days is based on the average statewide Medicaid NF rate for the prior calendar year, adjusted to approximate the average NF rate for the current calendar year.

(iv) The sum of total Medicare SNF-type days multiplied by the cost per diem attributable to Medicare SNF-type services and the total NF-type days multiplied by the cost per diem attributable to all non-Medicare days is subtracted from total inpatient general routine service costs. The cost per diem for inpatient routine hospital care is computed based on the remaining inpatient routine service costs.

(3) *Cost per visit by type-of-service method—HHAs.* For cost reporting periods beginning on or after October 1, 1980, all HHAs must use the cost per visit by type-of-service method of apportioning costs between Medicare and non-Medicare beneficiaries. Under this method, the total allowable cost of all visits for each type of service is divided by the total number of visits for that type of service. Next, for each type of service, the number of Medicare covered visits is multiplied by the average cost per visit just computed. This represents the cost Medicare will recognize as the cost for that service, subject to cost limits published by CMS (see § 413.30).

(b) *Definitions.* As used in this section—

Ancillary services means the services for which charges are customarily made in addition to routine services.

Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the Medicare program and other patients.

Average cost per diem for general routine services means the following:

(1) For cost reporting periods beginning on or after October 1, 1982, subject to the provisions on swing-bed hospitals, the average cost of general routine services net of the private room cost differential. The average cost per diem is computed by the following methodology:

(i) Determine the total private room cost differential by multiplying the average per diem private room cost differential determined in paragraph (c) of this section by the total number of private room patient days.

(ii) Determine the total inpatient general routine service costs net of the total private room cost differential by subtracting the total private room cost differential from total inpatient general routine service costs.

(iii) Determine the average cost per diem by dividing the total inpatient general routine service cost net of private room cost differential by all inpatient general routine days, including total private room days.

(2) For swing-bed hospitals, the amount computed by—

(i) Subtracting the routine costs associated with Medicare SNF-type days and non-Medicare NF-type days from the total allowable inpatient cost for routine services (excluding the cost of services provided in intensive care units, coronary care units, and other intensive care type inpatient hospital units and nursery costs); and

(ii) Dividing the remainder (excluding the total private room cost differential) by the total number of inpatient hospital days of care (excluding Medicare SNF-type days and non-Medicare NF-type days of care, days of care in intensive care units, coronary care units, and other intensive care type inpatient hospital units; and newborn days; but including total private room days).

Average cost per diem for hospital intensive care type units means the amount computed by dividing the total allowable costs for routine services in each of these units by the total number of inpatient days of care furnished in each of these units.

Average per diem private room cost differential means the difference in the average per diem cost of furnishing routine services in a private room and in a semi-private room. (This differential is not applicable to hospital intensive care type units.) (The method for computing this differential is described in paragraph (c) of this section.)

Charges means the regular rates for various services that are charged to both beneficiaries and other paying pa-

tients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

Intensive care type inpatient hospital unit means a hospital unit that furnishes services to critically ill inpatients. Examples of intensive care type units include, but are not limited to, intensive care units, trauma units, coronary care units, pulmonary care units, and burn units. Excluded as intensive care type units are post-operative recovery rooms, postanesthesia recovery rooms, maternity labor rooms, and subintensive or intermediate care units. (The unit must also meet the criteria of paragraph (d) of this section.)

Nursing facility (NF)-type services, formerly known as ICF and SNF-type services, are routine services furnished by a swing-bed hospital to Medicaid and other non-Medicare patients. Under the Medicaid program, effective October 1, 1990, facilities are no longer certified as SNFs or ICFs but instead are certified only as NFs and can provide services as defined in section 1919(a)(1) of the Act.

Skilled nursing facility (SNF)-type services are routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNF-type services include routine SNF services furnished in the distinct part SNF of a hospital complex that is combined with the hospital general routine service area cost center under § 413.24(d)(5). Effective October 1, 1990, only Medicare covered services are included in the definition of SNF-type services.

Ratio of beneficiary charges to total charges on a departmental basis means the ratio of charges to beneficiaries of the Medicare program for services of a revenue-producing department or center to the charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services furnished to beneficiaries of the Medicare program is computed by applying the individual ratio for the center to the cost of the related center for the period.

Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(c) *Method for computing the average per diem private room cost differential.* Compute the average per diem private room cost differential as follows:

(1) Determine the average per diem private room charge differential by subtracting the average per diem charge for all semi-private room accommodations from the average per diem charge for all private room accommodations. The average per diem charge for private room accommodations is determined by dividing the total charges for private room accommodations by the total number of days of care furnished in private room accommodations. The average per diem charge for semi-private accommodations is determined by dividing the total charges for semi-private room accommodations by the total number of days of care furnished in semi-private accommodations.

(2) Determine the inpatient general routine cost to charge ratio by dividing total inpatient general routine service cost by the total inpatient general routine service charges.

(3) Determine the average per diem private room cost differential by multiplying the average per diem private room charge differential determined in paragraph (c)(1) of this section by the ratio determined in paragraph (c)(2) of this section.

(d) *Criteria for identifying intensive care type units.* For purposes of determining costs under this section, a unit will be identified as an intensive care type inpatient hospital unit only if the unit—

(1) Is in a hospital;

(2) Is physically and identifiably separate from general routine patient care areas, including subintensive or intermediate care units, and ancillary service areas. There cannot be a concurrent sharing of nursing staff between an intensive care type unit and units or areas furnishing different levels or types of care. However, two or more intensive care type units that concurrently share nursing staff can be reim-

bursed as one combined intensive care type unit if all other criteria are met. Float nurses (nurses who work in different units on an as-needed basis) can be utilized in the intensive care type unit. If a float nurse works in two different units during the same eight hour shift, then the costs must be allocated to the appropriate units depending upon the time spent in those units. The hospital must maintain adequate records to support the allocation. If such records are not available, then the costs must be allocated to the general routine services cost areas;

(3) Has specific written policies that include criteria for admission to, and discharge from, the unit;

(4) Has registered nursing care available on a continuous 24-hour basis with at least one registered nurse present in the unit at all times;

(5) Maintains a minimum nurse-patient ratio of one nurse to two patients per patient day. Included in the calculation of this nurse-patient ratio are registered nurses, licensed vocational nurses, licensed practical nurses, and nursing assistants who provide patient care. Not included are general support personnel such as ward clerks, custodians, and housekeeping personnel; and

(6) Is equipped, or has available for immediate use, life-saving equipment necessary to treat the critically ill patients for which it is designed. This equipment may include, but is not limited to, respiratory and cardiac monitoring equipment, respirators, cardiac defibrillators, and wall or canister oxygen and compressed air.

(e) *Application—*(1) *Departmental method; Cost reporting periods beginning on or after October 1, 1982.* (i) The following example illustrates how costs would be determined, using only inpatient data, for cost reporting periods beginning on or after October 1, 1982, based on apportionment of—

(A) The average cost per diem for general routine services (subject to the private room differential provisions of paragraph (a)(1)(iii) of this section);

(B) The average cost per diem for each intensive care type unit;

(C) The ratio of beneficiary charges to total charges applied to cost by department.

HOSPITAL Y

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
	Percent				
Operating rooms	\$20,000	\$70,000	28½	\$77,000	\$22,000
Delivery rooms	0	12,000	0	30,000	0
Pharmacy	20,000	60,000	33⅓	45,000	15,000
X-ray	24,000	100,000	24	75,000	18,000
Laboratory	40,000	140,000	28½	98,000	28,000
Others	6,000	30,000	20	25,000	5,000
Total	110,000	412,000	350,000	88,000

	Total inpatient days	Total cost	Average cost per diem	Program inpatient days	Cost of beneficiary services
General routine	30,000	\$630,000	\$21	8,000	\$168,000
Coronary care unit	500	20,000	40	200	8,000
Intensive care unit	3,000	108,000	36	1,000	36,000
	33,500	758,000	9,200	212,000
Total	300,000

(ii) The following illustrates how apportionment based on an average cost per diem for general routine services is determined.

HOSPITAL E

Facts	Private accommodations	Semi-private accommodations	Total
Total charges	\$20,000	\$175,000	\$195,000
Total days	100	1,000	1,100
Programs days	70	400	470
Medically necessary for program beneficiaries	20	20
Total general routine service costs	165,000
Average private room per diem charge (\$20,000 private room charges ÷ 100 days)	¹ \$200
Average semi-private room per diem charge (\$175,000 semi-private charge ÷ 1,000 days)	¹ \$175

¹ Per diem.

Average per diem private room cost differential.

1. Average per diem private room charge differential (\$200 private room per diem—\$175, semi-private room per diem), \$25.

2. Inpatient general routine cost/charge ratio (\$165,000 total costs ÷ \$195,000 total charges), 0.8461538.

3. Average per diem private room cost differential (\$25 charge differential × .8461538 cost/charge ratio), \$21.15.

Average cost per diem for inpatient general routine services.

4. Total private room cost differential (\$21.15 average per diem cost differential × 100 private room days), \$2,115.

5. Total inpatient general routine service costs net of private room cost differential (\$165,000 total routine cost – \$2,115 private room cost differential), \$162,885.

6. Average cost per diem for inpatient general routine services (\$162,885 routine cost net of private room cost differential ÷ 1,100 patient days), \$148.08.

Medicare general routine service cost.

7. Total routine per diem cost applicable to Medicare (\$148.08 average cost per diem × 470 Medicare private and semi-private patient days), \$69,598.

8. Total private room cost differential applicable to Medicare (\$21.15 average per diem private room cost differential × 20 medically necessary private room days), \$423.

9. Medicare inpatient general routine service cost (\$423 Medicare private room cost differential + \$69,598 Medicare cost of general routine inpatient services), \$70,021.

Centers for Medicare & Medicaid Services, HHS

§ 413.64

(2) *Carve out method.* The following illustrates how apportionment is determined in a hospital reimbursed under the carve out method (subject to the private room differential provisions of paragraph (a)(1)(ii) of this section):

HOSPITAL K			
[Determination of cost of routine SNF-type and ICF-type services and general routine hospital services ¹]			
Facts	Days of care		
	General routine hospital	SNF-type	ICF-type
Total days of care	2,000	400	100
Medicare days of care ...	600	300	
Average Medicaid rate ..	N/A	\$35	\$20
Total inpatient general routine service costs: \$250,000			
Calculation of cost of routine SNF-type services applicable to Medicare:			
$\$35 \times 300 = \$10,500$			
Calculation of cost of general routine hospital services:			
Cost of SNF-type services: $\$35 \times 400$..		\$14,000	
Cost of ICF-type services: $\$20 \times 100$...			2,000
Total			\$16,000
Average cost per diem of general routine hospital services:			
$\$250,000 - \$16,000 \div 2,000 \text{ days} = \117			
Medicare general routine hospital cost:			
$\$117 \times 600 = \$70,200$			
Total Medicare reasonable cost for general routine inpatient days:			
$\$10,500 + \$70,200 = \$80,700$			

[51 FR 34793, Sept. 30, 1986, as amended at 59 FR 45401, Sept. 1, 1994; 61 FR 51616, Oct. 3, 1996; 61 FR 58631, Nov. 18, 1996]

§ 413.56 [Reserved]

Subpart E—Payments to Providers

§ 413.60 Payments to providers: General.

(a) The fiscal contractors will establish a basis for interim payments to each provider. This may be done by one of several methods. If an contractor is already paying the provider on a cost basis, the contractor may adjust its rate of payment to an estimate of the result under the Medicare principles of reimbursement. If no organization is paying the provider on a cost basis, the contractor may obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per

diem, or to charges, or to any other ready basis of approximating costs.

(b) At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, determines the Medicare reimbursement for the actual services provided to beneficiaries during the period.

(c) Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

§ 413.64 Payments to providers: Specific rules.

(a) *Reimbursement on a reasonable cost basis.* Providers of services paid on the basis of the reasonable cost of services furnished to beneficiaries will receive interim payments approximating the actual costs of the provider. These payments will be made on the most expeditious schedule administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of a reporting period.

(b) *Amount and frequency of payment.* Medicare states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While Medicare provides that interim payments will be made no less often than monthly, contractors are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

(c) *Interim payments during initial reporting period.* At the beginning of the

program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the Medicare program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) If the contractor is already paying the provider on a cost or cost-related basis, the contractor will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services furnished to the program's beneficiaries.

(2) If an organization other than the contractor is paying the provider for services on a cost or cost-related basis, the contractor may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) If no organization is paying the provider on a cost or cost-related basis, the contractor will obtain the previous year's financial statement from the provider. By analysis of such statement in light of the principles of reimbursement, the contractor will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the contractor that costs have increased. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(d) *Interim payments for new providers.*

(1) Newly-established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the contractor will use the following methods to determine an appropriate rate:

(i) If there is a provider or providers comparable in substantially all rel-

evant factors to the provider for which the rate is needed, the contractor will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the contractor will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the contractor will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

(e) *Interim payments after initial reporting period.* Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering Medicare services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the contractor during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(f) *Retroactive adjustment.* (1) Medicare provides that providers of services will be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the

period into agreement with the reimbursable amount payable to the provider for the services furnished to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services furnished during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

(g) *Accelerated payments to providers.* Upon request, an accelerated payment may be made to a provider of services that is not receiving periodic interim payments under paragraph (h) of this section if the provider has experienced financial difficulties due to a delay by the contractor in making payments or in exceptional situations, in which the provider has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle. Any such payment must be approved first by the contractor and then by CMS. The amount of the payment is computed as a percentage of the net reimbursement for unbilled or unpaid covered services. Recovery of the accelerated payment may be made by recoupment as provider bills are processed or by direct payment.

(h) *Periodic interim payment method of reimbursement—(1) Covered services furnished before July 1, 1987.* In addition to the regular methods of interim payment on individual provider billings for covered services, the periodic interim

payment (PIP) method is available for Part A hospital and SNF inpatient services.

(2) *Covered services furnished on or after July 1, 1987.* Effective with claims received on or after July 1, 1987, or as otherwise specified, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient services furnished in hospitals that are excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter under subpart B of part 412 of this subchapter, or are paid under the prospective payment systems described in subpart N, O, and P of part 412 of this chapter.

(ii) Part A services furnished in hospitals receiving payment in accordance with a demonstration project authorized under section 402(a) of Public Law 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Public Law 92-603 (42 U.S.C. 1395b-1 (note)), or a State reimbursement control system approved under section 1886(c) of the Act and subpart C of part 403 of this chapter, if that type of payment is specifically approved by CMS as an integral part of the demonstration or control system. If that type of payment is not an integral part of the demonstration or control system, PIP is available for the hospital under paragraph (h)(1)(i) of this section for hospitals excluded from the prospective payment systems or under § 412.116(b) of this chapter for prospective payment hospitals.

(iii) Part A SNF services furnished in cost reporting periods beginning before July 1, 1998. (For services furnished in subsequent cost reporting periods, see § 413.350 regarding periodic interim payments for skilled nursing facilities).

(iv) Part A services furnished in hospitals paid under the prospective payment system, including distinct part psychiatric or rehabilitation units, as described in § 412.116(b) of this chapter.

(v) Services furnished in a hospice as specified in part 418 of this chapter. Payment on a PIP basis is described in § 418.307 of this chapter.

(vi) Effective for payments made on or after July 1, 2004, inpatient CAH services furnished by a CAH as specified in § 413.70. Payment on a PIP basis is described in § 413.70(d).

(3) Any participating provider furnishing the services described in paragraphs (h)(1) and (h)(2) of this section that establishes to the satisfaction of the contractor that it meets the following requirements may elect to be reimbursed under the PIP method, beginning with the first month after its request that the contractor finds administratively feasible:

(i) The provider's estimated total Medicare reimbursement for inpatient services is at least \$25,000 a year computed under the PIP formula or, in the case of an HHA, either its estimated—

(A) Total Medicare reimbursement for Part A and Part B services is at least \$25,000 a year computed under the PIP formula; or

(B) Medicare reimbursement computed under the PIP formula is at least 50 percent of estimated total allowable cost.

(ii) The provider has filed at least one completed Medicare cost report accepted by the contractor as providing an accurate basis for computation of program payment (except in the case of a provider requesting reimbursement under the PIP method upon first entering the Medicare program).

(iii) The provider has the continuing capability of maintaining in its records the cost, charge, and statistical data needed to accurately complete a Medicare cost report on a timely basis.

(4) [Reserved]

(5) The contractor's approval of a provider's request for reimbursement under the PIP method will be conditioned upon the contractor's best judgment as to whether payment can be made to the provider under the PIP method without undue risk of its resulting in an overpayment because of greatly varying or substantially declining Medicare utilization, inadequate billing practices, or other circumstances. The contractor may terminate PIP reimbursement to a provider at any time it determines that the provider no longer meets the qualifying requirements or that the provider's experience under the PIP method shows that proper payment cannot be made under this method.

(6) Payment will be made biweekly under the PIP method unless the provider requests a longer fixed interval

(not to exceed one month) between payments. The payment amount will be computed by the contractor to approximate, on the average, the cost of covered inpatient or home health services furnished by the provider during the period for which the payment is to be made, and each payment will be made two weeks after the end of such period of services. Upon request, the contractor will, if feasible, compute the provider's payments to recognize significant seasonal variation in Medicare utilization of services on a quarterly basis starting with the beginning of the provider's reporting year.

(7) A provider's PIP amount may be appropriately adjusted at any time if the provider presents or the contractor otherwise obtains evidence relating to the provider's costs or Medicare utilization that warrants such adjustment. In addition, the contractor will recompute the payment immediately upon completion of the desk review of a provider's cost report and also at regular intervals not less often than quarterly. The contractor may make a retroactive lump sum interim payment to a provider, based upon an increase in its PIP amount, in order to bring past interim payments for the provider's current cost reporting period into line with the adjusted payment amount. The objective of contractor monitoring of provider costs and utilization is to assure payments approximating, as closely as possible, the reimbursement to be determined at settlement for the cost reporting period. A significant factor in evaluating the amount of the payment in terms of the realization of the projected Medicare utilization of services is the timely submittal to the contractor of completed admission and billing forms. All providers must complete billings in detail under this method as under regular interim payment procedures.

(i) *Bankruptcy or insolvency of provider.* If on the basis of reliable evidence, the contractor has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a State or Federal court for purposes of determining whether such provider is insolvent or bankrupt under an appropriate State or Federal law, any payments to the

provider will be adjusted by the contractor, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) *Interest payments resulting from judicial review*—(1) *Application*. If a provider of services seeks judicial review by a Federal court (see § 405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see § 413.153 for treatment of interest). The interest begins to accrue on the first day of the first month following the 180-day period described in § 405.1835(a)(3)(i) or (a)(3)(ii) of this chapter, as applicable.

(2) *Amount due*. Section 1878(f) of the Act, 42 U.S.C. 1395oof, authorizes a court to award interest in favor of the prevailing party on any amount due as a result of the court's decision. If the contractor withheld any portion of the amount in controversy prior to the date the provider seeks judicial review by a Federal court, and the Medicare program is the prevailing party, interest is payable by the provider only on the amount not withheld. Similarly, if the Medicare program seeks to recover amounts previously paid to a provider, and the provider is the prevailing party, interest on the amounts previously paid to a provider is not payable by the Medicare program since that amount had been paid and is not due the provider.

(3) *Rate*. The amount of interest to be paid is equal to the rate of return on equity capital (see § 413.157) in effect for the month in which the civil action is commenced.

Example: An contractor made a final determination on the amount of Medicare program reimbursement on June 15, 1974, and the provider appealed that determination to the Provider Reimbursement Review Board. The Board heard the appeal and rendered a decision adverse to the provider. On October 28, 1974, the provider commenced civil action to have such decision reviewed. The rate of return on equity capital for the month of October 1974 was 11.625 percent. The period for

which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994; 64 FR 41682, July 30, 1999; 65 FR 41211, July 3, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 56056, Aug. 30, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004; 73 FR 30267, May 23, 2008]

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions*. (1) *Scope*. (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

(A) Ambulatory surgical centers (ASCs).

(B) Comprehensive outpatient rehabilitation facilities (CORFs).

(C) Home health agencies (HHAs).

(D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in § 483.5 of this chapter).

(E) Hospices.

(F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, other than those clinical diagnostic laboratories operating as parts of CAHs on or after October 1, 2010, or facilities that furnish only some combination of these services.

(H) Facilities, other than those operating as parts of CAHs, furnishing only

physical, occupational, or speech therapy to ambulatory patients, throughout any period during which the annual financial cap amount on payment for coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, is suspended by legislation.

(I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(K) Ambulances.

(L) Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds.

(2) *Definitions.* In this subpart E, unless the context indicates otherwise—

Campus means 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, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term

“department of a provider” does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital

comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term “remote location of a hospital” does not include a satellite facility as defined in §§412.22(h)(1) and 412.25(e)(1) of this chapter.

(b) *Provider-based determinations.* (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and

to CMS contractors upon request. If the facility is operated as a joint venture, the provider would also have to attest that it will comply with the requirements of paragraph (f) of this section.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services

of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.

(5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS

will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as

evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

(ii) The main provider and the facility or organization seeking status as a department of the main provider, a re-

mote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the

provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.

(i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as

the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).

(iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(v) The facility or organization meets all of the following criteria:

(A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in § 412.23(d) for reimbursement under Medicare as a children's hospital;

(B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under § 413.53(d).

(C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

(D) The hospital in which the facility or organization is physically located is in a rural area as defined in § 412.64(b)(1)(ii)(C) of this chapter.

(E) The facility or organization is located within a 100-mile radius of the children's hospital that is the potential main provider.

Centers for Medicare & Medicaid Services, HHS

§413.65

(F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.

(G) The facility or organization meets all other requirements for provider-based status under this section.

(vi) Both of the following criteria are met:

(A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under §412.105(b) of this chapter; and

(B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in §412.64(b)(1)(ii)(C) of this subchapter.

(vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(f) *Provider-based status for joint ventures.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of

§§489.20(l), (m), (q), and (r) and 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in §489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in §489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at §412.2(c)(5) of this chapter and at §413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the anti-dumping rules in §489.24 of this chapter, and the beneficiary will incur a co-insurance liability for an outpatient visit to the hospital as well as for the

physician service, the following requirements must be met:

(i) The hospital must provide written notice to the beneficiary, before the delivery of services, of—

(A) The amount of the beneficiary's potential financial liability; or

(B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.

(ii) The notice must be one that the beneficiary can read and understand.

(iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care

services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of "leased" employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based—*(1) *Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the

provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date

CMS issues notice that necessary applications or information have not been submitted.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(1) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the

failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Services and Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if they furnish only services that are billed, using the CCN of the main provider and with the consent of the main provider, as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes; or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(n) *FQHCs and “look alikes.”* A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility—

(1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000

under section 330 of the Public Health Service Act under a contract with the beneficiary of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.

(o) *Effective date of provider-based status*—(1) *General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

[65 FR 18538, Apr. 7, 2000, as amended at 65 FR 58920, Oct. 3, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59920, Nov. 30, 2001; 67 FR 50114, Aug. 1, 2002; 68 FR 46070, Aug. 4, 2003; 68 FR 53261, Sept. 9, 2003; 70 FR 47487, Aug. 12, 2005; 74 FR 44000, Aug. 27, 2009; 82 FR 38515, Aug. 14, 2017]

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services

of a distinct part unit of the CAH and other than the items included in the incentive payment described in paragraph (a)(5) of this section and subject to the adjustments described in paragraph (a)(6) of this section, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

- (i) Lesser of cost or charges;
- (ii) Ceilings on hospital operating costs;
- (iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and
- (iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2) of this part.

(2) Except as specified in paragraph (a)(3) of this section, payment to a CAH for inpatient services does not include any costs of physician services or other professional services to CAH inpatients, and is subject to the Part A hospital deductible and coinsurance, as determined under subpart G of part 409 of this chapter.

(3) If a CAH meets the criteria in § 412.113(c) of this subchapter for pass-through of costs of anesthesia services furnished by qualified nonphysician anesthesiologists employed by the CAH or obtained under arrangements, payment to the CAH for the costs of those services is made in accordance with § 412.113(c).

(4) Payment for inpatient services of distinct part psychiatric or rehabilitation units is described in paragraph (e) of this section.

(5) A qualifying CAH receives an incentive payment for the reasonable costs of purchasing certified EHR technology in a cost reporting period during a payment year as determined under § 495.106 of this chapter in lieu of payment for such reasonable costs under paragraph (a)(1) of this section.

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH for the applicable

EHR reporting period, as defined in §§ 495.4 and 495.106(a) of this chapter, then notwithstanding the percentage applicable in paragraph (a)(1) of this section, the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentage:

(A) For cost reporting periods beginning in FY 2015, 100.66 percent.

(B) For cost reporting periods beginning in FY 2016, 100.33 percent.

(C) For cost reporting periods beginning in FY 2017 and each subsequent fiscal year, 100 percent.

(ii) The Secretary may on a case-by-case basis, exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the CAH. In order to be considered for an exception, a CAH must submit an application demonstrating that it meets one or more of the criteria specified in this paragraph (a)(6) for the applicable payment adjustment year no later than November 30 after the close of the applicable EHR reporting period, or a later date specified by CMS. The Secretary may grant an exception for one or more of the following:

(A) During any 90-day period from the beginning of the cost reporting period that begins in the fiscal year before the payment adjustment year to November 30 after the end of the payment adjustment year, or a later date specified by CMS, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring Internet connectivity, and faced insurmountable barriers to obtaining such Internet connectivity.

(B) A CAH that faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user during the payment adjustment year.

(C) The CAH is new in the payment adjustment year and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the

hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare-covered patient. For the purposes of this exception, the following CAHs are not considered new CAHs:

(1) A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(2) A CAH that closes and subsequently reopens.

(3) A CAH that has been converted from an eligible hospital as defined at § 495.4 of this chapter.

(iii) *Exception for decertified EHR technology.* Beginning with the fiscal year 2018 payment adjustment year, the Secretary shall exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the CAH has been decertified under ONC's Health IT Certification Program. In order to be considered for an exception, a CAH must submit an application, in the manner specified by CMS, demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year, and that the CAH made a good faith effort to obtain another certified EHR technology for that EHR reporting period. Applications requesting this exception must be submitted by November 30 after the end of the applicable payment adjustment year, or a later date specified by CMS.

(iv) Exceptions granted under paragraphs (a)(6)(ii) and (iii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

(7) There is no administrative or judicial review under section 1869 and 1878 of the Act otherwise of the following:

(i) The methodology and standards for determining the amount of payment under paragraph (a)(5) of this section, including the calculation of reasonable costs under §495.106(c) of this chapter.

(ii) The methodology and standards for determining the amount of payment adjustments made under paragraph (a)(6).

(iii) The methodology and standards for determining a CAH to be a qualifying CAH under §495.106 of this chapter.

(iv) The methodology and standards for determining if the hardship exemption applies to a CAH under paragraph (a)(6)(ii) of this section.

(v) The specification of the cost reporting periods, payment years, or fiscal years as applied under this paragraph.

(b) *Payment for outpatient services furnished by CAH*—(1) *General*. (i) Unless the CAH elects to be paid for services to its outpatients under the method specified in paragraph (b)(3) of this section, the amount of payment for outpatient services of a CAH is determined under paragraph (b)(2) of this section.

(ii) Except as specified in paragraph (b)(6) of this section, payment to a CAH for outpatient services does not include any costs of physician services or other professional services to CAH outpatients.

(2) *Reasonable costs for facility services*. (i) Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient services of a CAH is 101 percent of the reasonable costs of the CAH in providing CAH services to its outpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH outpatient services:

(A) Lesser of cost or charges; and

(B) RCE limits.

(ii) Payment to a CAH under paragraph (b)(2) of this section does not include any costs of physician services or other professional services to CAH outpatients and, other than for clinical diagnostic laboratory tests, is subject to

the Part B deductible and coinsurance amounts as determined under §§410.152(k), 410.160, and 410.161 of this chapter.

(iii) [Reserved]

(3) *Election to be paid reasonable costs for facility services plus fee schedule for professional services*. (i) A CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section.

(A)(1) *For cost reporting periods beginning before October 1, 2010*. The election must be made in writing, made on an annual basis, and delivered to the contractor or MAC servicing the CAH at least 30 days before the start of the cost reporting period for which the election is made. An election, once made for a cost reporting period, remains in effect for all of that period.

(2) *For cost reporting periods beginning on or after October 1, 2010*. If a CAH had elected the method specified in paragraph (b)(3)(i) of this section in its most recent cost reporting period beginning prior to October 1, 2010, that election remains in effect for all of that period and for all subsequent cost reporting periods, unless the CAH submits a termination request to the contractor or MAC servicing the CAH at least 30 days before the start of the next cost reporting period. However, for cost reporting periods beginning in October 2010 and November 2010, if a CAH wishes to terminate its previous election, the CAH must submit a termination request to the contractor or MAC servicing the CAH prior to December 1, 2010. If a CAH had no election in effect in its most recent preceding cost reporting period and chooses to elect the method specified in paragraph (b)(3)(i) of this section on or after October 1, 2010, the election must be made in writing and delivered to the contractor or MAC servicing the CAH at least 30 days before the start of the first cost reporting period for which the election is made. Once the election is made, it remains in effect for all of that period and for all subsequent cost reporting periods unless the CAH submits a termination request to the contractor or MAC servicing the CAH at

least 30 days before the start of the next cost reporting period.

(B) An election of the payment method specified under paragraph (b)(3)(i) of this section applies to all services furnished to outpatients by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with subpart F of part 424 of this chapter. If a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with subpart F of part 424 of this chapter, payment for the physician's or practitioner's services furnished to CAH outpatients will be made on a fee schedule or other applicable basis as specified in subpart B of part 414 of this subchapter.

(C) In the case of a CAH that made an election under this section before November 1, 2003, for a cost reporting period beginning before December 1, 2003, the rules in paragraph (b)(3)(i)(B) of this section are applicable to cost reporting periods beginning on or after July 1, 2001.

(D) An election made under paragraph (b)(3)(i) of this section is effective as provided for under paragraph (b)(3)(i)(A) or paragraph (b)(3)(i)(C) of this section and does not apply to an election that was terminated prior to the start of the cost reporting period for which it would otherwise apply.

(ii) If the CAH elects payment under this method, payment to the CAH for each outpatient visit will be the sum of the following:

(A) Effective for cost reporting periods beginning on or after January 1, 2004, for facility services not including any services for which payment may be made under paragraph (b)(3)(ii)(B) of this section, 101 percent of the reasonable costs of the services as determined under paragraph (b)(2)(i) of this section; and

(B) For professional services that are furnished by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with part 424, subpart F of this chapter, and that would otherwise be payable to the physician or other practitioner if the rights to bill for them had not been reassigned, 115 percent of the amounts that otherwise would be paid for the service if the

CAH had not elected payment under this method. Effective for primary care services furnished by primary care practitioners (as defined in § 414.80(a)) and major surgical procedures furnished by general surgeons in health professional shortage areas (as defined in § 414.2) furnished on or after January 1, 2011 and before January 1, 2016, incentive payments specified under § 414.80 and § 414.67(b), respectively, of this title must not be included in determining payment made under this paragraph.

(iii) Payment to a CAH, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts, as determined under §§ 410.152(k), 410.160, and 410.161 of this chapter.

(4) *Costs of certain emergency room on-call providers.* (i) Effective for cost reporting periods beginning on or after October 1, 2001, the reasonable costs of outpatient CAH services under paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the CAH involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility. Effective for costs incurred for services furnished on or after January 1, 2005, the payment amount of 101 percent of the reasonable costs of outpatient CAH services may also include amounts for reasonable compensation and related costs for the following emergency room providers who are on call but who are not present on the premises of the CAH involved, are not otherwise furnishing physicians' services, and are not on call at any other provider or facility: physician assistants, nurse practitioners, and clinical nurse specialists.

(ii) For purposes of this paragraph (b)(4)—

(A) “Amounts for reasonable compensation and related costs” means all allowable costs of compensating emergency room physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on call to the extent that the costs are found to be reasonable under the rules specified in paragraph (b)(2) of this section and

the applicable sections of part 413. Costs of compensating these specified medical emergency room staff are allowable only if the costs are incurred under written contracts that require the physician, physician assistant, nurse practitioner, or clinical nurse specialist to come to the CAH when the physician's or other practitioner's presence is medically required.

(B) Effective for costs incurred on or after January 1, 2005, an "emergency room physician, physician assistant, nurse practitioner, or clinical nurse specialist who is on call" means a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care who is immediately available by telephone or radio contact, and is available onsite within the timeframes specified in § 485.618(d) of this chapter.

(5) *Costs of ambulance services.* (i)(A) Effective for services furnished on or after December 21, 2000 and on or before December 31, 2003, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(B) Effective for cost reporting periods beginning on or after January 1, 2004 and on or before September 30, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(C) Effective for cost reporting periods beginning on or after October 1, 2011 and on or before September 30, 2019, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no

provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

(D) Effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

(ii) For purposes of paragraph (b)(5) of this section, the distance between the CAH or the entity and the other provider or supplier of ambulance services will be determined as the shortest distance in miles measured over improved roads between the CAH or the entity and the site at which the vehicles of the closest provider or supplier of ambulance services are garaged. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road will be considered to include the paved surface up to the front entrance of the hospital and the front entrance of the garage.

(6) If a CAH meets the criteria in § 412.113(c) of this subchapter for pass-through of costs of anesthesia services

§ 413.70

42 CFR Ch. IV (10–1–24 Edition)

furnished by nonphysician anesthetists employed by the CAH or obtained under arrangement, payment to the CAH for the costs of those services is made in accordance with § 412.113(c) of this chapter.

(7) *Payment for clinical diagnostic laboratory tests included as outpatient CAH services.* (i) Payment for clinical diagnostic laboratory tests is not subject to the Medicare Part B deductible and coinsurance amounts.

(ii) Subject to the provisions of paragraphs (b)(7)(iii) through (b)(7)(vi) of this section, payment to a CAH for clinical diagnostic laboratory tests will be made at 101 percent of reasonable costs of the services as determined in accordance paragraph (b)(2)(i) of this section.

(iii) For services furnished before July 1, 2009, payment to a CAH for clinical diagnostic laboratory tests will be made under paragraph (b)(7)(ii) of this section only if the individual is an outpatient of the CAH, as defined in § 410.2 of this chapter, and is physically present in the CAH at the time the specimen is collected.

(iv) Except as provided in paragraphs (b)(7)(iii) and (b)(7)(v) of this section, payment to a CAH for clinical diagnostic laboratory tests will be made under paragraph (b)(7)(ii) of this section only if the individual is an outpatient of the CAH, as defined in § 410.2 of this chapter, without regard to whether the individual is physically present in the CAH at the time the specimen is collected and at least one of the following conditions is met:

(A) The individual is receiving outpatient services in the CAH on the same day the specimen is collected; or

(B) The specimen is collected by an employee of the CAH.

(v) Notwithstanding paragraph (b)(7)(iv) of this section, payment for outpatient clinical diagnostic laboratory tests will not be made under paragraph (b)(7)(ii) of this section if the billing rules under § 411.15(p) of this chapter apply.

(vi) Payment for clinical diagnostic laboratory tests for which payment may not be made under paragraph (b)(7)(iii) or paragraph (b)(7)(iv) of this section will be made in accordance with the provisions of sections

1833(a)(1)(D) and 1833(a)(2)(D) of the Act.

(c) *Final payment based on cost report.* Final payment to the CAH for CAH facility services to inpatients and outpatients furnished during a cost reporting is based on a cost report for that period, as required under § 413.20(b).

(d) *Periodic interim payments.* Subject to the provisions of § 413.64(h), a CAH receiving payments under this section may elect to receive periodic interim payments (PIP) for Part A inpatient CAH services, effective for payments made on or after July 1, 2004. Payment is made biweekly under the PIP method unless the CAH requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payment (after estimated beneficiary deductibles and coinsurance) for the cost reporting period. Each payment is made 2 weeks after the end of a biweekly period of service, as described in § 413.64(h)(6). These PIP provisions are further described in § 413.64(h)(6). Under certain circumstances that are described in § 413.64(g), a CAH that is not receiving PIP may request an accelerated payment.

(e) *Payment for service of distinct part psychiatric and rehabilitation units of CAHS.* Payment for inpatient services of distinct part psychiatric units of CAHS—

(1) For cost reporting periods beginning before January 1, 2005, payment is made on a reasonable cost basis, subject to the provisions of § 413.40.

(2) For cost reporting periods beginning on or after January 1, 2005, payment is made in accordance with regulations governing inpatient psychiatric facilities at subpart N (§ 412.400 through § 412.432) of Part 412 of this subchapter.

(3) Payment for inpatient services of distinct part rehabilitation units of CAHS is made in accordance with regulations governing the inpatient rehabilitation facilities prospective payment system at subpart P (§ 412.600 through § 412.632) of part 412 of this subchapter.

[65 FR 47109, Aug. 1, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.70, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at www.govinfo.gov.

§ 413.74 Payment to a foreign hospital.

(a) *Principle.* Section 1814(f) of the Act provides for the payment of emergency and nonemergency inpatient hospital services furnished by foreign hospitals to Medicare beneficiaries. Subpart H of part 424 of this chapter, together with this section, specifies the conditions for payment.

(b) *Amount of payment.* Effective with admissions on or after January 1, 1980, the reasonable cost for services covered under the Medicare program furnished to beneficiaries by a foreign hospital will be equal to 100 percent of the hospital's customary charges (as defined in § 413.13(b)) for the services.

(c) *Submittal of claims.* The hospital must establish its customary charges for the services by submitting an itemized bill with each claim it files in accordance with its election under § 424.104 of this chapter.

(d) *Exchange rate.* Payment to the hospital will be subject to the official exchange rate on the date the patient is discharged and to the applicable deductible and coinsurance amounts described in §§ 409.80 through 409.83.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 71 FR 48141, Aug. 18, 2006]

Subpart F—Specific Categories of Costs

§ 413.75 Direct GME payments: General requirements.

(a) *Statutory basis and scope—(1) Basis.* This section and §§ 413.76 through 413.83 implement section 1886(h) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities.

(2) *Scope.* This section and §§ 413.76 through 413.83 apply to Medicare payments to hospitals and hospital-based providers for the costs of approved residency programs in medicine, osteopathy, dentistry, and podiatry for cost reporting periods beginning on or after July 1, 1985.

(b) *Definitions.* For purposes of this section and §§ 413.76 through 413.83, the following definitions apply:

All or substantially all of the costs for the training program in the nonhospital setting means—

(1) Effective on or after January 1, 1999 and for cost reporting periods beginning before July 1, 2007, the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education (GME); and

(2) Effective for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2010, at least 90 percent of the total of the costs of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries attributable to nonpatient care direct GME activities.

Approved geriatric program means a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

Approved medical residency program means a program that meets one of the following criteria:

(1) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(i) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610; or

(ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(3) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(4) Is a program that would be accredited except for the accrediting

agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

Base period means a cost reporting period that began on or after October 1, 1983 but before October 1, 1984.

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.

CPI-U stands for the Consumer Price Index for All Urban Consumers as compiled by the Bureau of Labor Statistics.

Emergency Medicare GME affiliated group means at least one home hospital and one or more host hospitals, as those terms are defined below, that meet the requirements at § 413.79(f)(7). For purposes of an emergency Medicare GME affiliated group, the following definitions apply:

(1) *Home hospital* means a hospital that—

(i) Is located in section 1135 emergency area;

(ii) Had its inpatient bed occupancy decreased by 20 percent or more as the result of a section 1135 emergency period so that it is unable to train the number of residents it originally intended to train in that academic year; and

(iii) Needs to send the displaced residents to train at a host hospital.

(2) *Host hospital* means a hospital training residents displaced from a home hospital.

(i) *In-State host hospital* means a host hospital located in the same State as a home hospital.

(ii) *Out-of-State host hospital* means a host hospital located in a different State from the home hospital.

(3) *Section 1135 emergency area or section 1135 emergency period* mean, respec-

tively, a geographic area in which, or a period during which, there exists—

(i) An emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(ii) A public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

Foreign medical graduate means a resident who is not a graduate of a medical, osteopathy, dental, or podiatry school, respectively, accredited or approved as meeting the standards necessary for accreditation by one of the following organizations:

(1) The Liaison Committee on Medical Education of the American Medical Association.

(2) The American Osteopathic Association.

(3) The Commission on Dental Accreditation.

(4) The Council on Podiatric Medical Education.

FMGEMS stands for the Foreign Medical Graduate Examination in the Medical Sciences (Part I and Part II).

FTE stands for full-time equivalent.

GME stands for graduate medical education.

Medicare GME affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in subpart D of Part 412 of this subchapter) or in a contiguous area and meet the rotation requirements in § 413.79(f)(2).

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in § 413.79(f)(2), and are jointly listed—

(i) As the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory*; or

(ii) As the sponsor or is listed under “affiliations and outside rotations” for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs*.

(3) Two or more hospitals that are under common ownership and, effective

for all Medicare GME affiliation agreements beginning July 1, 2003, meet the rotation requirement in § 413.79(f)(2).

Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in this section, that specifies—

(1) The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

Medicare patient load means, with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded.

Nonprovider setting that is primarily engaged in furnishing patient care means a nonprovider setting in which the pri-

mary activity is the care and treatment of patients.

Orientation activities means activities that are principally designed to prepare an individual for employment as a resident in a particular setting, or for participation in a particular specialty program and patient care activities associated with that particular specialty program.

Patient care activities means the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities as defined in this section.

Primary care resident is a resident who is enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice. Effective for cost reporting periods beginning on or after October 1, 2010, *primary care resident* is a resident who is formally accepted, enrolled, and participating in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice.

Redistribution of costs occurs when a hospital counts FTE residents in medical residency programs and the costs of the program had previously been incurred by an educational institution.

Resident means an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board. Effective for cost reporting periods beginning on or after October 1, 2010, *resident* means an intern, resident, or fellow who is formally accepted, enrolled, and participating in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.

Rural track FTE limitation means the maximum number of residents (as specified in § 413.79(k)) training in a rural track residency program that an urban hospital or rural hospital may include in its FTE count and that is in addition

to the number of FTE residents already included in the hospital's FTE cap.

Rural track or integrated rural track means, for programs started in cost reporting periods prior to October 1, 2022, an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

Rural track Medicare GME affiliated group means an urban hospital and a rural hospital that—

- (i) Participate in a rural track program defined in this paragraph (b);
- (ii) Have rural track FTE limitations in effect prior to October 1, 2022; and
- (iii) Comply with the regulations at § 413.79(f)(1) through (6) for Medicare GME affiliated groups.

Rural track Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in this paragraph (b), that specifies all of the following:

- (i) A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.
- (ii) The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year.
- (iii) Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation.
- (iv) The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and indirect medical education (IME), that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount.
- (v) The adjustment to each participating hospital's FTE counts resulting

from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii) of this definition).

(vi) The names of the participating hospitals and their Medicare provider numbers.

Rural Track Program means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which residents/fellows gain both urban and rural experience with more than half of the education and training for a resident/fellow taking place in a rural area as defined at 42 CFR 412.62(f)(iii).

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(c) *Payment for GME costs—General rule.* Beginning with cost reporting periods starting on or after July 1, 1985, hospitals, including hospital-based providers, are paid for the costs of approved GME programs as described in §§ 413.76 through 413.83.

(d) *Documentation requirements.* To include a resident in the FTE count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

- (1) The name and social security number of the resident.
- (2) The type of residency program in which the individual participates and the number of years the resident has completed in all types of residency programs.
- (3) The dates the resident is assigned to the hospital and any hospital-based providers.

(4) The dates the resident is assigned to other hospitals, or other free-standing providers, and any nonprovider setting during the cost reporting period, if any.

(5) The name of the medical, osteopathic, dental, or podiatric school from which the resident graduated and the date of graduation.

(6) If the resident is an FMG, documentation concerning whether the resident has satisfied the requirements of this section.

(7) The name of the employer paying the resident's salary.

[69 FR 49254, Aug. 11, 2004, as amended at 70 FR 47489, Aug. 12, 2005; 71 FR 18666, Apr. 12, 2006; 71 FR 48141, Aug. 18, 2006; 72 FR 26995, May 11, 2007; 72 FR 47412, Aug. 22, 2007; 72 FR 66931, Nov. 27, 2007; 75 FR 50418, Aug. 16, 2010; 75 FR 72262, Nov. 24, 2010; 79 FR 50357, Aug. 22, 2014; 86 FR 73512, Dec. 27, 2021; 87 FR 49405, Aug. 10, 2022; 89 FR 69912, Aug. 28, 2024]

§ 413.76 Direct GME payments: Calculation of payments for GME costs.

A hospital's Medicare payment for the costs of an approved residency program is calculated as follows:

(a) *Step one.* The hospital's updated per resident amount (as determined under § 413.77) is multiplied by the actual number of FTE residents (as determined under § 413.79). This result is the aggregate approved amount for the cost reporting period.

(b) *Step two.* The product derived in step one is multiplied by the hospital's Medicare patient load.

(c) *Step three.* For portions of cost reporting periods occurring on or after January 1, 1998, the product derived in step one is multiplied by the proportion of the hospital's inpatient days attributable to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act and who are entitled to Medicare Part A or with a Medicare + Choice organization under Title XVIII, Part C of the Act. This amount is multiplied by an applicable payment percentage equal to—

- (1) 20 percent for 1998;
- (2) 40 percent for 1999;
- (3) 60 percent in 2000;
- (4) 80 percent in 2001; and
- (5) 100 percent in 2002 and subsequent years.

(d) *Step four.* Effective for portions of cost reporting periods occurring on or after January 1, 2000, the product derived from step three is reduced by a percentage equal to the ratio of the Medicare + Choice nursing and allied health payment "pool" for the current calendar year as described at § 413.87(f), to the projected total Medicare + Choice direct GME payments made to all hospitals for the current calendar year.

(e) *Step five.* (1) For portions of cost reporting periods beginning on or after January 1, 1998 and before January 1, 2000, add the results of steps two and three.

(2) Effective for portions of cost reporting periods beginning on or after January 1, 2000, add the results of steps two and four.

(f) *Step six.* The product derived in step two is apportioned between Part A and Part B of Medicare based on the ratio of Medicare's share of reasonable costs excluding GME costs attributable to each part as determined through the Medicare cost report.

[69 FR 49254, Aug. 11, 2004]

§ 413.77 Direct GME payments: Determination of per resident amounts.

(a) *Per resident amount for the base period.* (1) Except as provided in paragraph (d) of this section, the contractor determines a base-period per resident amount for each hospital as follows:

(i) Determine the allowable GME costs for the cost reporting period beginning on or after October 1, 1983 but before October 1, 1984. In determining these costs, GME costs allocated to the nursery cost center, research and other nonreimbursable cost centers, and hospital-based providers that are not participating in Medicare are excluded and GME costs allocated to distinct-part hospital units and hospital-based providers that participate in Medicare are included.

(ii) Divide the costs calculated in paragraph (a)(1)(i) of this section by the average number of FTE residents working in all areas of the hospital complex (including those areas whose costs were excluded under paragraph (a)(1)(i) of this section) for its cost reporting period beginning on or after

§ 413.77

42 CFR Ch. IV (10–1–24 Edition)

October 1, 1983 but before October 1, 1984.

(2) In determining the base-period per resident amount under paragraph (a)(1) of this section, the contractor—

(i) Verifies the hospital's base-period GME costs and the hospital's average number of FTE residents;

(ii) Excludes from the base-period GME costs any nonallowable or misclassified costs, including those previously allowed under § 412.113(b)(3) of this chapter; and

(iii) Upon a hospital's request, includes GME costs that were misclassified as operating costs during the hospital's prospective payment base year and were not allowable under § 412.113(b)(3) of this chapter during the GME base period. These costs may be included only if the hospital requests an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(3) If the hospital's cost report for its GME base period is no longer subject to reopening under § 405.1885 of this chapter, the contractor may modify the hospital's base-period costs solely for purposes of computing the per resident amount.

(4) If the contractor modifies a hospital's base-period GME costs as described in paragraph (a)(2)(ii) of this section, the hospital may request an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(5) The contractor notifies each hospital that either had direct GME costs or received indirect education payment in its cost reporting period beginning on or after October 1, 1984, and before October 1, 1985, of its base-period average per resident amount. A hospital may appeal this amount within 180 days of the date of that notice.

(b) *Per resident amount for cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986.* For cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) If a hospital's base period began on or after October 1, 1983, and before July 1, 1984, the amount is adjusted by

the percentage change in the CPI-U that occurred between the hospital's base period and the first cost reporting period to which the provisions of this section apply. The adjusted amount is then increased by one percent.

(2) If a hospital's base period began on or after July 1, 1984 and before October 1, 1984, the amount is increased by one percent.

(c) *Per resident amount for cost reporting periods beginning on or after July 1, 1986.* Subject to the provisions of paragraph (d) of this section, for cost reporting periods beginning on or after July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) Except as provided in paragraph (c)(2) of this section, each hospital's per resident amount for the previous cost reporting is adjusted by the projected change in the CPI-U for the 12-month cost reporting period. This adjustment is subject to revision during the settlement of the cost report to reflect actual changes in the CPI-U that occurred during the cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1993 through September 30, 1995, each hospital's per resident amount for the previous cost reporting period will not be adjusted for any resident FTEs who are not either a primary care resident or an obstetrics and gynecology resident.

(d) *Per resident amount for cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013.* For cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013, a hospital's per resident amount for each fiscal year is adjusted in accordance with the following provisions:

(1) *General provisions.* For purposes of this § 413.77—

(i) *Weighted average per resident amount.* The weighted average per resident amount is established as follows:

(A) Using data from hospitals' cost reporting periods ending during FY 1997, CMS calculates each hospital's single per resident amount by adding each hospital's primary care and non-primary care per resident amounts, weighted by its respective FTEs, and dividing by the sum of the FTEs for

primary care and nonprimary care residents.

(B) Each hospital's single per resident amount calculated under paragraph (d)(1)(i)(A) of this section is standardized by the 1999 geographic adjustment factor for the physician fee schedule area (as determined under § 414.26 of this chapter) in which the hospital is located.

(C) CMS calculates an average of all hospitals' standardized per resident amounts that are determined under paragraph (d)(1)(i)(B) of this section. The resulting amount is the weighted average per resident amount.

(ii) *Primary care/obstetrics and gynecology and nonprimary care per resident amounts.* A hospital's per resident amount is an amount inclusive of any CPI-U adjustments that the hospital may have received since the hospital's base year, including any CPI-U adjustments the hospital may have received because the hospital trains primary care/obstetrics and gynecology residents and nonprimary care residents as specified under paragraph (c)(2) of this section.

(2) *Adjustment beginning in FY 2001 and ending in FY 2013.* For cost reporting periods beginning on or after October 1, 2000, and ending on or before September 30, 2013, a hospital's per resident amount is adjusted in accordance with paragraphs (d)(2)(i) through (d)(2)(iv) of this section, in that order:

(i) *Updating the weighted average per resident amount for inflation.* The weighted average per resident amount (as determined under paragraph (d)(1)(i) of this section) is updated by the estimated percentage increase in the CPI-U during the period beginning with the month that represents the midpoint of the cost reporting periods ending during FY 1997 (that is, October 1, 1996) and ending with the midpoint of the hospital's cost reporting period that begins in FY 2001.

(ii) *Adjusting for locality.* The updated weighted average per resident amount determined under paragraph (d)(2)(i) of this section (the national average per resident amount) is adjusted for the locality of each hospital by multiplying the national average per resident amount by the 1999 geographic adjustment factor for the physician fee

schedule area in which each hospital is located, established in accordance with § 414.26 of this chapter.

(iii) *Determining necessary revisions to the per resident amount.* The locality-adjusted national average per resident amount, as calculated in accordance with paragraph (d)(2)(ii) of this section, is compared to the hospital's per resident amount and is revised, if appropriate, according to the following three categories:

(A) *Floor.* (1) For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, if the hospital's per resident amount would otherwise be less than 70 percent of the locality-adjusted national average per resident amount for FY 2001 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 70 percent of the locality-adjusted national average per resident amount for FY 2001.

(2) For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, if the hospital's per resident amount would otherwise be less than 85 percent of the locality-adjusted national average per resident amount for FY 2002 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 85 percent of the locality-adjusted national average per resident amount for FY 2002.

(3) For subsequent cost reporting periods beginning on or after October 1, 2002, the hospital's per resident amount is updated using the methodology specified under paragraph (c)(1) of this section.

(B) *Ceiling.* If the hospital's per resident amount is greater than 140 percent of the locality-adjusted national average per resident amount, the per resident amount is adjusted as follows for FY 2001 through FY 2013:

(1) *FY 2001.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2001, if the hospital's FY 2000 per resident amount exceeds 140 percent of the FY 2001 locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident

amount is frozen at the FY 2000 per resident amount and is not updated for FY 2001 by the CPI-U factor.

(2) *FY 2002.* For cost reporting periods beginning on or after October 1, 2001, and on or before September 30, 2002, if the hospital's FY 2001 per resident amount exceeds 140 percent of the FY 2002 locality-adjusted national average per resident amount, subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident amount is frozen at the FY 2001 per resident amount and is not updated for FY 2002 by the CPI-U factor.

(3) *FY 2003.* For cost reporting periods beginning on or after October 1, 2002, and on or before September 30, 2003, if the hospital's per resident amount for the previous cost reporting period is greater than 140 percent of the locality-adjusted national average per resident amount for that same previous cost reporting period (for example, for cost reporting periods beginning in FY 2003, compare the hospital's per resident amount from the FY 2002 cost report to the hospital's locality-adjusted national average per resident amount from FY 2002), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident amount is adjusted using the methodology specified in paragraph (c)(1) of this section, except that the CPI-U applied for a 12-month period is reduced (but not below zero) by 2 percentage points.

(4) *FY 2004 through FY 2013.* For cost reporting periods beginning on or after October 1, 2003, and on or before September 30, 2013, if the hospital's preceding year per resident amount exceeds 140 percent of the current year's locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital-specific per resident amount is frozen for the current year at the preceding year's hospital-specific per resident amount and is not updated by the CPI-U factor.

(5) *General rule for hospitals that exceed the ceiling.* For cost reporting periods beginning on or after October 1, 2000, and on or before September 30,

2013, if a hospital's per resident amount exceeds 140 percent of the hospital's locality-adjusted national average per resident amount and it is adjusted under any of the criteria under paragraphs (d)(2)(iii)(B)(1) through (d)(2)(iii)(B)(3) of this section, the current year per resident amount cannot be reduced below 140 percent of the locality-adjusted national average per resident amount.

(C) *Per resident amounts greater than or equal to the floor and less than or equal to the ceiling.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2013, if a hospital's per resident amount is greater than or equal to 70 percent and less than or equal to 140 percent of the hospital's locality-adjusted national average per resident amount for each respective fiscal year, the hospital's per resident amount is updated using the methodology specified in paragraph (c)(1) of this section.

(e) *Exceptions—(1) Base period for certain hospitals.* If a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after July 1, 1985, the contractor establishes a per resident amount for the hospital using the information from the first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. Effective for cost reporting periods beginning on or after October 1, 2006, if a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after October 1, 2006, and the residents are not on duty during the first month of that period, the contractor establishes a per resident amount for the hospital using the information from the first cost reporting period immediately following the cost reporting period during which the hospital participates in Medicare and residents began training at the hospital. The per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or paragraph (e)(1)(ii) of this

section, subject to the provisions of paragraph (e)(1)(iii) of this section. Any GME costs incurred by the hospital during the cost reporting period prior to the base period used for calculating the PRA are reimbursed on a reasonable cost basis.

(i) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period as established in paragraph (e)(1) of this section.

(ii) Except as specified in paragraph (e)(1)(iii) of this section—

(A) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under Part 412 of this chapter.

(B) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(iii) If, under paragraph (e)(1)(ii)(A) or (B) or (e)(1)(iv)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(iv) A hospital that, as of December 27, 2020, has a per resident amount based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997, may choose to receive a recalculated per resident amount either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost

reporting period beginning after December 27, 2021. A hospital that, as of December 27, 2020, has a per resident amount based on no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, may choose to receive a recalculated per resident amount either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after December 27, 2021. In either case, residents need not be on duty during the first month of the cost reporting period. The recalculated per resident amount is based on the lower of—

(A) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period, which is, for hospitals with a per resident amount previously based on less than 1.0 FTE, either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after December 27, 2021; and for hospitals with a per resident amount previously based on not more than 3.0 FTEs, either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning on or after December 27, 2021; or

(B) The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(v) Effective for a cost reporting periods beginning on or after December 27, 2020, a per resident amount must be established if a hospital trains less than 1.0 FTE resident and this training results from the hospital's participation

in a Medicare GME affiliation agreement under § 413.79(f). Effective for a cost reporting period beginning on or after December 27, 2020, a per resident amount must only be established when the hospital trains at least 1.0 FTE and does not participate in a Medicare GME affiliation agreement under § 413.79(f) for that training. Residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

(2) *Short or long base-period cost reporting periods.* If a hospital's base-period cost reporting period reflects GME costs for a period that is shorter than 50 weeks or longer than 54 weeks, the contractor converts the allowable costs for the base period into a daily figure. The daily figure is then multiplied by 365 or 366, as appropriate, to derive the approved per resident amount for a 12-month base-period cost reporting period. If a hospital has two cost reporting periods beginning in the base period, the later period serves as the base-period cost reporting period.

(3) *Short or long cost reporting periods beginning on or after July 1, 1985.* If a hospital's cost reporting period is shorter than 50 weeks or longer than 54 weeks, the hospital's contractor should contact CMS Central Office to receive a special CPI-U adjustment factor.

(f) *Residency match.* Effective for portions of cost reporting periods beginning on or after October 1, 2004, with respect to a resident who matches simultaneously for a first year of training in a primary care specialty, and for an additional year(s) of training in a nonprimary care specialty, the per resident amount that is used to determine direct GME payment with respect to that resident is the nonprimary care per resident amount for the first year of training in the primary care specialty and for the duration of the resident's training in the nonprimary care specialty.

(g) *Special use of locality-adjusted national average per resident amount.* Effective for portions of cost reporting periods beginning on or after July 1, 2005, for a hospital that counts additional residents as a result of an increase in its FTE resident cap under § 413.79(c)(4) direct GME payments attributable to

those additional FTE residents are calculated using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section. The hospital will receive direct GME payments based on the sum of the following two direct GME calculations:

(1) A calculation using the per resident amount(s) as determined under paragraph (d) of this section and the hospital's number of FTE residents that is not attributable to an FTE resident cap increase under § 413.79(c)(4); and

(2) A calculation using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section, inflated to the hospital's current cost reporting period, and the hospital's number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under § 413.79(c)(4).

(h) *Hospital mergers.* Effective for cost reporting periods beginning on or after October 1, 2006, when multiple hospitals merge, a primary care and obstetrics and gynecology weighted average per resident amount and a nonprimary care weighted average per resident amount is calculated, if applicable, for the surviving hospital, using FTE resident data and per resident amount data from the most recently settled cost reports of the respective hospitals prior to the merger.

[69 FR 49254, Aug. 11, 2004, as amended at 69 FR 60252, Oct. 7, 2004; 70 FR 47489, Aug. 12, 2005; 71 FR 48142, Aug. 18, 2006; 86 FR 73512, Dec. 27, 2021; 87 FR 4167, Jan. 27, 2022]

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

Subject to the weighting factors in §§ 413.79 and 413.80, and subject to the provisions of § 413.81, the count of FTE residents is determined as follows:

(a) Residents in an approved program working in all areas of the hospital complex may be counted.

(b) (1) No individual resident may be counted as more than one FTE based on the total time spent in training at all sites. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as

provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(2) Effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if it does not participate in a Medicare GME affiliation agreement (as defined under § 413.75(b)), and the hospital trains at least 1.0 FTE in an approved program or programs, or, if the hospital trains less than 1.0 FTE residents in an approved program or programs and this training results from the hospital's participation in a Medicare GME affiliation agreement (as defined under § 413.75(b)).

(c) On or after July 1, 1987, and for portions of cost reporting periods occurring before January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs is not excluded in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) There is a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital.

(d) For portions of cost reporting periods occurring on or after January 1, 1999, and before October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting in accordance with the definition in § 413.75(b).

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(e) For portions of cost reporting periods occurring on or after October 1, 2004, and for cost reporting periods beginning before July 1, 2007, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met:

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) The hospital must incur all or substantially all of the costs of the training program in a nonhospital setting(s) (in accordance with the definition under § 413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred.

(ii) There is a written agreement between the hospital and the nonhospital site that states that the hospital will incur the cost of the resident's salary

§ 413.78

42 CFR Ch. IV (10–1–24 Edition)

and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(iii) If the hospital has in place an emergency Medicare GME affiliation agreement in accordance with § 413.79(f)(7), during the period covered by the emergency Medicare GME affiliation agreement—

(A) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the sixth month following the month in which the training in the nonhospital site occurred. For the costs that would otherwise be required to be paid by the hospital during the period of August 29, 2005 through November 1, 2007, the participating hospital must pay the costs by April 29, 2008; or

(B) There is a written agreement that specifies that the hospital is incurring the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities. The written agreement must be submitted to the contractor by 180 days after the training at the nonhospital site begins. For written agreements that would otherwise be required to be submitted prior to the date the resident(s) begin training at the nonhospital site during the period of August 29, 2005 through November 1, 2007, the written agreement must be submitted to the CMS contractor by April 29, 2008.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(f) For cost reporting periods beginning on or after July 1, 2007, and before July 1, 2010, the time residents spend in nonprovider settings such as free-

standing clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities as defined at § 413.75(b), except that for cost reporting periods beginning on or after July 1, 2009, the time spent training in nonpatient care activities, such as didactic conferences and seminars, but excluding research not associated with the treatment or diagnosis of a particular patient, in a nonprovider setting that is primarily engaged in furnishing patient care activities, as defined at § 413.75(b), also may be counted.

(2) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting(s) (in accordance with the definition under § 413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay for all or substantially all of the costs for the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred.

(ii) There is a written agreement in place between the hospital and the nonhospital site before the training begins that states that the hospital will incur at least 90 percent of the total of the costs of the resident's salary and fringe benefits (and travel and lodging where applicable) while the resident is training in the nonhospital site and the portion of the cost of the teaching physician's salary attributable to nonpatient care direct GME activities. The written agreement must specify the total cost of the training program at the nonhospital site, and the amount the hospital will incur (at least 90 percent of the total), and must indicate the portion of the amount the hospital will incur that reflects residents' salaries and fringe benefits (and travel and lodging where applicable), and the portion of this amount that reflects teaching physician compensation. Hospitals

may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that at least 90 percent of the costs of the training program in the nonhospital site has been incurred.

(iii) If the hospital has in place an emergency Medicare GME affiliation agreement in accordance with § 413.79(f)(7), during the period covered by the emergency Medicare GME affiliation agreement—

(A) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the sixth month after the month in which the training in the nonhospital site occurs. For the costs that would otherwise be required to be incurred by the hospital during the period of August 29, 2005 through November 1, 2007, the participating hospital must incur the costs by April 29, 2008; or

(B) There is a written agreement that specifies that the hospital will incur at least 90 percent of the total of the costs of the resident's salary and fringe benefits (and travel and lodging where applicable) while the resident is training in the nonhospital site and the portion of the cost of the teaching physician's salary attributable to nonpatient care direct GME activities. The written agreement must specify the total cost of the training program at the nonhospital site, and the amount the hospital will incur (at least 90 percent of the total), and must indicate the portion of the amount the hospital will incur that reflects residents' salaries and fringe benefits (and travel and lodging where applicable), and the portion of this amount that reflects teaching physician compensation. The written agreement must be submitted to the contractor by 180 days after the training at the nonhospital site begins. Hospitals may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that at least 90 percent of the costs of the training program in the nonhospital site has been incurred. For written agreements that would otherwise be required to be submitted prior to the date the training begins in the nonhospital site during the period

of August 29, 2005 through November 1, 2007, the hospital must submit the written agreement to its contractor by April 29, 2008.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(g) For cost reporting periods beginning on or after July 1, 2010, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time—

(i) In patient care activities as defined at § 413.75(b); or

(ii) In nonpatient care activities, such as didactic conferences and seminars, but excluding research not associated with the treatment or diagnosis of a particular patient, in a nonprovider setting that is primarily engaged in furnishing patient care activities, as defined at § 413.75(b).

(2) The hospital or hospitals must incur the costs of the salaries and fringe benefits of the resident during the time the resident spends in the nonprovider setting. If more than one hospital incurs these costs, either directly or through a third party, the hospitals must count a proportional share of the time that residents train at the nonprovider setting(s) as recorded in a written agreement between the hospitals.

(i) Hospitals must have a reasonable basis for establishing that proportion of the cost and the FTE time that each will incur and count.

(ii) If hospitals already arrange payment to the nonprovider site via a written agreement as described in paragraph (g)(3)(ii) of this section, the proportion may be recorded in that agreement.

(iii) If hospitals choose to pay the nonprovider site concurrently as described in paragraph (g)(3)(i) of this section, the hospitals must record the proportion of cost and FTE time they are incurring and counting in a written agreement between the hospitals.

(3) The hospital or hospitals must comply with one of the following:

(i) The hospital or hospitals must incur the costs of the salaries and fringe benefits of the resident during the time the resident spends in the nonprovider setting by the end of the third month following the month in which the training in the nonprovider site occurred.

(ii) There is a written agreement between the hospital or hospitals and the outside entity that states that the residents' salaries and fringe benefits (including travel and lodging where applicable) during the time the resident spends in the nonprovider setting is to be paid by the hospital(s). Hospitals may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that the costs of the training program in the nonprovider site have been incurred.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(5) For cost reporting periods beginning on or after July 1, 2010, a hospital must maintain and make available records of the FTE count determined for direct GME purposes under this section that its residents spend in nonprovider sites, in order to compare that time to the time spent by its residents in nonprovider sites in the base year of cost reporting periods beginning on or after July 1, 2009, and before June 30, 2010. The hospital must supply the CMS contractor with the data for each of its primary care programs on a program-specific basis, and with data for its nonprimary care programs on an overall basis.

(6) The provisions of paragraphs (g)(1)(ii), (g)(2), (g)(3), and (g)(5) of this section shall not be applied in a manner that requires reopening of any settled cost reports as to which there is not a jurisdictionally proper appeal pending as of March 23, 2010, on direct GME or IME payments. Cost reporting periods beginning before July 1, 2010 are not governed by paragraph (g) of this section.

(h) Effective for cost reporting periods beginning on or after January 1, 1983, the time spent by a resident in an

approved medical residency program on vacation, sick leave, or other approved leave that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program is countable. This provision cannot be applied in a manner that would require the reopening of settled cost reports, except those cost reports on which there is a jurisdictionally proper appeal pending on direct GME or IME payments as of March 23, 2010.

(i) For the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID-19 was in effect, a sending hospital can include FTE residents training at another hospital in its FTE count if all of the following conditions are met.

(1) The sending hospital sends the resident to the other hospital in response to the COVID-19 pandemic.

(2) The time spent by the resident training at the other hospital is in lieu of time that would have been spent in approved training at the sending hospital.

(3) The time that the resident spent training immediately prior to and/or subsequent to the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID-19 was in effect is included in the FTE count for the sending hospital.

[69 FR 49254, Aug. 11, 2004, as amended at 71 FR 48142, Aug. 18, 2006; 72 FR 26995, May 11, 2007; 72 FR 66931, Nov. 27, 2007; 75 FR 72262, Nov. 24, 2010; 78 FR 50968, Aug. 19, 2013; 79 FR 50357, Aug. 22, 2014; 85 FR 27623, May 8, 2020; 86 FR 73513, Dec. 27, 2021; 89 FR 69912, Aug. 28, 2024]

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

Subject to the provisions in § 413.80, CMS determines a hospital's number of FTE residents by applying a weighting factor to each resident and then summing the resulting numbers that represent each resident. The weighting factor is determined as follows:

(a) *Initial residency period.* Generally, for purposes of this section, effective July 1, 1995, an initial residency period is defined as the minimum number of years required for board eligibility.

(1) Prior to July 1, 1995, the initial residency period equals the minimum number of years required for board eligibility in a specialty or subspecialty plus 1 year. An initial residency period may not exceed 5 years in order to be counted toward determining FTE status except in the case of a resident in an approved geriatric program whose initial residency period may last up to 2 additional years.

(2) Effective October 1, 2003, for a resident who trains in an approved geriatric program that requires the residents to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatrics program are treated as part of the resident's initial residency period.

(3) Effective July 1, 2000, for residency programs that began before, on, or after November 29, 1999, the period of board eligibility and the initial residency period for a resident in an approved child neurology program is the period of board eligibility for pediatrics plus 2 years.

(4) Effective August 10, 1993, residents or fellows in an approved preventive medicine residency or fellowship program also may be counted as a full FTE resident for up to 2 additional years beyond the initial residency period limitations.

(5) For combined residency programs, an initial residency period is defined as the time required for individual certification in the longer of the programs. If the resident is enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training primary care residents (as defined in §413.75(b)) or obstetrics and gynecology residents, the initial residency period is the time required for individual certification in the longer of the programs plus 1 year.

(6) For residency programs other than those specified in paragraphs (a)(2) through (a)(4) of this section, the initial residency period is the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training, as specified in the

most recently published edition of the Graduate Medical Education Directory.

(7) For residency programs in osteopathy, dentistry, and podiatry, the minimum requirement for certification in a specialty or subspecialty is the minimum number of years of formal training necessary to satisfy the requirements of the appropriate approving body listed in §415.152 of this chapter.

(8) For residency programs in geriatric medicine, accredited by the appropriate approving body listed in §415.152 of this chapter, these programs are considered approved programs on the later of—

(i) The starting date of the program within a hospital; or

(ii) The hospital's cost reporting periods beginning on or after July 1, 1985.

(9) The time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs, as described in §413.75(b), is counted toward the initial residency period limitation.

(10) Effective for portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident simultaneously matched for one year of training in a particular specialty program, and for a subsequent year(s) of training in a different specialty program, the resident's initial residency period will be determined based on the period of board eligibility for the specialty associated with the program for which the resident matched for the subsequent year(s) of training. Effective for portions of cost reporting periods beginning on or after October 1, 2005, if a hospital can document that a particular resident, prior to beginning the first year of residency training, matched in a specialty program for which training would begin at the conclusion of the first year of training, that resident's initial residency period will be determined in the resident's first year of training based on the period of board eligibility associated with the specialty program for which the resident matched for subsequent training year(s).

(b) *Weighting factor.* (1) If the resident is in an initial residency period, the weighting factor is one.

(2) If the resident is not in an initial residency period, the weighting factor is 1.00 during the period beginning on or after July 1, 1985 and before July 1, 1986, .75 during the period beginning on or after July 1, 1986 and before July 1, 1987, and .50 thereafter without regard to the hospital's cost reporting period.

(c) *Unweighted FTE counts*—(1) *Definitions*. As used in this paragraph (c):

(i) *Otherwise applicable resident cap* refers to a hospital's FTE resident cap that is determined for a particular cost reporting period under paragraph (c)(2) of this section.

(ii)(A) For purposes of paragraph (c)(3) of this section, *reference resident level* refers to a hospital's resident level in the applicable reference period specified under paragraph (c)(3) of this section.

(B) For purposes of paragraph (m) of this section, *reference resident level* means with respect to a hospital, the highest resident level for any of the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010.

(iii) *Resident level* refers to the number of unweighted allopathic and osteopathic FTE residents who are training in a hospital in a particular cost reporting period.

(2) *Determination of the FTE resident cap*. Subject to the provisions of paragraphs (c)(3) through (6) and (m) through (p) of this section and § 413.81, for purposes of determining direct GME payment—

(i) For cost reporting periods beginning on or after October 1, 1997, a hospital's resident level may not exceed the hospital's unweighted FTE count (or, effective for cost reporting periods beginning on or after April 1, 2000, 130 percent of the unweighted FTE count for a hospital located in a rural area) for these residents for the most recent cost reporting period ending on or before December 31, 1996.

(ii) If a hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 1997, and before October 1, 2001, exceeds the limit described in this section, the hospital's total weighted FTE count (before ap-

plication of the limit) will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iii) Effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section, and the number of weighted FTE residents in accordance with paragraph (b) of this section also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with paragraph (b) of this section does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

(iv) Hospitals that are part of the same Medicare GME affiliated group or the same emergency Medicare GME affiliated group (as described under § 413.75(b)) may elect to apply the limit on an aggregate basis as described under paragraph (f) of this section.

(v) The contractor may make appropriate modifications to apply the provisions of this paragraph (c) of this section based on the equivalent of a 12-month cost reporting period.

(3) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots under section 422 of Public Law 108–173*. If a hospital's reference resident level is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (c)(3)(ii) of this section), for portions of cost reporting periods beginning on or after July 1, 2005, the hospital's otherwise applicable FTE resident cap is reduced by 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. Under this provision—

(i) *Exemption for certain rural hospitals*. A rural hospital, as defined at

subpart D of part 412 of this subchapter, with less than 250 beds (as determined at § 412.105(b)) in its most recent cost reporting period ending on or before September 30, 2002, is exempt from any reduction to the otherwise applicable FTE resident cap limit under paragraph (c)(3) of this section.

(ii) *Reference cost reporting periods.*

(A) To determine a hospital's reference resident level, CMS uses one of the following periods:

(1) A hospital's most recent cost reporting period ending on or before September 30, 2002, for which a cost report has been settled or if the cost report has not been settled, the as-submitted cost report (subject to audit); or

(2) A hospital's cost reporting period that includes July 1, 2003 if the hospital submits a timely request to CMS to increase its resident level due to an expansion of an existing program and that expansion is not reflected on the hospital's most recent settled cost report. An expansion of an existing program means that, except for expansions due to newly approved programs under paragraph (c)(3)(ii)(A)(3) of this section, the number of unweighted allopathic and osteopathic FTE residents in any cost reporting period after the hospital's most recent settled cost report, up to and including the hospital's cost report that includes July 1, 2003, is greater than the number of unweighted allopathic and osteopathic FTE residents in programs that were existing at that hospital during the hospital's most recent settled cost report.

(3) A hospital may submit a timely request that CMS adjust the resident level for purposes of determining any reduction under paragraph (c)(3) of this section for the following purposes:

(i) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(1) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the reference cost reporting period under paragraph (c)(3)(ii)(A)(1); or

(ii) In the hospital's reference cost reporting period under paragraph

(c)(3)(ii)(A)(2) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the cost reporting period that includes July 1, 2003, and if the hospital also qualifies to use its cost report under paragraph (c)(3)(ii)(A)(2) of this section due to an expansion of an existing program.

(B) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the contractor may make appropriate modifications to apply the provisions of paragraph (c)(3)(i)(A) of this section based on the equivalent of a 12-month cost reporting period.

(iii) If the new program described in paragraph (c)(3)(ii)(A)(3)(i) or paragraph (c)(3)(ii)(A)(ii) was accredited for a range of residents, the hospital may request that its reference resident level in its applicable reference cost reporting period under paragraph (c)(3)(ii)(A)(1) or (c)(3)(ii)(A)(2) of this section be adjusted to reflect the maximum number of accredited slots applicable to that hospital.

(iv) *Consideration of Medicare GME affiliated group agreements.* For hospitals that are members of the same affiliated group for the program year July 1, 2003 through June 30, 2004, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph (c)(3) of this section, CMS treats these hospitals as a group. Using information from the hospitals' cost reports that include July 1, 2003, if the hospitals' aggregate FTE resident counts are equal to or greater than the aggregate otherwise applicable FTE resident cap for the affiliated group, then no reductions are made under paragraph (c)(3) of this section to the hospitals' otherwise applicable FTE resident caps. If the hospitals' aggregate FTE resident count is below the aggregate otherwise applicable FTE resident cap, then CMS determines on a hospital-specific basis whether the individual hospital's FTE

resident count is less than its otherwise applicable resident cap (as adjusted by affiliation agreement(s)) in the hospital's cost report that includes July 1, 2003. If the hospital's FTE resident count is in excess of its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (c)(3) of this section. Hospitals in the affiliated group that have FTE resident counts below their individual otherwise applicable FTE resident caps are subject to a pro rata reduction in their otherwise applicable FTE resident caps that is equal, in total, to 75 percent of the difference between the aggregate FTE cap and the aggregate FTE count for the affiliated group. The pro rata reduction to the individual hospital's otherwise applicable resident cap is calculated by dividing the difference between the hospital's individual otherwise applicable FTE resident cap and the hospital's FTE resident count by the total amount by which all of the hospitals' individual FTE resident counts are below their otherwise affiliated FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the affiliated group, and multiplying that result by 75 percent.

(4) *Determination of an increase in the otherwise applicable resident cap under section 422 of Public Law 108–173.* For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the timeframe specified by CMS.

(5) *Special rules for hospitals that participate in demonstration projects or voluntary resident reduction plans for purposes of section 422 of Public Law 108–173.*

(i) If a hospital was participating in a demonstration project under section 402 of Public Law 90–248 or the voluntary reduction plan under § 413.88 for a greater period of time than the time

period that elapsed since it withdrew from participation (or if it completed its participation) in the demonstration program or the voluntary reduction plan, for purposes of determining a possible reduction to the FTE resident caps under paragraph (c)(3) of this section, CMS compares the higher of the hospital's base number of residents (after subtracting any dental and podiatric FTE residents) or the hospital's reference resident level to the hospital's otherwise applicable resident cap determined under paragraph (c)(2) of this section.

(ii) If a hospital participated in the demonstration project or the voluntary resident reduction plan for a period of time that is less than the time that elapsed since it withdrew from participation in the demonstration project or the voluntary reduction plan, the special rules in paragraph (c)(5)(i) do not apply, and the hospital is subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps under paragraph (c)(3) of this section.

(iii) CMS will not redistribute residency positions that are attributable to a hospital's participation in a demonstration project or a voluntary resident reduction plan to other hospitals that seek to increase their FTE resident caps under paragraph (c)(4) of this section.

(6) *FTE resident caps for rural hospitals that are redesignated as urban.* A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (c)(2)(i), (e)(1)(iii), and (e)(3) of this section while it was located in a rural area. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, the redesignated urban hospital may retain any existing increases to its FTE resident cap that it had received prior to when the redesignation became effective. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical

areas adopted by CMS, the redesignated urban hospital may receive an increase to its FTE resident cap for a new program, in accordance with paragraph (e) of this section, if it received a letter of accreditation for the new program and/or started training residents in the new program prior to the redesignation becoming effective.

(d) *Weighted FTE counts.* Subject to the provisions of §413.81, for purposes of determining direct GME payment—

(1) For the hospital's first cost reporting period beginning on or after October 1, 1997, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1998, and before October 1, 2001, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding two cost reporting periods.

(3) For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE count for primary care and obstetrics and gynecology residents is equal to the average of the weighted primary care and obstetrics and gynecology counts for the payment year cost reporting period and the preceding two cost reporting periods, and the hospital's weighted FTE count for nonprimary care residents is equal to the average of the weighted nonprimary care FTE counts for the payment year cost reporting period and the preceding two cost reporting periods. For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE counts for the preceding two cost reporting periods are calculated in accordance with the payment formula in paragraph (c)(2)(iii) of this section.

(4) The contractor may make appropriate modifications to apply the provisions of this paragraph (d) based on the equivalent of 12-month cost reporting periods.

(5) (i) For new programs started prior to October 1, 2012, if a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency pro-

grams created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.

(ii) For new programs started on or after October 1, 2012, for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e), FTE residents participating in new medical residency training programs are excluded from the hospital's FTE count before applying the averaging rules during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, for hospitals for which the FTE may be adjusted in accordance with §413.79(e)(1), and prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started, for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(3). Beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(3), FTE residents participating in new medical

residency training programs are included in the hospital's FTE count before applying the averaging rules.

(6) Subject to the provisions of paragraph (h) of this section, FTE residents who are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the averaging rules in this paragraph (d), for the receiving hospital for the duration of the time that the displaced residents are training at the receiving hospital.

(7) (i) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000 and before cost reporting periods beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(ii) Subject to the provisions under paragraph (k) of this section, effective for rural track programs started in a cost reporting period beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital or rural hospital are excluded from rolling average calculation described in this paragraph (d) during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(e) *New medical residency training programs.* If a hospital establishes a new medical residency training program as defined in paragraph (l) of this section on or after January 1, 1995, the hospital's FTE cap described under paragraph (c) of this section may be adjusted as follows:

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of FTE residents in any program year during the

third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program. If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, and if the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for a new medical residency training program(s) is equal to the sum of the products of the highest number of FTE residents in any program year during the third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, and if the residents are spending portions of a program (or

years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for new residency training program (s) is equal to the sum of the products of three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

(ii) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's first new residency program(s), the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's first new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the sixth year of the hospital's first new residency program(s), the hospital's cap may be adjusted temporarily during each of the first 5 years of the hospital's first new residency program using the actual number of FTE residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) If a hospital begins training residents in a new medical residency training program for the first time on or after January 1, 1995, but before October 1, 2012, the cap will not be adjusted for new programs established more than 3 years after residents begin training in the first new program, or if a hospital begins training residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program.

(iv)(A) Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, except as provided in paragraph (e)(1)(iv)(B) of this section, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(B) Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap, provided the Medicare GME affiliated group meets one of the following conditions:

(1) The Medicare GME affiliated group consists solely of two or more urban hospitals that qualify for adjustments to their FTE caps under paragraph (e)(1) of this section.

(2) The Medicare GME affiliated group includes an urban hospital(s) that received FTE cap(s) under paragraph (c)(2)(i) of this section or §412.105(f)(1)(iv)(A) of this subchapter, or both. This Medicare GME affiliated group must be established effective with a July 1 date (the residency training year) that is at least 5 years after the start of the cost reporting period that coincides with or follows the start of the sixth program year of the first new program for which the hospital's

FTE cap was adjusted in accordance with paragraph (e)(1) of this section or § 412.105(f)(1)(v)(C) or (D) of this subchapter, or both.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(vi) In the case of a hospital that, as of December 27, 2020, has a FTE cap based on the training of less than 1.0 FTE in any cost reporting period beginning before October 1, 1997; or based on the training of no more than 3.0 FTEs in on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, if such a hospital begins training residents in a new approved program (as defined under § 413.79(l)) in a program year beginning on or after December 27, 2020 and before December 26, 2025, the hospital with a previous FTE cap of less than 1.0 FTE may receive an adjusted FTE cap when it begins to train at least 1.0 FTE in a new program(s); and the hospital with a previous FTE cap of no more than 3.0 FTEs may receive an adjusted FTE cap when it begins to train more than 3.0 FTEs in a new program(s). The adjusted FTE cap is equal to the sum of the original FTE cap and the products of the following three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence started in a program year beginning on or after December 27, 2020 and before December 26, 2025, at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

(2) If a hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or be-

fore December 31, 1996, the hospital's unweighted FTE cap may be adjusted for a new medical residency training program(s) established on or after January 1, 1995, and on or before August 5, 1997. The adjustment to the hospital's FTE resident cap for new residency training programs is based on the sum of the product of the highest number of FTE residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

(i) If the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each respective hospital's cap for each program is equal to the product of the highest number of FTE residents in any program year during the third year of each program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program, the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's new residency program, using the actual number of FTE residents in the new programs. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(3) If a rural hospital participates in new medical residency training programs, regardless of whether the rural hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted in the same manner described in paragraph (e)(2) of this section to reflect the increase for residents training in a new medical residency training program(s) established after August 5, 1997 and before October 1, 2012. If a rural hospital participates in new medical

residency training programs on or after October 1, 2012, the hospital's unweighted FTE cap is adjusted in accordance with paragraph (e)(1) of this section, except that the adjustment is based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of each new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program.

(4) A hospital seeking an adjustment to its FTE cap must provide documentation to its fiscal contractor justifying the adjustment.

(5) The cap will not be adjusted for expansion of existing or previously existing programs.

(6) Effective for a cost reporting period beginning on or after December 27, 2020, FTE resident caps must be established when the hospital trains 1.0 or more FTE residents in a new medical residency program (as defined under paragraph (1) of this section).

(f) *Medicare GME affiliated group.* A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (d) of this section, to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group (as defined under § 413.75(b)). Under this provision—

(1) Except as provided in paragraph (f)(6) of this section, each hospital in the Medicare GME affiliated group must submit the Medicare GME affiliation agreement, as defined under § 413.75(b) of this section, to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

(2) Each hospital in the Medicare GME affiliated group must have a shared rotational arrangement, as defined in § 413.75(b), with at least one other hospital within the Medicare GME affiliated group, and all of the hospitals within the Medicare GME affiliated group must be connected by a series of such shared rotational arrangements.

(3) During the shared rotational arrangements under a Medicare GME affiliation agreement, as defined in § 413.75(b), more than one of the hospitals in the Medicare GME affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(4) The net effect of the adjustments (positive or negative) on the Medicare GME affiliated hospitals' aggregate FTE cap for each Medicare GME affiliation agreement must not exceed zero.

(5) If the Medicare GME affiliation agreement terminates for any reason, the FTE cap of each hospital in the Medicare GME affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (c) of this section.

(6) Effective October 1, 2009, a hospital that is new after July 1 and begins training residents for the first time after the July 1 start date of an academic year may receive a temporary adjustment to its FTE resident cap to reflect its participation in an existing Medicare GME affiliated group by submitting the Medicare GME affiliation agreement, as defined under § 413.75(b), to the CMS contractor or MAC servicing the hospital and sending a copy to the CMS Central Office by the earlier of June 30 of the residency program year during which the Medicare GME affiliation agreement will be in effect or the end of the first cost reporting period during which the hospital begins training residents. The Medicare GME affiliation agreement must specify the effective period for the agreement, which may begin no earlier than the date the affiliation agreement is submitted to CMS. Each of the other hospitals participating in the Medicare GME affiliated group must submit an amended Medicare GME affiliation agreement that reflects the participation of the new hospital to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office no later than June 30 of the residency program year during which the Medicare GME affiliation agreement will be in effect. For

purposes of this paragraph, a new hospital is one for which a new Medicare provider agreement takes effect in accordance with § 489.13 of this chapter.

(7) *Emergency Medicare GME affiliated group.* Effective on or after August 29, 2005, home and host hospitals as defined in § 413.75(b) may form an emergency Medicare GME affiliated group by meeting the requirements provided in this section. The emergency Medicare GME affiliation agreements may be made effective beginning on or after the first day of a section 1135 emergency period, and must terminate no later than at the conclusion of 4 academic years following the academic year during which the section 1135 emergency period began.

(i) *Requirements for submission of emergency Medicare GME affiliation agreements.* Each hospital in the emergency Medicare GME affiliated group must submit an emergency Medicare GME affiliation agreement that is written, signed, and dated by responsible representatives of each participating hospital in the manner specified in paragraph (ii) and includes the following information:

(A) List each participating hospital and its provider number; and indicate whether each hospital is a home or host hospital.

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of four academic years following the academic year in which the section 1135 emergency period began).

(C) List each participating hospital's IME and direct GME FTE caps in effect before the emergency Medicare GME affiliation agreement (including any adjustments to those caps in effect as a result of other Medicare GME affiliation agreements but not including any slots gained under § 413.79(c)(4)).

(D) Specify the total adjustment to each participating hospital's FTE caps in each academic year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to the host hospital's direct and indirect FTE caps that is offset by a negative adjustment to the home hospital's (or hospitals') direct and in-

direct FTE caps of at least the same amount subject to the following—

(1) The sum total of adjustments to all the participating hospitals' FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted FTE caps of the hospitals participating in the emergency Medicare GME affiliated group.

(2) A home hospital's IME and direct GME FTE cap reductions in an emergency Medicare GME affiliation agreement are limited to the home hospital's IME and direct GME FTE resident caps at § 413.79(c) or § 413.79(f)(1) through (f)(5), that is, as adjusted by any and all existing affiliation agreements as applicable.

(3) For emergency Medicare GME affiliation agreements for the third or fourth academic years subsequent to the year in which the section 1135 emergency period began and involving an out-of-State host hospital, the positive adjustment to the out-of-State host hospital's direct and indirect FTE caps pursuant to the agreement shall reflect only FTE residents that were actually displaced from a home hospital immediately following the emergency.

(E) Attach copies of all existing Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements in which the hospital is participating at the time the emergency Medicare GME affiliation agreement is executed.

(ii) *Deadline for submission of the emergency Medicare GME affiliation agreement.* Each participating home and host hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to the CMS contractor/MAC by the applicable due date.

(A) For emergency Medicare GME affiliation agreements that would otherwise be required to be submitted by June 30, 2006, or July 1, 2006, each participating host and home hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to its CMS contractor/MAC on or before October 9, 2006.

(B) Except for emergency Medicare GME affiliation agreements specified in paragraph (f)(6)(ii)(A) of this section,

for emergency Medicare GME affiliation agreements that would otherwise be required to be submitted prior to October 1, 2008, the following due dates are applicable:

(1) *First year.* The later of 180 days after the section 1135 emergency period begins or by June 30 of the academic year in which the section 1135 emergency was declared; or

(2) *Subsequent academic years.* The later of 180 days after the section 1135 emergency period begins, or by July 1 of each academic year.

(C) For emergency Medicare GME affiliation agreements that would otherwise be required to be submitted after October 1, 2008, the following due dates are applicable:

(1) *First year.* By 180 days after the end of the academic year in which the section 1135 emergency was declared;

(2) *Second academic year.* By 180 days after the end of the next academic year following the academic year in which the section 1135 emergency was declared; or

(3) *Subsequent academic years.* By July 1 of each academic year.

(iii) *Exemption from the Shared Rotational Arrangement Requirement.* During the effective period of the emergency Medicare GME affiliation agreement, hospitals in the emergency Medicare GME affiliated group are not required to participate in a shared rotational arrangement as defined at §413.75(b).

(iv) *Host Hospital Exception from the Rolling Average for the Period from August 29, 2005 to June 30, 2006.* To determine the FTE resident count for a host hospital that is training residents in excess of its cap, a two step process will be applied. First, subject to the limit at paragraph (f)(6)(i)(D) of this section, a host hospital is to exclude the displaced FTE residents that are counted by a host hospital in excess of the hospital's cap pursuant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, from the current year's FTE resident count before applying the three-year rolling averaging rules under paragraph (d) of this section to calculate the average FTE resident count. Second, the displaced FTE residents that are counted by the host hospital in excess of the host hospital's cap pur-

suant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, are added to the hospital's 3-year rolling average FTE resident count to determine the host hospital's FTE resident count for payment purposes.

(8) FTE resident cap slots added under section 126 of Public Law 116-260 and section 4122 of Public Law 117-328 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

(g) *Newly constructed hospitals.* A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995, and on or before August 5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was completed, may receive an adjustment to its FTE cap.

(1) The newly constructed hospital's FTE cap is equal to the lesser of—

(i) The product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete the programs based on the minimum accredited length for each type of program; or

(ii) The number of accredited slots available to the hospital for each year of the programs.

(2) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for 3 years or more by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training in the third year of the programs begun at the temporary training site.

(3) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for less than 3 years by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents

training at the newly constructed hospital in the third year of the programs (including the years at the temporary training site).

(4) A hospital that qualifies for an adjustment to its FTE cap under this paragraph (g) may be part of an affiliated group for purposes of establishing an aggregate FTE cap.

(5) The provisions of this paragraph (g) are applicable during portions of cost reporting periods occurring on or after October 1, 1999.

(h) *Closure of hospital or hospital residency program*—(1) *Definitions*. For purposes of this section—

(i) *Closure of a hospital* means the hospital terminates its Medicare agreement under the provisions of § 489.52 of this chapter.

(ii) *Closure of a hospital residency training program* means the hospital ceases to offer training for residents in a particular approved medical residency training program.

(iii) *Displaced resident* means a resident who—

(A) Leaves a program after the hospital or program closure is publicly announced, but before the actual hospital or program closure;

(B) Is assigned to and training at planned rotations at another hospital who will be unable to return to his/her rotation at the closing hospital or program;

(C) Is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program;

(D) Is physically training in the hospital on the day prior to or day of program or hospital closure; or

(E) Is on approved leave at the time of the announcement of closure or actual closure, and therefore, cannot return to his/her rotation at the closing hospital or program.

(2) *Closure of a hospital*. A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following criteria:

(i) The hospital is training additional residents from a hospital that closed on or after July 1, 1996.

(ii) No later than 60 days after the hospital begins to train the residents,

the hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

(3) *Closure of a hospital's residency training program*. If a hospital that closes its residency training program voluntarily agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (h)(3)(ii) of this section, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in paragraph (h)(3)(i) of this section are met.

(i) *Receiving hospital(s)*. A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another hospital's residency training program if—

(A) The hospital is training additional residents from the residency training program of a hospital that closed a program; and

(B) No later than 60 days after the hospital begins to train the residents, the hospital submits to its contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from another hospital's closed program and have caused the hospital to exceed its cap, specifies the length of time the adjustment is needed, and submits to its contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (h)(3)(ii)(B) of this section.

(ii) *Hospital that closed its program(s)*. A hospital that agrees to train residents who have been displaced by the closure of another hospital's program may receive a temporary FTE cap adjustment only if the hospital with the closed program—

(A) Temporarily reduces its FTE cap based on the FTE residents in each program year training in the program at

the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those residents who would have been training in the program during that year had the program not closed; and

(B) No later than 60 days after the residents who were in the closed program begin training at another hospital, submit to its contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the hospital training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were in training at the time of the program's closure; identifies the hospitals to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(i) *Additional FTEs for residents on maternity or disability leave or other approved leave of absence.* Effective for cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional resident FTEs, if the hospital meets the following criteria:

(1) The additional residents are residents of a primary care program that would have been counted by the hospital as residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence during the hospital's most recent cost reporting period ending on or before December 31, 1996;

(2) The leave of absence was approved by the residency program director to allow the residents to be absent from the program and return to the program after the leave of absence; and

(3) No later than 6 months after August 1, 2000, the hospital submits to the contractor a request for an adjustment to its FTE cap, and provides contemporaneous documentation of the approval of the leave of absence by the residency director, specific to each additional resident that is to be counted for purposes of the adjustment.

(j) *Residents previously trained at VA hospitals.* For cost reporting periods beginning on or after October 1, 1997, a

non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if that hospital meets the following criteria:

(1) The transferred residents had been training previously at a VA hospital in a program that would have lost its accreditation by the ACGME if the residents continued to train at the VA hospital;

(2) The residents were transferred to the hospital from the VA hospital on or after January 1, 1997, and before July 31, 1998; and

(3) The hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from the VA hospital, and specifies the length of time those residents will be trained at the hospital.

(k) *Residents training in rural track programs.* Subject to the provisions of §413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may add the rotations of the residents in those rural tracks to its FTE cap specified under paragraph (c) of this section. An urban hospital (or, effective for a cost reporting period beginning on or after October 1, 2022, a rural hospital) with a Rural Track Program (as defined at section 413.75(b) of this subchapter) may count residents in those Rural Track Programs up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and before October 1, 2022, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital, not

to exceed its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if an urban hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural hospital(s) for more than one-half of the duration of the program, both the urban and the rural hospital may include those residents in their FTE counts for the time the rural track residents spend at the urban and rural hospital, respectively, not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the

rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012 and before October 1, 2022, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section. For Rural Track Programs started on or after October 1, 2022, beginning with the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). For cost reporting periods beginning on or after October 1, 2022, if an urban or rural hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural nonprovider site for more than one-half of the duration of the program, the urban or rural hospital may include those residents in its FTE count, subject to which hospital meets the requirements under § 413.78(g), not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i)(A) For rural track programs started before October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each

urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(B) For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(C) For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital and subject to the requirements under §413.78(g), at the rural nonprovider site(s).

(ii)(A) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(I) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(i) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonprovider site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(ii) The rural nonprovider site(s); and

(2) The number of years in which the residents are expected to complete each program based on the minimum

accredited length for the type of program.

(B) For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(4)(i) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after

April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g), as applicable. The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(2) The length of time in which the residents are training at the rural nonprovider site(s) only.

(C) For programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(ii) For rural track programs started on or after October 1, 2012 and prior to October 1, 2022, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its

FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) Prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is for one-half or less than one-half of the duration of the program; and

(2) The ratio of the length of time in which the residents are training at the rural nonprovider site(s) only to the total duration of the program.

(C) For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(5) All urban hospitals that wish to count FTE residents in rural tracks, not to exceed their respective rural track FTE limitation, must also comply with all of the following conditions:

(i) A hospital may not include in its rural track FTE limitation or (assuming the hospital's FTE count exceeds its FTE cap) FTE count residents who are training in a rural track residency program that were already included as part of the hospital's FTE cap.

(ii) Each hospital must base its count of residents in a rural track on written contemporaneous documentation that

each resident enrolled in a rural track program at the hospital intends to rotate for a portion of the residency program to a rural area.

(iii) All residents that are included by the hospital as part of its rural track FTE count (not to exceed its rural track FTE limitation) must train in the rural area. However, where a resident begins to train in the rural track program at the urban hospital but leaves the program before completing the total required portion of training in the rural area, the urban hospital may count the time the resident trained in the urban hospital if another resident fills the vacated FTE slot and completes the training in the rural portion of the rural track program. An urban hospital may not receive GME payment for the time the resident trained at the urban hospital if another resident fills the vacated FTE slot and first begins to train at the urban hospital.

(iv) Effective for cost reporting periods beginning on or after October 1, 2022, in order for an urban or rural hospital to receive a rural track FTE limitation, greater than 50 percent of the program must occur in a rural area.

(6) If CMS finds that residents who are included by the urban hospital as part of its FTE count did not actually complete the training in the rural area, CMS will reopen the urban hospital's cost report within the 3-year reopening period as specified in §405.1885 of this chapter and adjust the hospital's Medicare GME payments (and, where applicable, the hospital's rural track FTE limitation).

(7)(i) Effective prior to October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) for the rural track programs established prior to the adoption of such new labor market area definitions. In order to receive an adjustment to its FTE resi-

dent cap for a new rural track residency program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location delineations adopted by CMS.

(ii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(iii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by

CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 5-year period that is used to calculate

the urban hospital's rural track FTE limit, or after the 5-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(l) For purposes of this section, a new medical residency training program means a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.

(m) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots under section 5503 of Public Law 111–148.* If a hospital's reference resident level, as defined under paragraph (c)(1)(ii)(B) of this section is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (m)(6) of this section), for

portions of cost reporting periods beginning on or after July 1, 2011, the hospital's otherwise applicable FTE resident cap is reduced by 65 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. The reduction shall take into account the hospital's FTE resident cap as reduced under paragraph (c)(3) of this section. Under this provision—

(1) *Exemption for certain rural hospitals.* A rural hospital, as defined at subpart D of part 412 of this subchapter, with fewer than 250 beds (as determined at §412.105(b)) in its most recent cost reporting period ending on or before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(2) *Exemption for certain hospitals that participate in demonstration projects or voluntary residency reduction plans.* A hospital that was participating in a demonstration project under section 402 of Public Law 90-248 or the voluntary reduction plan under §413.88, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section if, by January 21, 2011, it submits a plan to CMS for filling all of its unused FTE resident slots by not later than March 23, 2012.

(3) *Exemption for a hospital described at section 1886(h)(4)(H)(v) of the Act.* A hospital described at section 1886(h)(4)(H)(v) of the Act, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(4) *Exemptions for certain other hospitals.* A hospital training at or above its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section for all three most recent cost reporting periods ending prior to March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(5) *New teaching hospital.* A new teaching hospital that does not have an otherwise applicable FTE resident cap as determined under paragraph (e)(1) of this section for all three most recent cost reporting periods ending prior to March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(6) *Reference cost reporting period.* (i) To determine a hospital's reference resident level, CMS determines, for a hospital's three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, the cost reporting period with the highest resident level.

(ii) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the Medicare contractor may make appropriate modifications to apply the provisions of paragraph (m) of this section based on the equivalent of a 12-month cost reporting period.

(7) *Consideration for members of Medicare GME affiliated groups.* For a hospital that is a member of a Medicare GME affiliated group at any point during any of the hospital's three most recent cost reporting periods ending before March 23, 2010 for which a cost report has been settled or has been submitted to Medicare contractor by March 23, 2010, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph (m) of this section, the Medicare contractor determines a hospital's reference cost reporting period by finding the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(i) If the reference resident level is less than the otherwise applicable resident limit in that reference cost reporting period, the Medicare contractor must then determine if the hospital was a member of a Medicare GME affiliated group as of the July 1 that

occurs during that reference cost reporting period.

(ii) If the hospital was a member of a Medicare GME affiliated group as of the July 1 that occurs during that reference cost report, the Medicare contractor does all of the following:

(A) Treat the members of the Medicare GME affiliated group as a group for that reference cost reporting period, for the purpose of determining a reduction to the particular hospital's FTE resident cap.

(B) Determine for each hospital in the Medicare GME affiliated group respectively the FTE resident cap and FTE resident count (IME and direct GME separately).

(C) Add each hospital's FTE resident caps (IME and direct GME separately) to determine the aggregate FTE resident cap.

(D) Add each hospital's FTE resident count (IME and direct GME separately) to determine the aggregate FTE resident count.

(iii) If the aggregate FTE resident count is equal to or exceeds the aggregate FTE resident cap, then the Medicare contractor would make no reduction to the particular hospital's otherwise applicable FTE resident cap under paragraph (m) of this section, and no further steps are necessary for that hospital.

(iv) If the hospitals' aggregate FTE resident count is less than the aggregate FTE resident cap, then the Medicare contractor would determine on a hospital-specific basis whether the particular hospital's FTE resident count is less than its otherwise applicable FTE resident cap (as adjusted by affiliation agreement(s)) in the hospital's reference cost report.

(v) If the hospital's FTE resident count exceeds its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (m) of this section.

(vi) If the particular hospital's FTE resident count is less than its otherwise applicable FTE resident cap, the Medicare contractor determines a pro rata cap reduction amount that is equal, in total, to 65 percent of the difference between the aggregate FTE resident cap and the aggregate FTE

resident count for the Medicare GME affiliated group.

(A) The pro rata cap reduction to the particular hospital's otherwise applicable FTE resident cap is calculated by dividing the difference between the hospital's otherwise applicable FTE resident cap and the hospital's FTE resident count, by the total amount by which all of the hospitals' individual FTE resident counts are below their affiliated FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the Medicare GME affiliated group, and multiplying that result by 65 percent.

(B) The final reduction takes into account the hospital's FTE resident cap as reduced under the provisions of paragraph (c)(3) of this section.

(n) *Determination of an increase in the otherwise applicable resident cap under section 5503 of Public Law 111–148.* (1) For portions of cost reporting periods beginning on or after July 1, 2011, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) of not more than 75 additional FTEs if the hospital meets the requirements and qualifying criteria of section 1886(h)(8) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the time-frame specified by CMS.

(2) A hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section must ensure, during the 5-year period beginning on July 1, 2011 and ending on June 30, 2016, that—

(i) The number of FTE primary care residents, as defined in § 413.75(b), excluding any additional positions under this paragraph, is not less than the average number of FTE primary care residents (as so determined) during the three most recent cost reporting periods ending prior to March 23, 2010 (and submitted to the Medicare contractor by March 23, 2010); and not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency programs.

(ii) If a hospital receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this

section, and does not use all of that increase in its final (12-month or partial) cost report of the 5-year period beginning July 1, 2011 and ending June 30, 2016, the Medicare contractor will remove the applicable unused slots, and the hospital's increase in the otherwise applicable FTE resident cap received under paragraph (n)(1) of this section will be reduced for portions of cost reporting periods on or after July 1, 2016. The number of applicable unused slots is equal to the difference between the increase in the otherwise applicable FTE resident cap and the applicable slots used. In determining the applicable slots used, the following amounts are added, as relevant:

(A) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to expand an existing program(s), the used slots are equal to the lesser of the number of slots used for an expansion(s) in the fourth 12-month cost report or the final cost report.

(B) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to start a new program(s), the used slots are equal to the number of slots used for a new program(s) in the final cost report.

(C) The portion, if any, of the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section used for cap relief, subject to the requirements in paragraph (n)(2)(i) of this section.

(iii) CMS may determine whether a hospital has met the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section during the 5-year period of July 1, 2011, through June 30, 2016, in such manner and at such time as CMS determines appropriate, including at the end of such 5-year period.

(iv) In a case where the Medicare contractor determines that a hospital did not meet the requirements under paragraphs (n)(2)(i), (n)(2)(ii), and (n)(2)(iii) of this section in a cost reporting period within the 5-year time period, the Medicare contractor will reduce the otherwise applicable FTE resident cap of the hospital by the amount by which such limit was increased under paragraph (n)(1) of this section from the earliest cost reporting

period that is reopenable in which it would be determined that the hospital did not meet the requirements.

(o) *Determination of an increase in the FTE resident cap due to slots redistributed from a closed hospital.* (1) Except in the case of the closure of the hospital with Medicare Provider Number 05-0578, in the instance of a hospital closure, as defined at paragraph (h)(1)(i) of this section, the FTE resident cap of the closed hospital would be redistributed, and a hospital that meets the requirements and qualifying criteria of section 1886(h)(4)(H)(vi) of the Act and implementing instructions issued by CMS, including submission of a timely application to CMS, may receive an increase in its FTE resident cap, as determined by CMS.

(2)(i) Except in the case of the closure of the hospital with Medicare Provider Number 05-0578, in redistributing the FTE resident cap of a closed hospital, consideration shall be given to ensure that there is no duplication of FTE slots between FTE slots redistributed under this paragraph and temporary adjustments to FTE resident caps provided under paragraph (h)(2) of this section.

(ii) The provisions of this paragraph (o) will not be applied in a manner that will require the reopening of settled cost reports, except where the provider has a jurisdictionally proper appeal pending on direct GME or IME payments as of March 23, 2010.

(p) *Determination of an increase in the otherwise applicable resident cap under section 126 of the Consolidated Appropriations Act (Pub. L. 116-260).* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

(q) *Determination of an increase in the otherwise applicable resident cap under section 4122 of the Consolidated Appropriations Act (Pub. L. 117-328).* For portions of cost reporting periods beginning on or after July 1, 2026, a hospital

§ 413.80

may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(10) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

[69 FR 49254, Aug. 11, 2004]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.79, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

(a) The weighting factor for a foreign medical graduate is determined under the provisions of § 413.79 if the foreign medical graduate—

(1) Has passed FMGEMS; or

(2) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

(b) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of § 413.79. On or after July 1, 1986, and before July 1, 1987, the weighting factor for a graduate of a foreign medical school who was in a residency program both before and after July 1, 1986 but who does not meet the requirements set forth in paragraph (a) of this section is .50 times the weight determined under the provisions of § 413.79.

(c) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.

(d) During the cost reporting period in which a foreign medical graduate passes FMGEMS, the weighting factor for that resident is determined under the provisions of § 413.79 for the part of the cost reporting period beginning with the month the resident passes the test.

(e) On or after September 1, 1989, the National Board of Medical Examiners Examination, Parts I and II, may be substituted for FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section.

42 CFR Ch. IV (10–1–24 Edition)

(f) On or after June 1, 1992, the United States Medical Licensing Examination may be substituted for the FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section. On or after July 1, 1993, only the results of steps I and II of the United States Medical Licensing Examination will be accepted for purposes of making this determination.

[69 FR 49254, Aug. 11, 2004]

§ 413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

(a) For purposes of determining direct GME payments, the following principles apply:

(1) *Community support.* If the community has undertaken to bear the costs of medical education through community support, the costs are not considered GME costs to the hospital for purposes of Medicare payment.

(2) *Redistribution of costs.* The costs of training residents that constitute a redistribution of costs from an educational institution to the hospital are not considered GME costs to the hospital for purposes of Medicare payment.

(b) *Application.* A hospital must continuously incur costs of direct GME of residents training in a particular program at a training site since the date the residents first began training in that program in order for the hospital to count the FTE residents in accordance with the provisions of §§ 413.78, 413.79 (c) through (e), and 413.79(k). This rule also applies to providers that are paid for direct GME in accordance with § 405.2468 of this chapter, § 422.270 of this subchapter, and § 413.70.

(c)(1) *Effective date.* Subject to the provisions of paragraph (c)(2) of this section, payments made in accordance with determinations made under the provisions of paragraphs (a) and (b) of this section will be effective for portions of cost reporting periods occurring on or after October 1, 2003.

(2) *Applicability for certain hospitals.* With respect to an FTE resident who begins training in a residency program on or before October 1, 2003, and with

respect to whom there has been a redistribution of costs or community support determined under the provisions of paragraphs (a) and (b) of this section, the hospital may continue to count the FTE resident until the resident has completed training in that program, or until 3 years after the date the resident began training in that program, whichever comes first.

[69 FR 49254, Aug. 11, 2004]

§ 413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

(a) Effective for cost reporting periods beginning on or after January 1, 1986, hospitals in States that, prior to becoming subject to the prospective payment system, had a waiver for the operation of a State reimbursement control system under section 1886(c) of the Act, section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1 or section 222(a) of the Social Security Amendment of 1972 (42 U.S.C. 1395b-1 (note)) are permitted to change the order in which they allocate administrative and general costs to the order specified in the instructions for the Medicare cost report.

(b) For hospitals making this election, the base-period costs for the purpose of determining the per resident amount are adjusted to take into account the change in the order by which they allocate administrative and general costs to interns and residents in approved program cost centers.

(c) Per resident amounts are determined for the base period and updated as described in § 413.77. For cost reporting periods beginning on or after January 1, 1986, payment is made based on the methodology described in § 413.76.

[69 FR 49254, Aug. 11, 2004]

§ 413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

(a) *Misclassified operating costs*—(1) *General rule.* If a hospital has its base-period GME costs reduced under § 413.77(a) of this section because those costs included misclassified operating costs, the hospital may request that the contractor review the classifica-

tion of the affected costs in its rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its rate-of-increase ceiling or prospective payment base year costs no later than 180 days after the date of the notice by the contractor of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the contractor that adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of contractor's review.* If the contractor, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate or the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

(b) *Misclassification of GME costs*—(1) *General rule.* If costs that should have been classified as GME costs were treated as operating costs during both the GME base period and the rate-of-increase ceiling base year or prospective payment base year and the hospital wishes to receive benefit for the appropriate classification of these costs as GME costs in the GME base period, the hospital must request that the contractor review the classification of the affected costs in the rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its costs no later than 180 days after the date of the contractor's notice of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the contractor that modification of the adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of contractor's review.* If the contractor, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate and the adjustment of the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

[69 FR 49254, Aug. 11, 2004]

§ 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 §§ 413.75 through 413.83.

(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 health 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 §§ 413.75 through 413.83, 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) Enhance the quality of health 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.

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

(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.* CMS 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 build-

ings 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 contractor 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.

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

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

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

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

(h) *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 or trainees participate that enhance the quality of medical care or operating efficiency of the provider and, effective October 1, 2003, do not lead to the ability to practice and begin employment in a nursing or allied health specialty.

(4) 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.

[66 FR 3374, Jan. 12, 2001, as amended at 66 FR 14342, Mar. 12, 2001; 68 FR 45471, Aug. 1, 2003; 69 FR 49254, Aug. 11, 2004; 71 FR 48142, Aug. 18, 2006; 75 FR 50418, Aug. 16, 2010]

§ 413.87 Payments for Medicare + Choice nursing and allied health education programs.

(a) *Statutory basis.* This section implements section 1886(l) of the Act, which provides for additional payments to hospitals that operate and receive Medicare reasonable cost reimbursement for approved nursing and allied health education programs and the methodology for determining the additional payments.

(b) *Scope.* This section sets forth the rules for determining an additional payment amount to hospitals that receive payments for the costs of operating approved nursing or allied health education programs under § 413.85.

(c) *Qualifying conditions for payment.*

(1) For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, a hospital that operates and receives payment for a nursing or allied health education program under § 413.85 may receive an additional payment amount associated with Medicare + Choice utilization. The hospital may receive the additional payment amount, which is calculated in accordance with the provisions of paragraph (d) of this section, if both of the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section are met.

(i) The hospital must have received Medicare reasonable cost payment for an approved nursing or allied health education program under § 413.85 in its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year. (For example, if the current year is calendar year 2000, the fiscal year that is 2 years prior to calendar year 2000 is FY 1998.) For a hospital that first establishes a nursing or allied health education program after FY 1998 and receives reasonable cost payment for the program as specified under § 413.85 after FY 1998, the hospital is eligible to receive an additional payment amount in a calendar year that is 2 years after the respective fiscal year so long as the hospital also meets the condition under paragraph (c)(1)(ii) of this section.

(ii) The hospital must be receiving reasonable cost payment for an approved nursing or allied health edu-

cation program under § 413.85 in the current calendar year.

(2) For portions of cost reporting periods occurring on or after January 1, 2001, in addition to meeting the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, the hospital must have had a Medicare + Choice utilization greater than zero in its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year.

(d) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, subject to the provisions of § 413.76(d)(4) relating to calculating a proportional reduction in Medicare + Choice direct GME payments, the additional payment amount specified in paragraph (c) of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine the hospital's total nursing and allied health education program payments from its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year.

(2) *Step two.* Determine the ratio of the hospital's payments from step one to the total of all nursing and allied health education program payments across all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year.

(3) *Step three.* Multiply the ratio calculated in step two by the Medicare + Choice nursing and allied health payment "pool" determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(e) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2001, subject to the provisions of § 413.76(d) relating to calculating a proportional reduction in Medicare + Choice direct GME payments, the additional payment amount specified in paragraph (c)

of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine for each eligible hospital the total—

(i) Medicare payments received for approved nursing or allied health education programs based on data from the settled cost reports for the period(s) ending in the fiscal year that is 2 years prior to the current calendar year; and

(ii) Inpatient days for that same cost reporting period.

(iii) Medicare + Choice inpatient days for that same cost reporting period.

(2) *Step two.* Using the data from step one, determine the ratio of the individual hospital's total nursing or allied health payments, to its total inpatient days. Multiply this ratio by the hospital's total Medicare + Choice inpatient days.

(3) *Step three.* CMS will determine, using the best available data, for all eligible hospitals the total of all—

(i) Nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year;

(ii) Inpatient days from those same cost reporting periods; and

(iii) Medicare + Choice inpatient days for those same cost reporting periods.

(4) *Step four.* Using the data from step three, CMS will determine the ratio of the total of all nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year, to the total of all inpatient days from those same cost reporting periods. CMS will multiply this ratio by the total of all Medicare + Choice inpatient days for those same cost reporting periods.

(5) *Step 5.* Calculate the ratio of the product determined in step two to the product determined in step four.

(6) *Step 6.* Multiply the ratio calculated in step five by the amount determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(f) *Calculation of the payment "pool."*

(1) Subject to paragraph (f)(3) of this section, each calendar year, CMS will calculate a Medicare + Choice nursing and allied health payment "pool" according to the following steps:

(i) Determine the ratio of projected total Medicare + Choice direct GME payments made in accordance with the provisions of § 413.76(c) across all hospitals in the current calendar year to projected total direct GME payments made across all hospitals in the current calendar year.

(ii) Multiply the ratio calculated in paragraph (f)(1)(i) of this section by projected total Medicare nursing and allied health education reasonable cost payments made to all hospitals in the current calendar year.

(2) The resulting product of the steps under paragraphs (f)(1)(i) and (f)(1)(ii) of this section is the Medicare + Choice nursing and allied health payment "pool" for the current calendar year.

(3) The payment pool may not exceed \$60 million in any calendar year.

[65 FR 47051, Aug. 1, 2000, as amended at 66 FR 32195, June 13, 2001; 69 FR 49265, Aug. 11, 2004; 70 FR 47489, Aug. 12, 2005]

§ 413.88 Incentive payments under plans for voluntary reduction in number of medical residents.

(a) *Statutory basis.* This section implements section 1886(h)(6) of the Act, which establishes a program under which incentive payments may be made to qualifying entities that develop and implement approved plans to voluntarily reduce the number of residents in medical residency training.

(b) *Qualifying entity defined.* "Qualifying entity" means:

(1) An individual hospital that is operating one or more approved medical residency training programs as defined in § 413.75(b) of this chapter; or

(2) Two or more hospitals that are operating approved medical residency training programs as defined in § 413.75(b) of this chapter and that submit a residency reduction application as a single entity.

(c) *Conditions for payments.* (1) A qualifying entity must submit an application for a voluntary residency reduction plan that meets the requirements and conditions of this section in

order to receive incentive payments for reducing the number of residents in its medical residency training programs.

(2) The incentive payments will be determined as specified under paragraph (g) of this section.

(d) *Requirements for voluntary plans.* In order for a qualifying entity to receive incentive payments under a voluntary residency reduction plan, the qualifying entity must submit an application that contains the following information, documents, and agreements—

(1) A description of the operation of a plan for reducing the full-time equivalent (FTE) residents in its approved medical residency training programs, consistent with the percentage reduction requirements specified in paragraphs (g)(2) and (g)(3) of this section;

(2) An election of the period of residency training years during which the reductions will occur. The reductions must be fully implemented by not later than the fifth residency training year in which the plan is effective;

(3) FTE counts for the base number of residents, as defined in paragraph (g)(1) of this section, with a breakdown of the number of primary care residents compared to the total number of residents; and the direct and indirect FTE counts of the entity on June 30, 1997. For joint applicants, these counts must be provided individually and collectively;

(4) Data on the annual and cumulative targets for reducing the number of FTE residents and the ratios of the number of primary care residents to the total number of residents for the base year and for each year in the 5-year reduction period. For joint applicants, these data must be provided individually and collectively;

(5) An agreement to not reduce the proportion of its primary care residents to its total number of residents below the proportion that exists in the base year, as specified in paragraph (g)(1) of this section;

(6) An agreement to comply with data submission requirements deemed necessary by CMS to make annual incentive payments during the 5-year residency reduction plan, and to fully cooperate with additional audit and

monitoring activities deemed necessary by CMS;

(7) For a qualifying entity that is a member of an affiliated group as defined in § 413.75(b), a statement that all members of the group agree to an aggregate FTE cap that reflects—

(i) The reduction in the qualifying entity's FTE count as specified in the plan during each year of the plan; and

(ii) The 1996 FTE count of the other hospital(s) in the affiliated group.

(8) A statement indicating voluntary participation in the plan under the terms of this section, signed by each hospital that is part of the applying entity.

(e) *Deadline for applications.* A qualifying entity must submit an application that meets the requirements of paragraph (d) of this section at least one day prior to the first day of the period to which the plan would be effective but no later than November 1, 1999. The application must be submitted to the contractor, with a copy to CMS.

(f) *Effective dates of plans.* Residency reduction plans that are submitted to the contractor on or after September 17, 1999 but on or before November 1, 1999, may be effective for portions of cost reporting periods beginning no earlier than the day after the date of the application.

(g) *Residency reduction requirements—*

(1) *Base number of residents defined.* (i) “Base number of residents” means the lesser of—

(A) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for the most recent residency training year ending June 30, 1996; or

(B) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for any subsequent residency training year that ends before the date the entity submits its plan to the contractor and CMS.

(ii) The residency training year used to determine the base number of residents is the “base year” for determining reduction requirements.

(iii) The qualifying entity's base number of residents may not be adjusted to reflect adjustments that may otherwise be made to the entity's FTE caps for new medical residency training programs.

(2) *Qualifying entity consisting of individual hospital.* The base number of FTE residents in all the approved medical residency training programs operated by or through a qualifying entity consisting of an individual hospital must be reduced as follows:

(i) If the base number of residents exceeds 750, residents, by at least 20 percent of the base number.

(ii) If the base number of residents exceeds 600 but is less than or equal to 750 residents—

(A) By 150 residents; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number by at least 20 percent.

(iii) If the base number of residents is 600 or less residents—

(A) By 25 percent; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(3) *Qualifying entity consisting of two or more hospitals.* The base number of FTE residents in the aggregate for all the approved medical residency training programs operated by or through a qualifying entity consisting of two or more hospitals must be reduced—

(i) By 25 percent; or

(ii) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(4) *Treatment of rotating residents.* A qualifying entity will not be eligible for incentive payments for a reduction in the base number of residents if the reduction is a result of the entity rotating residents to another hospital that is not a part of its voluntary residency reduction plan.

(5) *Updates to annual and cumulative targets* (i) Except as provided in paragraph (g)(5)(ii) of this section an entity with an approved voluntary residency reduction plan may not change the annual and cumulative reduction targets

that are specified in its plan in accordance with paragraphs (g)(2) and (g)(3) of this section.

(ii) An entity may update annual reduction targets specified in its plan only if—

(A) It has failed to meet a specified annual target for a plan year in the 5-year period; and

(B) It wishes to adjust future annual targets for the remaining years of the plan in order to comply with its cumulative target.

(iii) An updated plan allowed under paragraph (g)(5)(ii) of this section must be submitted prior to the beginning of each July 1 medical residency training year during the plan years.

(h) *Computation of incentive payment amount.* (1) Incentive payments to qualifying entities that meets the requirements and conditions of paragraphs (d) and (g) of this section will be computed as follows:

(i) *Step 1.* Determine the amount (if any) by which the payment amount that would have been made under § 413.76 if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the amount of payment that would have been made under § 413.76 in each year under the voluntary residency reduction plan, taking into account the reduction in the number of FTE residents under the plan.

(ii) *Step 2.* Determine the amount (if any) by which the payment amount that would have been made under § 412.105 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.105 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iii) *Step 3.* Determine the amount (if any) by which the payment amount that would have been made under § 412.322 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs

of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.322 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iv) *Step 4.* Multiply the sum of the amounts determined under paragraph (h)(i), (ii), and (iii) of this section by the applicable hold harmless percentages specified in paragraph (i) of this section.

(2) The determination of the amounts under paragraph (h)(1) of this section for any year is based on the applicable Medicare statutory provisions in effect on the application deadline date for the voluntary reduction plan specified under paragraph (e) of this section.

(i) *Applicable hold-harmless percentage.* The applicable hold-harmless percentages for each year in which the residency reduction plan is in effect are as follows:

- (1) 100 percent for the first and second residency training years;
- (2) 75 percent for the third year;
- (3) 50 percent for the fourth year; and
- (4) 25 percent for the fifth year.

(j) *Payments to qualifying entities.* Annual incentive payments through cost reports will be made to each hospital that is or is part of a qualifying entity over the 5-year reduction period if the qualifying entity meets the annual and cumulative reduction targets specified in its voluntary reduction plan.

(k) *Penalty for noncompliance—(1) Nonpayment.* No incentive payment may be made to a qualifying entity for a residency training year if the qualifying entity has failed to reduce the number of FTE residents according to its voluntary residency reduction plan.

(2) *Repayment of incentive amounts.* The qualifying entity is liable for repayment of the total amount of incentive payments it has received if the qualifying entity—

(i) Fails to reduce the base number of residents by the percentages specified in paragraphs (g)(2) and (g)(3) of this section by the end of the fifth residency training year; or

(ii) Increases the number of FTE residents above the number of residents permitted under the voluntary resi-

dency reduction plan as of the completion date of the plan.

(1) *Postplan determination of FTE caps for qualifying entities—(1) No penalty imposed.* Upon completion of a voluntary residency reduction plan, if no penalty is imposed, the qualifying entity's 1996 FTE count is permanently adjusted to equal the unweighted FTE count used for direct GME payments for the last residency training year in which a qualifying entity participates.

(2) *Penalty imposed.* Upon completion of the voluntary residency reduction plan—

(i) *During repayment period.* If a penalty is imposed under paragraph (k)(2) of this section, during the period of repayment, the qualifying entity's FTE count is as specified in paragraph (1)(1) of this section.

(ii) *After repayment period.* Once the penalty repayment is completed, the qualifying entity's FTE reverts back to its original 1996 FTE cap.

[64 FR 44855, Aug. 18, 1999, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.89 Bad debts, charity, and courtesy allowances.

(a) *Principle.* Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost. However, subject to the limitations described under paragraph (h) of this section and the exception for services described under paragraph (i) of this section, bad debts attributable to the deductibles and co-insurance amounts are reimbursable under the program.

(b) *Definitions—(1) Bad debts.* (i) For cost reporting periods beginning before October 1, 2020:

(A) “Bad debts” are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.

(B) “Accounts receivable” and “notes receivable” are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(ii) For cost reporting periods beginning on or after October 1, 2020, “bad debts” are amounts considered to be uncollectible from patient accounts that were created or acquired in providing services and are categorized as

implicit price concessions for cost reporting purposes and are recorded in the provider's accounting records as a component of net patient revenue.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill-Burton obligation are considered as charity allowances.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

(c) *Normal accounting treatment: Reduction in revenue.* (1) For cost reporting periods beginning before October 1, 2020:

(i) Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts.

(2) For cost reporting periods beginning on or after October 1, 2020:

(i) Bad debts, also known as "implicit price concessions," charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be recorded as an implicit price concession that results in a reduction in revenue.

(d) *Requirements for Medicare.* Under Medicare, costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the Medicare program, and conversely, costs of

services provided for other than beneficiaries are not to be borne by the Medicare program. Uncollected revenue related to services furnished to beneficiaries of the program generally means the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts could result in the related costs of covered services being borne by other than Medicare beneficiaries. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs. Bad debts arising from other sources are not allowable costs.

(e) *Criteria for allowable bad debt.* A bad debt must meet the following criteria to be allowable:

(1) The debt must be related to covered services and derived from deductible and coinsurance amounts.

(2) The provider must be able to establish that reasonable collection efforts were made.

(i) *Non-indigent beneficiary.* A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes. To be considered a reasonable collection effort for non-indigent beneficiaries, all of the following are applicable:

(A) A provider's collection effort or the effort of a collection agency acting on the provider's behalf, or both, to collect Medicare deductible or coinsurance amounts must consist of all of the following:

(1) Be similar to the collection effort put forth to collect comparable amounts from non-Medicare patients.

(2) For cost reporting periods beginning before October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.

(3) For cost reporting periods beginning on or after October 1, 2020, involve the issuance of a bill to the beneficiary

or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:

(i) The date of the Medicare remittance advice that results from processing the claim for services furnished to the beneficiary and generates the beneficiary's cost sharing amounts.

(ii) The date of the remittance advice from the beneficiary's secondary payer, if any.

(iii) The date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary.

(4) Include other actions such as subsequent billings, collection letters, and telephone calls, emails, text messages, or personal contacts with this party.

(5)(i) Last at least 120 days after paragraph (e)(2)(i)(A)(2) or (3) of this section is met before being written off as uncollectible under paragraph (e)(3) of this section.

(ii) Start a new 120-day collection period each time a payment is received within a 120-day collection period.

(6) Maintaining and, upon request, furnishing verifiable documentation to its contractor that includes all of the following:

(i) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients.

(ii) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.

(iii) The beneficiary's file with copies of the bill(s) and follow-up notices.

(B) A provider that uses a collection agency to perform its collection effort must do all of the following:

(1) Reduce the beneficiary's account receivable by the gross amount collected.

(2) Include any fee charged by the collection agency as an administrative cost.

(3) Before claiming the unpaid amounts as a Medicare bad debt, cease all collection efforts, including the collection agency efforts, and ensure that the collection accounts have been re-

turned to the provider from the agency.

(ii) *Indigent non-dual eligible beneficiary.* An indigent non-dual eligible beneficiary is a beneficiary who is determined to be indigent or medically indigent by the provider and is not eligible for Medicaid as categorically or medically needy.

(A) To determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider—

(1) Must not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence;

(2) Must take into account the analysis of both the beneficiary's assets (only those convertible to cash and unnecessary for the beneficiary's daily living) and income;

(3) May consider extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence which may include an analysis of both the beneficiary's liabilities and expenses, if indigence is unable to be determined under paragraph (e)(ii)(A)(2) of this section;

(4) Must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program; and

(5) Must maintain and, upon request, furnish its contractor its indigence policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence.

(B) Once indigence is determined the bad debt may be deemed uncollectible without applying a collection effort under paragraph (e)(2)(i)(A) or (B) of this section.

(iii) *Indigent dual-eligible beneficiaries (including qualified Medicare beneficiaries).* Providers may deem Medicare beneficiaries indigent or medically indigent when such individuals have also been determined eligible for Medicaid

under a State's Title XIX Medicaid program as either categorically needy individuals or medically needy individuals. To be considered a reasonable collection effort for dual-eligible beneficiaries:

(A) When a State permits a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, to determine the State's liability for the beneficiary's Medicare cost sharing, the provider—

(1) Must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible or coinsurance amounts;

(2) Must submit a bill to its Medicaid/ Title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance;

(3) Must submit the Medicaid remittance advice received from the State to its Medicare contractor;

(4) Must reduce allowable Medicare bad debt by any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, regardless of whether the State actually pays its obligated amount to the provider; and

(5) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(B) When, through no fault of the provider, a provider does not receive a Medicaid remittance advice because the State does not permit a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, or because the State does not generate a Medicaid remittance advice, the provider—

(1) Must submit to its contractor, all of the following auditable and verifiable documentation:

(i) The State's Medicaid notification stating that the State has no legal obligation to pay the provider for the beneficiary's Medicare cost sharing.

(ii) A calculation of the amount the State owes the provider for Medicare cost sharing.

(iii) Verification of the beneficiary's eligibility for Medicaid for the date of service;

(2) Must reduce allowable Medicare bad debt by any amount the State is obligated to pay, regardless of whether the State actually pays its obligated amount to the provider; and

(3) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(3) The debt was actually uncollectible when claimed as worthless.

(4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

(f) *Reporting period for writing off bad debts and reporting of recoveries of bad debts reimbursed in prior periods.* For cost reporting periods beginning before, on, or after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless.

(1) Any payment on the account made by the beneficiary or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

(2) In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent period.

(i) In situations described in this paragraph (f)(2), the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered.

(ii) The amount of reduction in the period of recovery (as specified in paragraph (f)(2)(i) of this section) must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period.

(g) *Charity allowances.* Charity allowances have no relationship to beneficiaries of the Medicare program and are not allowable costs. These charity

allowances include the costs of uncompensated services furnished under a Hill-Burton obligation. (Note: In accordance with section 106(b) of Pub. L. 97–248 (enacted September 3, 1982), this sentence is effective with respect to any costs incurred under Medicare except that it does not apply to costs which have been allowed prior to September 3, 1982, pursuant to a final court order affirmed by a United States Court of Appeals.) The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

(h) *Limitations on bad debts*—(1) *Hospitals*. In determining reasonable costs for hospitals, the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

- (i) For cost reporting periods beginning during fiscal year 1998, by 25 percent;
 - (ii) For cost reporting periods beginning during fiscal year 1999, by 40 percent;
 - (iii) For cost reporting periods beginning during fiscal year 2000, by 45 percent; and
 - (iv) For cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent.
- (v) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(2) *Skilled nursing facilities and swing bed hospitals*. For the purposes of this paragraph (h)(2), a dual eligible individual is defined as an individual that is entitled to benefits under Part A of Medicare and is determined eligible by the State for medical assistance under Title XIX of the Act as described under paragraph (2) of the definition of a “full-benefit dual eligible individual” at § 423.772 of this chapter. In determining reasonable costs for a skilled nursing facility and for post-hospital SNF care furnished in a swing bed hospital, as defined in § 413.114(b), the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

- (i) *For non-dual eligible individuals*—(A) For cost reporting periods beginning during fiscal years 2006 through 2012, by 30 percent, for a patient in a skilled nursing facility.

(B) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(ii) *For dual eligible individuals*—(A) For cost reporting periods beginning during fiscal year 2013, by 12 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(B) For cost reporting periods beginning during fiscal year 2014, by 24 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(C) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(3) *End-stage renal dialysis facilities*. In determining reasonable costs for an end-stage renal dialysis facility, the amount of allowable bad debt (as defined in paragraph (e) of this section) is:

- (i) For cost reporting periods beginning before October 1, 2012, reimbursed up to the facility’s costs.
- (ii) For cost reporting periods beginning on or after October 1, 2012 and before January 1, 2013, reduced by 12 percent with the resulting amount reimbursed up to the facility’s costs.
- (iii) For cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, reduced by 12 percent.

(iv) For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, reduced by 35 percent.

(4) *All other providers*. In determining reasonable costs for all other providers, suppliers and other entities not described elsewhere in paragraph (h) of this section that are eligible to receive reimbursement for bad debts under this section, the amount of allowable bad debts (as defined in paragraph (e) of this section) is reduced:

- (i) For cost reporting periods beginning during fiscal year 2013, by 12 percent.

(ii) For cost reporting periods beginning during fiscal year 2014, by 24 percent.

(iii) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(i) *Exceptions applicable to bad debt reimbursement.* (1) Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For end-stage renal dialysis services furnished on or after January 1, 2011 and paid for under the end-stage renal dialysis prospective payment system described in § 413.215, bad debts arising from covered items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 33898, July 31, 1992; 60 FR 63189, Dec. 8, 1995; 63 FR 41005, July 31, 1998; 66 FR 32195, June 13, 2001. Redesignated at 69 FR 49254, Aug. 11, 2004, and amended at 71 FR 48142, Aug. 18, 2006; 71 FR 69785, Dec. 1, 2006; 75 FR 49198, Aug. 12, 2010; 77 FR 67350, Nov. 9, 2012; 85 FR 59023, Sept. 18, 2020]

§ 413.90 Research costs.

(a) *Principle.* Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

(b) *Application.* (1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the Medicare programs.

(2) If research is conducted in conjunction with, and as a part of, the

care of patients, the costs of usual patient care and studies, analyses, surveys, and related activities to serve the provider's administrative and program needs are allowable costs in the determination of payment under Medicare.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 413.92 Costs of surety bonds.

Costs incurred by a provider to obtain a surety bond required by part 489, subpart F of this chapter are not included as allowable costs.

[63 FR 310, Jan. 5, 1998]

§ 413.94 Value of services of nonpaid workers.

(a) *Principle.* The value of services in positions customarily held by full-time employees performed on a regular, scheduled basis by individuals as nonpaid members of organizations under arrangements between such organizations and a provider for the performance of such services without direct remuneration from the provider to such individuals is allowable as an operating expense for the determination of allowable cost subject to the limitation contained in paragraph (b) of this section. The amounts allowed are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institutions as a legal obligation for operating expenses.

(b) *Limitations: Services of nonpaid workers.* The services must be performed on a regular, scheduled basis in positions customarily held by full-time employees and necessary to enable the provider to carry out the functions of normal patient care and operation of the institution. The value of services of a type for which providers generally do not remunerate individuals performing such services is not allowable as a reimbursable cost under the Medicare program. For example, donated services of individuals in distributing books and magazines to patients, or in serving in a provider canteen or cafeteria or in a provider gift shop, would not be reimbursable.

(c) *Application.* The following illustrates how a provider would determine an amount to be allowed under this

principle: The prevailing salary for a lay nurse working in Hospital A is \$5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital \$2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional \$3,000 to bring the value of the services rendered to \$5,000. The amount of \$3,000 would be allowable if the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

§ 413.98 Purchase discounts and allowances, and refunds of expenses.

(a) *Principle.* Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

(b) *Definitions*—(1) *Discounts.* Discounts, in general, are reductions granted for the settlement of debts.

(2) *Allowances.* Allowances are deductions granted for damage, delay, shortage, imperfection, or other causes, excluding discounts and returns.

(3) *Refunds.* Refunds are amounts paid back or a credit allowed on account of an overcollection.

(c) *Normal accounting treatment—Reduction of costs.* All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. If they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, if they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

(d) *Application.* (1) Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before

consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required. In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

(2) As with discounts, allowances, and rebates received from purchases of goods or services, refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

§ 413.99 Qualified and Non-Qualified Deferred Compensation Plans.

(a) *Statutory basis, scope, and definitions*—(1) *Basis.* All payments to providers of services must be based on the reasonable cost of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in this part.

(2) *Scope.* This section and § 413.100(c)(2)(vii) apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

(3) *Definitions.* As used in this section the following definitions apply:

Deferred Compensation means remuneration currently earned by an employee that is not received until a subsequent period, usually after retirement.

Employee Retirement Income Security Act of 1974 (ERISA) is a Federal law that sets standards of protection for individuals in most voluntarily established, private-sector retirement plans.

The law is set forth in Title 29, Chapter 18 of the U.S. Code.

Funded Plan means a plan in which assets have been irrevocably and unconditionally set aside with a third party for the payment of plan benefits (for example, in a trust or escrow account), and those assets are beyond the reach of the employer or its general creditors.

Non-Qualified Deferred Compensation Plan (NQDC) means an elective or non-elective plan, agreement, method, or arrangement between an employer and an employee to pay the employee compensation in the future. In comparison with qualified plans, nonqualified plans do not provide employers and employees with the tax benefits associated with qualified plans because NQDC plans do not satisfy all the requirements of 26 U.S.C. 401(a).

Non-Qualified Defined Benefit Plan (NQDB) means a type of NQDC that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees.

Pension Benefit Guaranty Corporation (PBGC) is a Federal agency created by ERISA to protect benefits in private-sector QDBP plans described in section 3(35) of ERISA.

Qualified Defined Benefit Plan (QDBP) means a type of Qualified Deferred Compensation Plan that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees. A QDBP meets the applicable requirements of ERISA, as amended, and the requirements for a QDBP under 26 U.S.C. 401(a). Under a qualified plan, employers are entitled to deduct expenses in the year the employer makes contributions even though employees will not recognize income until the receipt of distributions.

Qualified Defined Contribution or Individual Account Plan (QDCP) means a type of Deferred Compensation Plan in which the employee, the employer, or both, contribute to an employee's individual account under the plan. The amount in the account at distribution includes the contributions and investment gains or losses, minus any investment and administrative fees. The value of the account changes based on contributions and the value and performance of the investments. A QDCP meets the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and, if applicable 26 U.S.C. 401(k).

Unfunded Plan means a plan in which benefits are supported by assets that have not been set aside (that is, a "pay as you go" plan), or by assets that have been set aside, but remain subject to the claims of the employer's general creditors.

(b) *Principle requirements*—(1) *General*. Deferred Compensation contributions or payments must be made by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable, when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

(2) *Deferred Compensation for provider-based physicians services in a hospital or SNF*. Costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet the following requirements to be allowable under the program:

(i) The allocation of physician compensation costs required under §415.60 of this chapter does not attribute the provider-based physician's Deferred Compensation entirely to one category

of service and his current compensation to another.

(ii) Contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at § 415.60(a) of this chapter.

(iii) The amount of Deferred Compensation does not exceed the amount specified in the agreement required by § 415.60(g) of this chapter.

(iv) An arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed.

(v) The costs incurred for physician guaranteed arrangements for hospital emergency room availability services, must meet the following additional requirements:

(A) The terms of both the guarantee arrangements and the Deferred Compensation Plan establish the amounts to be included at the beginning of the hospital's cost reporting period.

(B) The amount of Deferred Compensation is included in the guaranteed amount.

(C) The hospital contributes to the Deferred Compensation Plan from its own funds.

(D) The amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services.

(E) When the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

(c) *Requirements for Non-Qualified and Qualified Deferred Compensation Plans—*(1) *NQDC requirements.* In order for contributions or payments by a provider of services to an NQDC as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDC must meet the general requirements at paragraph (c)(1)(i) of this section, and it must either meet the requirements for a funded NQDC at paragraph (c)(1)(ii) of this section or the require-

ments for an unfunded NQDC at paragraph (c)(1)(iii) of this section, as applicable.

(i) *General requirements.* An NQDC must satisfy the requirements for document compliance and operational compliance set forth in 26 U.S.C. 409A.

(ii) *Funded NQDCs.* A funded NQDC must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDCs.* An NQDC that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDC as a result of contributions made by a provider of services.

(2) *QDCP requirements.* A QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and if applicable 26 U.S.C. 401(k). A QDCP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(3) *QDBP requirements.* A QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a defined benefit plan under 26 U.S.C. 401(a). A QDBP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(4) *NQDB requirements.* In order for contributions or payments by a provider of services to an NQDB as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDB must meet the general requirements at paragraph (c)(4)(i) of this section, and it must either meet the requirements for a funded NQDB at paragraph (c)(4)(ii) of this section or the requirements for an unfunded NQDB at paragraph (c)(4)(iii) of this section, as applicable.

(i) *General requirements.* An NQDB must satisfy the requirements for document compliance set forth in 26 U.S.C. 409A and operational compliance set forth in 26 U.S.C. 409A(a).

(ii) *Funded NQDBs.* An NQDB that is funded must meet the definition of a Funded Plan in paragraph (a)(3) of this

section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDBs*. An NQDB that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDB as a result of contributions made by a provider of services.

(5) *Funded Plan requirements*—(i) *Acceptable funding mechanism*. Both provider of services contributions and employee contributions must be used either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee.

(ii) *Life insurance contracts*. The purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee.

(iii) *Sole benefit of participating employees*. Regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

(d) *Recognition of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plans*—(1) *General rule*. Except as provided for in paragraph (c)(1)(iii) of this section with respect to QDBPs and funded NQDBs, contributions to Qualified Deferred Compensation Plans or payments to plan participants from Non-Qualified Deferred Compensation Plans are recognized as allowable costs in accordance with paragraph (c)(1)(i) of this section (in the case of Unfunded Plans) and paragraph (c)(1)(ii) of this section (in the case of Funded Plans).

(i) *Unfunded Plans*. Contributions or payments made to an unfunded Deferred Compensation Plans (including unfunded NQDBs) by a provider of services on behalf of its employees are included in allowable costs only during

the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable, in accordance with § 413.100(c)(2)(vii)(A).

(ii) *Funded Plans*. Reasonable provider of services payments made under funded Deferred Compensation Plans (specifically, funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs) are included in allowable costs in accordance with § 413.100(c)(2)(vii)(B).

(iii) *Exception for QDBPs and funded NQDBs*. (A) QDBP and NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB.

(B) Payments to a QDBP or funded NQDB for a cost reporting period must be measured on a cash basis. A contribution or payment is deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

(C) Payments or contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn.

(D) QDBP and funded NQDB annual allowable costs are computed as follows:

(1) QDBP and funded NQDB costs and limits are computed in accordance with § 413.100(c)(2)(vii)(D).

(2) For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(2), provider of services contribution payments for each applicable cost reporting period must be determined on a cash basis without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions.

(3) The averaging period used to determine the QDBP or funded NQDB cost limit must be determined without

regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) must be defined as consecutive 12-month periods ending immediately prior to the provider of services initial Medicare cost reporting period.

(4) The averaging period used to determine the QDBP or funded NQDB cost limit must exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger).

(5) In general, the current period defined benefit cost and limit is computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contributions or payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan are treated as contribution payments made to the successor plan.

(2) [Reserved]

(e) *Documentation requirements.* Documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plan(s) that it has included in its cost reports.

(1) *Required documentation.* The provider of services must maintain and make available, upon request by the contractor or CMS, certain specified documentation, to substantiate the allowability of the contributions or payments to its Qualified or Non-Qualified Deferred Compensation Plan(s), or both:

(i) Documentation that demonstrates that the provider of services is in compliance with 26 U.S.C. 409A and 409A(a), and, if applicable, 26 U.S.C. 457.

(ii) Ledger accounts/account statements for each plan participant noting current year deferrals, distributions and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests.

(iii) Documentation that demonstrates the amount(s) and date(s) of

actual contributions or payments made to the Qualified or Non-Qualified Deferred Compensation Plan during the current cost reporting period.

(iv) Schedule SB of Form 5500 (tri-agency form (Department of Labor (DOL), Internal Revenue Service (IRS), and PBGC) that plans file with the DOL's "EFAST" electronic filing system) for a QDBP for the current cost reporting period, or any applicable prior periods.

(v) In the case of a system-wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (that is, as a result of carry forward contributions), the provider of services must also have data available to track and reconcile the difference.

(2) *Additional documentation.* The following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of the payments/contributions by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan:

(i) The plan document, the trust document and all amendments related to the current cost reporting period.

(ii) If applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period.

(iii)(A) Supporting documents for all plan assets and liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc.

(B) Verification of how assets are valued.

(iv)(A) Trustee or administrator reports.

(B) Ledgers.

(C) Journals.

(D) Trustee, administrator, and investment committee minutes.

(E) Certified audit report and other financial reports for the trust.

(F) Any other financial reports, including receipt and disbursement statements, a detailed income statement, and a detailed balance sheet.

(v) For each covered QDBP, documentation of the certified premium information and payments to the PBGC.

(f) *Administrative and other costs associated with Deferred Compensation Plans.* The provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the policies set forth in this section.

(1) *Trustee and custodial fees.* Reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost except where the plan provides that such fees are paid out of the corpus or earnings of the fund.

(2) *Vested benefits.* The forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs.

(3) *Benefits to be paid.* If an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable non-vested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead the non-vested contributions or payments should be used to reduce the provider of services contributions or payments to the Deferred Compensation Plan, in the cost reporting period in which the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions or payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then the provider of services costs are reduced by the contractor to the extent of such non-vested funds.

(4) *DOL, IRS, or PBGC penalties.* If the provider of services is assessed an excise tax or other remedy by the DOL, IRS, or PBGC for failure to follow DOL, IRS, or PBGC requirements under ERISA or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the cost is

unallowable in accordance with section 1861(v)(8) of the Act.

(5) *Loans made from a Deferred Compensation Plan.* A provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted.

(6) *Termination/discontinuation of a Deferred Compensation Plan.* If the provider of services declines to vest its outstanding required contributions or payments (that is, matching or non-elective) to a Deferred Compensation Plan as a result of a termination in full or in part or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

(7) *Required offset against interest expense.* Investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

(8) *Treatment of residual assets following termination of a Funded Plan.* (i) Residual assets arising from the termination of a funded Deferred Compensation Plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions or payments, usually the administrative and general cost center.

(ii) Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years.

(iii) The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

(g) *Treatment of costs associated with the PBGC.* Costs associated with the requirements set forth in ERISA and by the PBGC and incurred by a provider of services who sponsors a QDBP are allowable or unallowable under the program as provided for in this paragraph (g).

(1) *Costs paid out of the plan trust.* PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed under paragraph (d)(1)(iii)(A) of this section, and are not allowable as separate costs.

(2) *Premium payments for single- and multi-employer plans.* The amount of PBGC premiums paid for basic benefits (flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program.

(3) *Liability for missing participants or beneficiaries.* The total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (as described in 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP, is allowable under the program.

(4) *Plan termination due to distress.* For a defined benefit plan that terminated with insufficient assets to pay all of the plan benefits, which resulted in the PBGC making payment of vested benefits up to limits defined by law in accordance with 29 CFR part 4022, such amounts contributed to the QDBP by the provider of services who sponsors the QDBP are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

(5) *Restored plan payments.* If the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

[87 FR 49406, Aug. 10, 2022]

§ 413.100 Special treatment of certain accrued costs.

(a) *Principle.* As described in § 413.24(b)(2), under the accrual basis of accounting, revenue is reported in the period in which it is earned and expenses are reported in the period in which they are incurred. In the case of accrued costs described in this section, for Medicare payment purposes the costs are allowable in the year in which the costs are accrued and claimed for Medicare payment only under the conditions set forth in paragraph (c) of this section.

(b) *Definitions—*(1) *All-inclusive paid days off benefit.* An all-inclusive paid days off benefit replaces other vacation and sick pay plans. It is a formal plan under which, based on actual hours worked, all employees accrue vested leave or payment in lieu of vested leave for any combination of types of leave, such as illness, medical appointments, holidays, and vacations.

(2) *Self-insurance.* Self-insurance is a means by which a provider independently or as part of a group undertakes the risk of protecting itself against anticipated liabilities by providing funds in an amount equal to anticipated liabilities, rather than by purchasing insurance coverage.

(c) *Recognition of accrued costs—*(1) *General.* Although Medicare recognizes, in the year of accrual, the accrual of costs for which a provider has not actually expended funds during the current cost reporting period, for purposes of payment Medicare does not recognize the accrual of costs unless the related liabilities are liquidated timely.

(2) *Requirements for liquidation of liabilities.* For accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements set forth below must be met with respect to the liquidation of related liabilities. If liquidation does not meet these requirements, the cost is disallowed, generally in the year of accrual, except as specified in paragraph (c)(2)(ii) of this section.

(i) *A short-term liability.* (A) Except as provided in paragraph (c)(2)(i)(B) of this section, a short-term liability, including the current portion of a long-term liability (for example, mortgage interest payments due to be paid in the

current year), must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred.

(B) If, within the 1-year time limit, the provider furnishes to the contractor sufficient written justification (based upon documented evidence) for nonpayment of the liability, the contractor may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred.

(ii) *Vacation pay and all-inclusive paid days off.* (A) If the provider's vacation policy, or its policy for all-inclusive paid days off, is consistent for all employees, liquidation of the liability must be made within the period provided for by that policy.

(B) If the provider's vacation policy, or its policy for all-inclusive paid days off, is not consistent for all employees, liquidation of the liability must be made within 2 years after the close of the cost reporting period in which the liability is accrued.

(C) If payment is not made within the required time period or if benefits are forfeited by the employee, an adjustment to disallow the accrued cost is made in the current period (that is, the latest year in which payment should have been made or the year in which the benefits are forfeited) rather than in the period in which the cost was accrued and claimed for Medicare payment. However, an contractor may choose to require the adjustment in the period in which the cost was accrued and claimed for Medicare payment if the cost report for that period is open or can be reopened as provided in §405.1885 of this chapter, and if the contractor believes the adjustment is more appropriate in that period.

(iii) *Sick pay.* (A) If sick leave is vested and funded in a deferred compensation plan, liabilities related to the contributions to the fund must be liquidated, generally within 1 year after the end of the cost reporting period in which the liability is incurred. If, within the 1-year time limit, the provider furnishes to the contractor sufficient written justification (based upon documented evidence) for nonpayment of the liability, the contractor may grant

an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred. Contributions to the deferred compensation plan must be reduced to reflect estimated forfeitures. Actual forfeitures above or below estimated forfeitures must be used to adjust annual contributions to the fund.

(B) If the sick leave plan grants employees the nonforfeitable right to demand cash payment for unused sick leave at the end of each year, sick pay is includable in allowable costs, without funding, in the cost reporting period in which it is earned.

(C) Sick pay paid on any basis other than that specified in paragraphs (c)(2)(iii) (A) or (B) of this section can be claimed for Medicare payment only on a cash basis for the year in which the benefits are paid.

(iv) *Compensation of owners.* Accrued liability related to compensation of owners other than sole proprietors and partners must be liquidated within 75 days after the close of the cost reporting period in which the liability occurs.

(v) *Nonpaid workers.* Obligations incurred under a legally-enforceable agreement to remunerate an organization of nonpaid workers must be discharged no later than the end of the provider's cost reporting period following the period in which the services were furnished.

(vi) *FICA and other payroll taxes—(A) General rule.* The provider's share of FICA and other payroll taxes that the provider becomes obligated to remit to governmental agencies is included in allowable costs only during the cost reporting period in which payment (upon which the payroll taxes are based) is actually made to the employee. For example, payroll taxes applicable to vacation benefits are not to be accrued in the period in which the vacation benefits themselves are accrued but rather are allowable only in the period in which the employee takes the vacation.

(B) *Exception.* If payment would be made to an employee during a cost reporting period but for the fact the regularly scheduled payment date is after the end of the period, costs of accrued payroll taxes related to the portion of

payroll accrued through the end of the period, but paid to the employee after the beginning of the new period, are allowable costs in the year of accrual, subject to the liquidation requirements specified in paragraph (c)(2)(i) of this section.

(vii) *Deferred compensation.* (A) Reasonable provider payments made under unfunded deferred compensation plans are included in allowable costs only during the cost reporting period in which actual payment is made to the participating employee.

(B) Accrued liability related to contributions to a funded deferred compensation plan must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. An extension, not to exceed 3 years beyond the end of the cost reporting year in which the liability was incurred, may be granted by the contractor for good cause if the provider, within the 1-year time limit, furnishes to the contractor sufficient written justification for non-payment of the liability.

(C) Postretirement benefit plans (including those addressed in Statement of Financial Accounting Standards No. 106 (December 1990)) are deferred compensation arrangements and thus are subject to the provisions of this section regarding deferred compensation and to applicable program instructions for determining Medicare payment for deferred compensation.

(D) Exception: Qualified defined benefit pension plans, which are funded deferred compensation arrangements, shall be reported on a cash accounting basis as follows:

(1) The allowable pension cost shall be equal to the amount of actual pension contributions funded during the hospital's current Medicare cost reporting period, plus any contributions funded in a prior period and carried forward, subject to the limit under paragraph (c)(2)(vii)(D)(2) of this section.

(2) Except as provided in paragraph (c)(2)(vii)(D)(3) of this section, the allowable pension cost shall not exceed 150 percent of the average contribution(s) funded during the three consecutive Medicare cost reporting periods that produce the highest average contribution(s), out of the five most re-

cent Medicare cost reporting periods (ending with the current cost reporting period). Contributions in excess of the limit may be carried forward to future period(s). In the case of a newly adopted pension plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

(3) A waiver of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section may be granted for a specific Medicare cost reporting period for all or a portion of the contributions in excess of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section if it is determined that such excess costs are reasonable and necessary for that period.

(viii) *Self-insurance.* Accrued liability related to contributions to a self-insurance program that are systematically made to a funding agency and that cover malpractice and comprehensive general liability, unemployment compensation, workers' compensation insurance losses, or employee health benefits, must be liquidated within 75 days after the close of the cost reporting period.

[60 FR 33136, June 27, 1995, as amended at 64 FR 51909, Sept. 27, 1999; 77 FR 53682, Aug. 31, 2012]

§ 413.102 Compensation of owners.

(a) *Principle.* A reasonable allowance of compensation for services of owners is an allowable cost provided that the services are actually performed in a necessary function.

(b) *Definitions—(1) Compensation.* Compensation means the total benefit received by the owner for the services he furnishes to the institution. It includes the following items:

(i) Salary amounts paid for managerial, administrative, professional, and other services.

(ii) Amounts paid by the institution for the personal benefit of the proprietor.

(iii) The cost of assets and services that the proprietor receives from the institution.

(iv) Deferred compensation.

(2) *Reasonableness.* Reasonableness requires that the compensation allowance—

(i) Be such an amount as would ordinarily be paid for comparable services by comparable institutions; and

(ii) Depend upon the facts and circumstances of each case.

(3) *Necessary.* Necessary requires that the function be—

(i) Such that had the owner not furnished the services, the institution would have had to employ another person to perform the services; and

(ii) Pertinent to the operation and sound conduct of the institution.

(c) *Application.* (1) Owners of provider organizations often furnish services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services furnished to be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

(2) Ordinarily, compensation paid to proprietors is a distribution of profits. However, if a proprietor furnishes necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. If the services are furnished on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be determined by other appropriate means.

§413.106 Reasonable cost of physical and other therapy services furnished under arrangements.

(a) *Principle.* The reasonable cost of the services of physical, occupational, speech, and other therapists, and services of other health specialists (other than physicians), furnished under arrangements (as defined in section 1861(w) of the Act) with a provider of

services, a clinic, a rehabilitation agency or a public health agency, may not exceed an amount equivalent to the prevailing salary and additional costs that would reasonably have been incurred by the provider or other organization had such services been performed by such person in an employment relationship, plus the cost of other reasonable expenses incurred by such person in furnishing services under such an arrangement. However, if the services of a therapist are required on a limited part-time basis, or to perform intermittent services, payment may be made on the basis of a reasonable rate per unit of service, even though this rate may be greater per unit of time than salary-related amounts, if the greater payment is, in the aggregate, less than the amount that would have been paid had a therapist been employed on a full-time or regular part-time salaried basis. Pursuant to section 17(a) of Public Law 93-233 (87 Stat. 967), the provisions of this section are effective for cost reporting periods beginning after March, 1975.

(b) *Definitions*—(1) *Prevailing salary.* The prevailing salary is the hourly salary rate based on the 75th percentile of salary ranges paid by providers in the geographical area, by type of therapy, to therapists working full time in an employment relationship.

(2) *Fringe benefit and expense factor.* The standard fringe benefit and expense factor is an amount that takes account of fringe benefits, such as vacation pay, insurance premiums, pension payments, allowances for job-related training, meals, etc., generally received by an employee therapist, as well as expenses, such as maintaining an office, appropriate insurance, etc., an individual not working as an employee might incur in furnishing services under arrangements.

(3) *Adjusted hourly salary equivalency amount.* The adjusted hourly salary equivalency amount is the prevailing hourly salary rate plus the standard fringe benefit and expense factor. This amount is determined on a periodic basis for appropriate geographical areas.

(4) *Travel allowance.* A standard travel allowance is an amount that is recognized, in addition to the adjusted hourly salary equivalency amount.

(5) *Limited part-time or intermittent services.* Therapy services are considered to be on a limited part-time or intermittent basis if the provider or other organization furnishing the services under arrangements requires the services of a therapist or therapists on an average of less than 15 hours per week. This determination is made by dividing the total hours of services furnished during the cost reporting period by the number of weeks in which the services were furnished in the cost reporting period regardless of the number of days in each week in which services were performed.

(6) *Guidelines.* Guidelines are the amounts published by CMS reflecting the application of paragraphs (b) (1) through (4) of this section to an individual therapy service and a geographical area. Other statistically valid data may be used to establish guidelines for a geographical area, provided that the study designs, questionnaires and instructions, as well as the resultant survey data for determining the guidelines are submitted to and approved in advance by CMS. Such data must be arrayed so as to permit the determination of the 75th percentile of the range of salaries paid to full-time employee therapists.

(7) *Administrative responsibility.* Administrative responsibility is the performance of those duties that normally fall within the purview of a department head or other supervisor. This term does not apply to directing aides or other assistants in furnishing direct patient care.

(c) *Application.* (1) Under this provision, CMS will establish criteria for use in determining the reasonable cost of physical, occupational, speech, and other therapy services and the services of other health specialists (other than physicians) furnished by individuals under arrangements with a provider of services, a clinic, a rehabilitation agency, or public health agency. It is recognized that providers have a wide variety of arrangements with such individuals. These individuals may be independent practitioners or employees

of organizations furnishing various health care specialists. This provision does not require change in the substance of these arrangements.

(2) If therapy services are performed under arrangements at a provider site on a full-time or regular part-time basis, the reasonable cost of such services may not exceed the amount determined by taking into account the total number of hours of services furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished and a standard travel allowance.

(3) If therapy services are performed under arrangements on a limited part-time or intermittent basis at the provider site, the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis, except that payment for these services, in the aggregate, during the cost reporting period, may not exceed the amount that would be determined to be reasonable under paragraph (c)(2) of this section, had a therapist furnished the provider or other organization furnishing the services under arrangements 15 hours of service per week on a regular part-time basis for the weeks in which services were furnished by the non-employee therapist.

(4) If an HHA furnishes services under arrangements at the patient's residence or in other situations in which therapy services are not performed at the provider's site, the reasonable cost of such services is evaluated as follows:

(i) *Time records available.* If time records of HHA visits are maintained by the provider, the reasonable cost of such services is evaluated on a unit-of-time basis, by taking into account the total number of hours of service furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance for each visit. However, if the travel time of the therapist is accurately recorded by the therapist, and approved and maintained by the provider, the reasonable cost of such

services may be evaluated, at the option of the provider, by taking into account the total number of hours of service furnished by the therapist, including travel time, and the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished. This option does not apply to services furnished by HHAs under arrangements with providers other than HHAs.

(ii) *No time records available.* If time records are unavailable or found to be inaccurate, each HHA visit is considered the equivalent of one hour of service. In such cases, the reasonable cost of such services is determined by taking into account the number of visits made by the therapist under arrangements with such agency, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance.

(iii) *Limited part-time or intermittent services.* If under paragraph (c)(4) (i) or (ii) of this section, the provider required therapy services on an average of less than 15 hours per week, the services are considered limited part-time or intermittent services, and the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis as described in paragraph (c)(3) of this section.

(5) If therapy services are performed in situations where compensation to a therapist employed by the provider is based, at least in part, on a fee-for-service or on a percentage of income (or commission), the guidelines will apply. The entire compensation will be subject to the guidelines in cases where the nature of the arrangements is most like an under "arrangement" situation, although technically the provider may treat the therapists as employees. The intent of this section is to prevent an employment relationship from being used to circumvent the guidelines.

(6) These provisions are applicable to individual therapy services or disciplines by means of separate guidelines by geographical area and apply to costs incurred after issuance of the guidelines but no earlier than the be-

ginning of the provider's cost reporting period described in paragraph (a) of this section. Until a guideline is issued for a specific therapy or discipline, costs are evaluated so that such costs do not exceed what a prudent and cost-conscious buyer would pay for the given service.

(d) *Notice of guidelines to be imposed.* Prior to the beginning of a period to which a guideline will be applied, a notice will be published in the FEDERAL REGISTER establishing the guideline amounts to be applied to each geographical area by type of therapy.

(e) *Additional allowances.* (1) If a therapist supervises other therapists or has administrative responsibility for operating a provider's therapy department, a reasonable allowance may be added to the adjusted hourly salary equivalency amount by the contractor based on its knowledge of the differential between therapy supervisors' and therapists' salaries in similar provider settings in the area.

(2) If a therapist performing services under arrangements furnishes equipment and supplies used in furnishing therapy services, the guideline amount may be supplemented by the cost of the equipment and supplies, provided the cost does not exceed the amount the provider, as a prudent and cost-conscious buyer, would have been able to include as allowable cost.

(f) *Exceptions.* The following exceptions may be granted but only upon the provider's demonstration that the conditions indicated are present:

(1) *Exception because of unique circumstances or special labor market conditions.* An exception may be granted under this section by the contractor if a provider demonstrates that the costs for therapy services established by the guideline amounts are inappropriate to a particular provider because of some unique circumstances or special labor market conditions in the area.

(2) *Exception for services furnished by risk-basis HMO providers.* For special rules concerning services furnished to an HMO's enrollees who are Medicare beneficiaries by a provider owned or operated by a risk-basis HMO (see §417.201(b) of this chapter) or related to

§ 413.114

42 CFR Ch. IV (10–1–24 Edition)

a risk-basis HMO by common ownership or control (see § 417.250(c) of this chapter).

(3) *Exception for inpatient hospital services.* Effective with cost reporting periods beginning on or after October 1, 1983, the costs of therapy services furnished under arrangements to a hospital inpatient are excepted from the guidelines issued under this section if such costs are subject to the provisions of § 413.40 or part 412 of this chapter. The contractor will grant the exception without request from the provider.

(g) *Appeals.* A request by a provider for a hearing on the determination of an contractor concerning the therapy costs determined to be allowable based on the provisions of this section, including a determination with respect to an exception under paragraph (f) of this section, is made to the contractor only after submission of its cost report and receipt of the notice of amount of program reimbursement reflecting such determination, in accordance with the provisions of subpart R of part 405 of this chapter.

[51 FR 34793, Sept. 30, 1986, as amended at 63 FR 5139, Jan. 30, 1998]

§ 413.114 Payment for posthospital SNF care furnished by a swing-bed hospital.

(a) *Purpose and basis.* This section implements section 1883 of the Act, which provides for payment for posthospital SNF care furnished by rural hospitals and CAHs having a swing-bed approval.

(1) *Services furnished in cost reporting periods beginning prior to July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals and CAHs is paid in accordance with the special rules in paragraph (c) of this section for determining the reasonable cost of this care. When furnished by rural and CAH swing-bed hospitals approved after March 31, 1988 with more than 49 beds (but fewer than 100), these services must also meet the additional payment requirements set forth in paragraph (d) of this section.

(2) *Services furnished in cost reporting periods beginning on and after July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals (other than CAHs) is

paid in accordance with the provisions of the prospective payment system for SNFs described in subpart J of this part, except that for purposes of this paragraph, the requirements of § 413.343(a) must be met using the specific assessment instrument and data designated by CMS for this purpose. Posthospital SNF care furnished in general routine inpatient beds in CAHs is paid based on reasonable cost for cost reporting periods beginning on and after July 1, 2002 and before January 1, 2004, and is paid based on 101 percent of reasonable cost for cost reporting periods beginning on and after January 1, 2004, in accordance with the provisions of subparts A through G of this part (other than paragraphs (c) and (d) of this section).

(b) *Definitions.* For purposes of this section—

Availability date means with respect to a posthospital SNF care patient in a swing-bed hospital, the later of—

(i) Any date on which a bed is available for the patient in a Medicare-participating SNF located within the hospital's geographic region;

(ii) The date that a hospital learns that a bed is available in a Medicare-participating SNF; or

(iii) If the notice is prospective, the date that a bed will become available in a Medicare-participating SNF.

Geographic region means an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles (as defined in § 412.92(c)(1) of this chapter) of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether an SNF is within a hospital's geographic region or the SNF is inaccessible to hospital patients, the CMS Regional Office makes a determination.

Swing-bed hospital means a hospital or CAH participating in Medicare that has an approval from CMS to provide posthospital SNF care as defined in § 409.20 of this chapter, and meets the

requirements specified in §482.58 or §485.645 of this chapter, respectively.

(c) *Special rules for determining the reasonable cost of posthospital SNF care furnished in cost reporting periods beginning prior to July 1, 2002.* The reasonable cost of posthospital SNF care furnished by a swing-bed hospital is determined as follows:

(1) The reasonable cost of routine SNF services is based on the average Medicare rate per patient day for routine services provided in freestanding SNFs in the region where the swing-bed hospital is located. The rates are calculated using the regions as defined in section 1886(d)(2)(D) of the Social Security Act. The rates are based on the most recent year for which settled cost reporting period data are available, increased in a compounded manner, using the increase applicable to the SNF routine cost limits, up to and including the calendar year for which the rates are in effect. If the current Medicare swing-bed rate for routine extended care services furnished by a swing-bed hospital during a calendar year is less than the rate for the prior calendar year, payment is made based on the prior calendar year's rate.

(2) The reasonable cost of ancillary services furnished as posthospital SNF care is determined in the same manner as the reasonable cost of other ancillary services furnished by the hospital in accordance with §413.53(a)(1).

(d) *Additional requirements—(1) General rule.* For services furnished in cost reporting periods beginning prior to July 1, 2002, in order for Medicare payment to be made to a swing-bed hospital with more than 49 beds (but fewer than 100), the following payment requirements must be met:

(i) If there is an available SNF bed in the geographic region, a posthospital SNF care patient must be transferred within 5 days (excluding weekends and holidays) of the availability date, unless the patient's physician certifies within the 5-day period that transfer is not medically appropriate.

(ii) The number of patient days for posthospital SNF care in a cost reporting period does not exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the pe-

riod. In those States that do not license their hospital beds, the hospitals must use the total number of hospital beds reported on their most recent Certificate of Need (CON), excluding bassinets. If during the cost reporting period, there is an increase or decrease in the number of "licensed" beds, the number of "licensed" beds for each part of the period is to be multiplied by the number of days for which that number of "licensed" beds was available. After totalling the results, compute 15 percent of the total available "licensed" bed days to determine the payment limitation.

(2) *Payment restrictions.* (i) The hospital must not seek payment for posthospital SNF care after the end of the 5 day period (excluding weekends and holidays) beginning on the availability date of a SNF bed unless the patient's physician has certified, within that 5 day period, that the transfer of the patient to the SNF was not medically appropriate.

(ii) The hospital must not seek payment for posthospital SNF care in a cost reporting period to the extent that they exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the period. In those States that do not license hospital beds, the hospital must use the average number of hospital beds reported on its most recent CON, excluding bassinets.

(3) *Payment exception.* Payment will continue to be made during the cost reporting period in which the 15 percent limit specified in paragraph (d)(1)(ii) of this section is reached for those patients who are receiving posthospital SNF care at the time the hospital reaches the limit.

[51 FR 34793, Sept. 30, 1986, as amended at 54 FR 37274, Sept. 7, 1989; 56 FR 54545, Oct. 22, 1991; 58 FR 30671, May 26, 1993; 61 FR 51616, Oct. 3, 1996; 62 FR 46037, Aug. 29, 1997; 66 FR 39600, July 31, 2001; 69 FR 49265, Aug. 11, 2004; 79 FR 27153, May 12, 2014; 85 FR 47633, Aug. 5, 2020]

§413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1833(a)(4) and (i)(3) of the Act and establishes the method for

determining Medicare payments for services related to covered ambulatory surgical center (ASC) procedures performed in a hospital on an outpatient basis. It does not apply to services furnished by an ASC operated by a hospital that has an agreement with CMS to be paid in accordance with § 416.30 of this chapter. (For regulations governing ASCs see part 416 of this chapter.)

(b) *Definitions.* For purposes of this section—

Facility services are those items and services, as specified in § 416.61 of this chapter, that are furnished by a hospital on an outpatient basis in connection with covered ASC surgical procedures, as described in § 416.65 of this chapter.

Standard overhead amount means an amount equal to the prospectively determined payment rate that would be paid for the procedure if it had been furnished by an ASC in the same geographic area.

(c) *Payment principle.* The aggregate amount of payments for facility services, furnished in a hospital on an outpatient basis, that are related to covered ASC surgical procedures (covered under § 416.65 of this chapter) is equal to the lesser of—

(1) The hospital's reasonable cost or customary charges, as determined in accordance with § 413.13, reduced by deductibles and coinsurance; or

(2) The blended payment amount as described in paragraph (d) of this section, which is based on hospital-specific cost and charge data and rates paid to free-standing ASCs.

(d) *Blended payment amount.* (1) For cost reporting periods beginning on or after October 1, 1987 but before October 1, 1988, the blended payment amount is equal to the sum of—

(i) 75 percent of the hospital-specific amount (the lesser of the hospital's reasonable cost or customary charges, reduced by deductibles and coinsurance); and

(ii) 25 percent of the ASC payment amount (that is, 80 percent of the result obtained by subtracting the deductibles from the sum of the standard overhead amounts.)

(2) For the period of time beginning with the first day of a hospital's cost

reporting period that begins on or after October 1, 1988 and ends on December 31, 1990, the blended payment amount is equal to 50 percent of the hospital-specific amount and 50 percent of the ASC payment amount.

(3) For portions of cost reporting periods beginning on or after January 1, 1991, the blended payment amount is equal to 42 percent of the hospital-specific amount and 58 percent of the ASC payment amount.

(4) For cost reporting periods beginning on or after October 1, 1988 and before January 1, 1995, the blended payment amount is equal to the sum of 75 percent of the hospital-specific amount and 25 percent of the ASC payment amount for a hospital that makes an application to its contractor and meets the following requirements.

(i) More than 60 percent of the hospital's inpatient hospital discharges, as described in § 412.60 of this chapter, occurring during its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, are classified in diagnosis related groups 36 through 74.

(ii) During its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, more than 30 percent of the hospital's total revenues is derived from outpatient services.

(5) For portions of cost reporting periods beginning on or after October 1, 1997, for purposes of calculating the blended payment amount under paragraph (d)(4) of this section, the ASC payment amount is the sum of the standard overhead amounts reduced by deductibles and coinsurance as defined in section 1866(a)(2)(ii) of the Act.

(e) *Aggregation of cost, charges, and the blended amount.* For purposes of determining the correct payment amount under paragraphs (c) and (d) of this section, all reasonable costs and customary charges attributable to facility services furnished during a cost reporting period are aggregated and treated separately from the reasonable costs and customary charges attributable to

all other services furnished in the hospital.

[52 FR 36773, Oct. 1, 1987; 52 FR 37715, Oct. 8, 1987, as amended at 55 FR 33699, Aug. 17, 1990; 55 FR 34797, Aug. 24, 1990; 57 FR 36017, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992; 65 FR 18541, Apr. 7, 2000]

§413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

(a) *Basis and purpose.* (1) This section implements section 1833(n) of the Act and establishes the method for determining Medicare payments for radiology services and other diagnostic procedures performed by a hospital on an outpatient basis.

(2) For purposes of this section—

(i) Radiology services include diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, ultrasound and other imaging services; and

(ii) Other diagnostic procedures are those identified by CMS, and do not include diagnostic radiology procedures or diagnostic laboratory tests.

(b) *Payment for hospital outpatient radiology services.* (1) The aggregate payment for hospital outpatient radiology services furnished on or after October 1, 1988 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with §413.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment amount described in paragraph (b)(2) of this section.

(2) The blended payment amount for hospital outpatient radiology services furnished on or after October 1, 1988, but before October 1, 1989, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge or fee schedule amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual deductible from 62 per-

cent of the prevailing charges (or for services furnished on or after January 1, 1989, the fee schedule amount established) for the same services when furnished by participating physicians in their offices in the same locality.

(3) For hospital outpatient radiology services furnished on or after October 1, 1989, the blended payment amount is equal to the sum of 50 percent of the hospital-specific amount and 50 percent of the fee schedule amount.

(4) For hospital outpatient radiology services furnished on or after January 1, 1991, the blended payment amount is equal to the sum of 42 percent of the hospital-specific amount and 58 percent of the fee schedule amount.

(5) For hospital outpatient radiology services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 42 percent of the hospital-specific amount; and

(ii) 58 percent of the fee schedule amount calculated as 62 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality, less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

(c) *Payment for other diagnostic procedures.* (1) The aggregate payment for other diagnostic procedures performed by a hospital on an outpatient basis on or after October 1, 1989 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with §414.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment described in paragraph (c)(2) of this section.

(2) The blended payment amount for other diagnostic procedures furnished on or after October 1, 1989, but before October 1, 1990, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual

§ 413.123

deductible from 42 percent of the prevailing charges for the same services furnished by participating physicians in their offices in the same locality.

(3) For other diagnostic procedures performed by a hospital on or after October 1, 1990, the blended payment is equal to 50 percent of the hospital-specific amount and 50 percent of the prevailing charge amount.

(4) For other diagnostic services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 50 percent of the hospital-specific amount; and

(ii) 50 percent of the fee schedule amount calculated as 42 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

[56 FR 8842, Mar. 1, 1991, as amended at 57 FR 36017, Aug. 12, 1992; 65 FR 18542, Apr. 7, 2000]

§ 413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1834(c)(1)(C) of the Act and establishes the method for determining Medicare payment for screening mammographies performed by hospitals.

(b) *Payment to hospitals for outpatient services.* Payment to hospitals for screening mammography services performed on an outpatient basis is determined in accordance with the technical component billing requirements in § 405.534(d) of this chapter.

[55 FR 53522, Dec. 31, 1990, as amended at 59 FR 49834, Sept. 30, 1994]

§ 413.124 Reduction to hospital outpatient operating costs.

(a) Except for sole community hospitals, as defined in § 412.92 of this chapter, and critical access hospitals, the reasonable costs of outpatient hospital services (other than capital-related costs of these services) are reduced by 5.8 percent for services furnished during portions of cost reporting periods occurring on or after October 1, 1990 and until the first date that

42 CFR Ch. IV (10–1–24 Edition)

the prospective payment system under part 419 of this chapter is implemented.

(b) For purposes of determining the blended payment amounts of ambulatory surgical center approved surgical procedures performed in the hospital outpatient setting under § 413.118 and hospital outpatient radiology services and other diagnostic procedures under § 413.122, the reduction is applicable only to the hospital-specific portion of the blended payment amounts.

[57 FR 36017, Aug. 12, 1992, as amended at 59 FR 26960, May 25, 1994; 62 FR 46037, Aug. 29, 1997; 65 FR 18542, Apr. 07, 2000]

§ 413.125 Payment for home health agency services.

(a) For additional rules on the allowability of certain costs incurred by home health agencies, see §§ 409.46 and 409.49(b) of this chapter.

(b) The reasonable cost of outpatient rehabilitation services furnished by a home health agency to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the physician fee schedule for comparable services effective January 1, 1999.

[59 FR 65497, Dec. 20, 1994, as amended at 63 FR 58910, Nov. 2, 1998]

Subpart G—Capital-Related Costs

§ 413.130 Introduction to capital-related costs.

(a) *General rule.* Capital-related costs and an allowance for return on equity are limited to the following:

(1) Net depreciation expense as determined under §§ 413.134, 413.144, and 413.149, adjusted by gains and losses realized from the disposal of depreciable assets under § 413.134(f).

(2) Taxes on land or depreciable assets used for patient care.

(3) Leases and rentals, including license and royalty fees, for the use of depreciable assets or land, as described in paragraph (b) of this section.

(4) The costs of betterments and improvements as described in paragraph (c) of this section.

(5) The costs of minor equipment that are capitalized, rather than expensed, as described in paragraph (d) of this section.

(6) Insurance expense on depreciable assets, as described in paragraph (e) of this section.

(7) Interest expense as determined under §413.153, subject to the qualifications of paragraph (f) of this section.

(8) For certain proprietary providers, return on equity capital, as determined under §413.157.

(9) The capital-related costs of related organizations (as described in §413.17), as determined in accordance with paragraph (g) of this section.

(10) Debt issuance costs, debt discounts, and debt redemption costs, if the associated debt was incurred to acquire land or depreciable assets used for patient care or to refinance existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(11) The apportionment of the capital-related costs of jointly owned assets among the owners must be on a basis that reflects the relative use by each owner, rather than the ownership share or the amount of time the asset is located at each owners site.

(b) *Leases and rentals.* (1) Subject to the qualifications of paragraphs (b) (2), (4), (5), and (8) of this section, leases and rentals, including licenses and royalty fees, are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright or they relate to land, which is neither depreciable nor amortizable if owned outright. The terms “*leases*” and “*rentals of assets*” signify that a provider has possession, use, and enjoyment of the assets.

(2) For sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992 and for sale and leaseback agreements for other providers entered into at any time, a provider may include incurred rental charges in its capital-related costs, as specified in a sale and leaseback agreement with a nonrelated purchaser (including shared service organizations not related within the meaning of §413.17) involving plant facilities or equipment only if the following conditions are met:

(i) The rental charges are reasonable based on the following—

(A) Consideration of rental charges of comparable facilities and market conditions in the area;

(B) The type, expected life, condition, and value of the facilities or equipment rented; and

(C) Other provisions of the rental agreements.

(ii) Adequate alternative facilities or equipment that would serve the purpose are not or were not available at lower cost.

(iii) The leasing was based on economic and technical considerations.

(3) If the conditions of paragraph (b)(2) of this section are not met, the amount a provider may include in its capital-related costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest on mortgage, taxes, depreciation, and insurance costs.

(4) For sale and leaseback agreements for hospitals and SNFs entered into on or after October 23, 1992, the amount a provider may include in its capital-related costs as rental or lease expense may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership). This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the annual costs of ownership, the provider may include in capital-related costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in capital-related costs may not exceed the aggregate costs of ownership that would have been included in capital-related costs over the useful life of the asset had the

provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in capital-related costs in the early years of the lease due to the costs of ownership limitation, and include these amounts in capital-related costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership.

(iii) In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iv) In the aggregate, the amount of rental or lease costs included in capital-related costs may not exceed the amount of the costs of ownership that the provider could have included in capital-related costs had the provider retained legal title to the asset.

(5) For lease purchase transactions entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(6)(i) If a lease is a virtual purchase under paragraph (b)(5) of this section, the rental charge is includable in capital-related costs only to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. A provider may not include in its capital-re-

lated costs accelerated depreciation in this situation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner, instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in the capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(7) Amounts included in lease or rental payments for repair or maintenance agreements are excluded from capital-related costs. If no amount is identified in the lease or rental agreement for maintenance, the entire lease payment is considered a capital-related cost subject to the provisions of paragraph (b)(1) of this section.

(8) For lease purchase transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is at least 75 percent of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (payments to be made during the lease term including bargain purchase option, guaranteed

residual value, and penalties for failure to renew) equals at least 90 percent of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. Present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is less than the lessee's incremental borrowing rate, in which case the interest rate implicit in the lease is used.

(9)(i) If a lease establishes a virtual purchase under paragraph (b)(8) of this section, the rental charge is includable in capital-related costs to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership). The cost of ownership includes straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the

amount considered as depreciation, for the purpose of having computed the limitation on rental charges in paragraph (b)(9)(i) of this section, must be used in calculating the limitation on adjustments for the purpose of determining any gain or loss under §413.134(f) upon disposal of an asset.

(c) *Betterments and improvements.* (1) Betterments and improvements are changes which extend the estimated useful life of an asset at least two years beyond its original estimated useful life, or increase the productivity of an asset significantly over its original productivity.

(2) A provider must capitalize and prorate the costs of betterments and improvements over the remaining estimated useful life of the asset, as modified by the betterment or improvement.

(d) *Minor equipment.* A provider must include in its capital-related costs the costs of minor equipment that are capitalized rather than charged off to expense if—

(1) The net book value of minor equipment at the time the provider enters the program is prorated over three years (that is, one-third of the net book value is written off each year), and new purchases are also prorated over a 3-year period; or

(2) The cost of minor equipment is prorated over their actual useful lives.

(e) *Insurance.* (1) A provider must include in its capital-related costs the costs of insurance on depreciable assets used for patient care or insurance that provides for the payment of capital-related costs during business interruption.

(2) If an insurance policy also provides protection for other than the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance, only that portion of the premium related to the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance is includable in capital-related costs.

(f) *Debt premiums and debt discounts.* Debt premiums or debt discount are applied as adjustments to capital-related costs if the associated debt is incurred for acquiring land or depreciable assets used for patient care or for refinancing

existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(g) *Interest expense.* (1) A provider must include in its capital-related costs interest expense, as described in § 413.153, if such expense is incurred in—

(i) Acquiring land or depreciable assets (either through purchase or lease) used for patient care; or

(ii) Refinancing existing debt, if the original purpose of the refinanced debt was to acquire land or depreciable assets used for patient care.

(2) If investment income offset is required under § 413.153(b)(2)(iii), only that portion of investment income that bears the same relationship to total investment income, as the portion of capital-related interest expense bears to total interest expense, is offset against capital-related costs.

(h) *Costs of supplying organizations—* (1) *Supplying organizations related to the provider.* (i) If the supplying organization is related to the provider within the meaning of § 413.17, except as provided in paragraph (g)(1)(ii) of this section, a provider's capital-related costs include the capital-related costs of the supplying organization.

(ii) If the costs of the services, facilities or supplies being furnished exceed the open market price, or if the provisions of § 413.17(d) apply, no part of the cost to the provider of the services, facilities, or supplies are considered capital-related costs, unless the services, facilities, or supplies would otherwise be considered capital-related.

(2) *Supplying organizations not related to the provider.* If the supplying organization is not related to the provider within the meaning of § 413.17, no part of the charge to the provider may be considered a capital-related cost (unless the services, facilities, or supplies are capital-related in nature) unless—

(i) The capital-related equipment is leased or rented (as described in paragraph (b) of this section) by the provider;

(ii) The capital-related equipment is located on the provider's premises, or is located offsite and is on real estate owned, leased or rented by the provider; and

(iii) The capital-related portion of the charge is separately specified in the charge to the provider.

(i) *Costs excluded from capital-related costs.* The following costs are not capital-related costs. To the extent that they are allowable, they must be included in determining each provider's operating costs:

(1) Costs incurred for the repair or maintenance of equipment or facilities.

(2) Amounts included in rentals or lease payments for repair or maintenance agreements.

(3) Interest expense incurred to borrow working capital (for operating expenses).

(4) General liability insurance or any other form of insurance to provide protection other than for the replacement of depreciable assets or to pay capital-related costs in the case of business interruption.

(5) Taxes other than those assessed on the basis of some valuation of land or depreciable assets used for patient care. (Taxes not related to patient care, such as income taxes, are not allowable, and are therefore not included among either capital-related or operating costs.)

(6) The costs of minor equipment that are charged off to expense rather than capitalized as described in paragraph (d) of this section.

(7) The costs incurred for maintenance and repair insurance agreements (commonly referred to as maintenance agreements).

(j) *Reduction to capital-related costs.* (1) Except for sole community hospitals and critical access hospitals, the amount of capital-related costs of all hospital outpatient services is reduced by—

(i) 15 percent for portions of cost reporting periods occurring on or after October 1, 1989, through September 30, 1991; and

(ii) 10 percent for portions of cost reporting periods occurring on or after October 1, 1991 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

(2) For purposes of determining the blended payment amounts for hospital outpatient services under §§ 413.118 and 413.122, the reduction is applicable only

to the hospital-specific portion of the blended amounts.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 56 FR 43456, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992; 57 FR 36017, Aug. 12, 1992; 57 FR 43917, Sept. 23, 1992; 58 FR 17528, Apr. 5, 1993; 59 FR 26960, May 25, 1994; 62 FR 46037, Aug. 29, 1997; 65 FR 18542, Apr. 7, 2000]

§413.134 Depreciation: Allowance for depreciation based on asset costs.

(a) *Principle.* An appropriate allowance for depreciation on buildings and equipment used in the provision of patient care is an allowable cost. The depreciation must be—

(1) Identifiable and recorded in the provider's accounting records;

(2) Based on the historical cost of the asset, except as specified in paragraph (j) of this section regarding donated assets; and

(3) Prorated over the estimated useful life of the asset using—

(i) The straight-line method; or

(ii) Accelerated depreciation under a declining balance method (not to exceed double the straight-line rate) or the sum-of-the-years' digits method in the following situations:

(A) Depreciable assets for which accelerated depreciation was used for Medicare purposes before August 1, 1970, including those assets for which a timely request to change from straight-line depreciation to accelerated depreciation was received by an contractor before August 1, 1970;

(B) Depreciable assets acquired before August 1, 1970, if no election to use straight-line or accelerated depreciation was in effect on August 1, 1970, and the provider was participating in the program on August 1, 1970;

(C) Depreciable assets of a provider if construction of such depreciable asset began before February 5, 1970, and the provider was participating in the program on February 5, 1970; or

(D) Depreciable assets of a provider if a valid written contract was entered into by a provider participating in the program before February 5, 1970, for construction, acquisition, or for the permanent financing thereof, and such contract was binding on a provider on February 5, 1970, and at all times thereafter; or

(iii) A declining balance method, not to exceed 150 percent of the straight-line rate, for a depreciable asset acquired after July 31, 1970; however, this declining balance method may be used only if the cash flow from depreciation on the total assets of the institution during the reporting period, including straight-line depreciation on the assets in question, is insufficient (assuming funding of available capital not required currently for amortization and assuming reasonable interest income on such funds) to supply the funds required to meet the reasonable principal amortization schedules on the capital debts related to the provider's total depreciable assets. For each depreciable asset for which a provider requests authorization to use a declining balance method for Medicare reimbursement purposes, but not to exceed 150 percent of the straight-line rate, the provider must demonstrate to the contractor's satisfaction that the required cash flow need exists. For each depreciable asset in which a provider justifies the use of accelerated depreciation, the contractor must give written approval for the use of a depreciation method other than straight-line before basing any interim payment on this accelerated depreciation or making its reasonable cost determination which includes an allowance for such depreciation.

(b) *General rules—*(1) *Historical cost.* Historical cost is the cost incurred by the present owner in acquiring the asset.

(i) *All providers—*(A) *Depreciable assets acquired after July 31, 1970 and before December 1, 1997.* For depreciable assets acquired after July 31, 1970 and before December 1, 1997, and for a hospital or an SNF, acquired before July 18, 1984, the historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase or the fair market value of the asset at the time of its purchase.

(B) *Depreciable assets acquired on or after December 1, 1997.* For depreciable assets acquired on or after December 1, 1997, the historical cost of the asset that will be recognized under this program must not exceed the historical cost less depreciation allowed to the owner of record as of August 5, 1997 (or

if an asset did not exist as of August 5, 1997, the first owner of record after August 5, 1997). For this paragraph (b)(1)(i)(B), the following apply:

(1) An asset that was not in existence as of August 5, 1997 includes an asset that physically existed but was not owned by a provider participating in the Medicare program as of that date.

(2) The acquisition cost to the owner of record is subject to the limitation on historical costs described in paragraphs (g) (1), (2), and (3) of this section, and is reduced by any depreciation taken by the owner of record. The limitation on historical cost is also applied to the purchase of land, which is a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§ 413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining the allowable interest expense.)

(3) Acquisition cost to the owner of record includes the costs of betterment or improvements that extend the estimated useful life of an asset at least 2 years beyond its original estimated useful life or that increase the productivity of an asset significantly over its original productivity.

(4) For assets acquired prior to a provider's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost when acquired, rather than when the provider entered the program.

(5) For assets subject to the optional depreciation allowance as described in § 413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the provider changed to actual depreciation as described in § 413.139(e). If the provider did not change to actual depreciation, as described in § 413.139(e), for optional allowance assets, the acquisition cost to the owner of record is based on the provider's recorded historical cost of the asset when acquired. If the provider has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(6) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or con-

solidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the contractor under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(ii) *Hospitals and SNFs only.* (A) For assets acquired on or after July 18, 1984 and before December 1, 1997 and not subject to an enforceable agreement entered into before July 18, 1984, historical cost may not exceed the lowest of the following:

(1) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of July 18, 1984, the first owner of record of the asset after that date);

(2) The acquisition cost of the asset to the new owner; or

(3) The fair market value of the asset on the date of acquisition.

(B) For purposes of applying paragraph (b)(1)(ii)(A) of this section, an asset not in existence as of July 18, 1984 includes any asset that physically existed, but was not owned by a hospital or SNF participating in the Medicare program as of July 18, 1984.

(C) The acquisition cost to the owner of record is subject to any limitation on historical costs described in paragraphs (b)(1)(i) or (g)(1) and (2) of this section, and is not reduced by any depreciation taken by the owner of record. This limitation on historical cost is also applied to the purchase of land, a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§ 413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining allowable interest expense and return on equity capital or proprietary providers.)

(D) Acquisition cost to the owner of record includes the costs of betterments or improvements that extend the estimated useful life of an asset at least two years beyond its original estimated useful life or increase the productivity of an asset significantly over its original productivity.

(E) For assets acquired prior to a hospital's or SNF's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost of the asset when acquired, rather than when the hospital or SNF entered the program.

(F) For assets subject to the optional depreciation allowance as described in §413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the hospital or SNF changed to actual depreciation as described in §413.139(e). If the hospital or SNF did not change to actual depreciation, as described in §413.139(e), for optional allowance assets, the acquisition cost to the owner of record is established by reference to the hospital's or SNF's recorded historical cost of the asset when acquired. If the hospital or SNF has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(G) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or consolidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the contractor under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(iii) *Hospital-based providers other than SNFs and SNF-based providers.* For changes of ownership that involve assets of a hospital-based provider other than a SNF, or assets of a SNF-based provider, the provisions of paragraph (b)(1)(ii) of this section are not applicable. A reasonable allocation of the purchase price must be made, so that the hospital-based provider other than a SNF, or a SNF-based provider, is not affected by the limitations described in paragraph (b)(1)(ii) of this section. The historical cost of assets of providers other than hospitals and SNFs is governed by paragraph (b)(1)(i) of this section.

(2) *Fair market value.* Fair market value is the price that the asset would

bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

(3) *The straight-line method.* Under the straight-line method of depreciation, the cost or other basis (for example, fair market value in the case of donated assets) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

(4) *Declining balance method.* Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated cost of the asset each year by a uniform rate up to double the straight-line rate or 150 percent, as the case may be (see paragraph (a)(3) of this section for limitations on use of accelerated methods of depreciation).

(5) *Sum-of-the-years' digits method.* Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years' digits of useful life at the time of acquisition.

(6) *Current reproduction cost.* Current reproduction cost is the cost at current prices, in a particular locality or market area, of reproducing an item of property or a group of assets. Where depreciable assets are concerned, this means the reasonable cost to have built, reproduce in kind, or, in the case of equipment or similar assets, to purchase in the competitive market.

(7) *Useful life.* The estimated useful life of a depreciable asset is its normal operating or service life to the provider, subject to the provisions in paragraph (b)(7)(i) of this section. Factors to be considered in determining useful life include normal wear and tear; obsolescence due to normal economic and

technological changes; climatic and other local conditions; and the provider's policy for repairs and replacement.

(i) *Initial selection of useful life.* In selecting a proper useful life for computing depreciation under the Medicare program, providers must use the useful life guidelines published by CMS. If CMS has not published applicable useful life guidelines, providers must use—

(A) The edition of the American Hospital Association useful life guidelines, as specified in CMS Medicare program manuals; or

(B) A different useful life specifically requested by the provider and approved by the contractor. A different useful life may be approved by the contractor if the provider's request is properly supported by acceptable factors that affect the determination of useful life. However, such factors as an expected early sale, retirement, demolition or abandonment of an asset, or termination of the provider from the Medicare program may not be used.

(ii) *Application of guidelines.* The provisions concerning the selection of useful life guidelines described in paragraph (b)(7)(i) of this section apply to assets acquired on or after January 1, 1981. For assets acquired before January 1, 1981, providers must use the useful life guidelines published by the American Hospital Association in its 1973 edition of *Chart of Accounts for Hospitals*, or those published by the Internal Revenue Service, or those approved for use by contractors as provided in paragraph (b)(7)(i)(B) of this section.

(iii) *Changing useful life.* A change in the estimated useful life may be made if clear and convincing evidence justifies a redetermination of the useful life used by the provider. Such a change must be approved by the contractor in writing, and the factors cited in paragraphs (b)(7) and (b)(7)(i) of this section are applicable in making such redeterminations of useful life. If the request is approved, the change is effective with the reporting period immediately following the period in which the provider's request is submitted for approval.

(8) *Donated asset.* An asset is considered donated when the provider ac-

quires the asset without making payment in the form of cash, new debt, assumed debt, property or services. Except as provided in paragraph (j)(3) of this section, if a provider makes payment in any form to acquire an asset, the payment is considered the purchase price for the purpose of determining allowable historical cost.

(9) *Net book value.* The net book value of an asset is the depreciable basis used for the Medicare program by the asset's last participating owner less depreciation recognized under the Medicare program.

(c) *Recording of depreciation.* Appropriate recording of depreciation includes the identification of the depreciable assets in use, the assets' historical costs, the assets' dates of acquisition, the method of depreciation, estimated useful lives, and the assets' accumulated depreciation.

(d) *Depreciation methods—(1) General.* Proration of the cost of an asset over its useful life is allowed on the straight-line method, or, when permitted under paragraph (a)(3) of this section, the declining balance or the sum-of-the-years' digits methods. One method may be used on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the un depreciated cost of the asset is treated as the cost of a new asset in computing depreciation.

(2) *Change in method.* Prior to August 1, 1970, a provider may change from the straight-line method to an accelerated method or vice versa, upon advance approval from the contractor on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider. Effective with August 1, 1970, a provider may only change from an accelerated method or optional method (see § 413.139) to the straight-line method. Such a change may be made without contractor approval and the basis for depreciation is the un depreciated cost reduced by the salvage value. Thereafter, once straight-line depreciation is selected for a particular asset,

an accelerated method may not be established for that asset.

(3) *Recovery of accelerated depreciation*—(i) *General*. If a provider who has used an accelerated method of depreciation for any of its assets terminates participation in the program, or if the Medicare proportion of its allowable costs decreases so that cumulatively substantially more depreciation was paid than would have been paid using the straight-line method of depreciation, the excess of reimbursable cost determined by using accelerated depreciation methods and paid under the program over the reimbursable cost that would have been determined and paid under the program by using the straight-line method of depreciation, will be recovered as an offset to current reimbursement due or, if the provider has terminated participation in the program, as an overpayment. In this determination of excess payment, recognition will be given to the effects the adjustment to straight-line depreciation would have on the return on equity capital and on the allowance in lieu of specific recognition of other costs in the respective years.

(ii) *Transaction between related organizations*—(A) *General*. If the termination of the provider agreement is due to a change in provider ownership, as defined in §489.18 of this chapter, resulting from a transaction between related organizations, as defined in §413.17, and the criteria in paragraph (b) of this section are met, the excess of reimbursable cost, as determined in paragraph (d)(3)(i) of this section may not be recovered if there is a continuation of participation by the facility in the Medicare program.

(B) *Criteria*. The following criteria must be met if the recovery of excess reimbursable cost is not to be made:

(1) The termination of the provider agreement is due to a change in ownership of the provider resulting from a transaction between related organizations.

(2) The successor provider continues to participate in the Medicare program.

(3) Control and the extent of the financial interest of the owners of the provider before and after the termination remain the same; that is, the

successor owners acquire the same percentage of control or financial investment as the transferors had.

(4) All assets and liabilities of the terminated provider are transferred to the related successor participating provider.

(C) *Effect of transaction*. In transactions meeting the criteria specified in paragraph (d)(3)(ii)(B) of this section, the provision concerning recovery of excess reimbursable cost (§413.134(d)(3)(i)) is not applied, and the transaction is treated as follows:

(1) The successor provider must record the historical cost and accumulated depreciation and the method of depreciation recognized under the Medicare program, and these are considered as incurred by the successor provider for Medicare purposes.

(2) The Medicare program's utilization of the terminated provider is considered as having been incurred by the successor provider for Medicare purposes.

(3) The equity capital of the terminated provider as of the closing of its final cost reporting period must be wholly contained in the equity capital of the successor provider as of the beginning of its first cost reporting period.

(e) *Funding of depreciation*. Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets. Funded depreciation account funds must be placed in readily marketable investments of the type that assures the availability and conservation of the funds. Additions to the funded depreciation account must remain in the account for at least 6 months to be considered valid funding transactions.

(1) *Incentive*. As an incentive for funding, investment income on funded depreciation is not treated as a reduction of allowable interest expense provided such investment income is deposited in, and becomes part of, the funded depreciation account at the time of receipt by the provider. Investment income earned on deposits before the 6-month period elapses are not offset unless the deposits are withdrawn for an improper purpose during this period. If

a provider transfers assets of the funded depreciation account to a related organization (for example, pooling of several chain organization providers' funded depreciation accounts at the chain home office for investment purposes), these assets shall be treated as the provider's funds and are subject to all the requirements specified in paragraph (e) of this section.

(2) *Availability of funded depreciation.*

(i) CMS considers funded depreciation available for use in the acquisition or replacement of depreciable assets related to patient care unless the funded depreciation funds have been committed by contract for the acquisition of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(ii) Borrowing for a purpose for which funded depreciation account funds should have been used makes the borrowing unnecessary to the extent that funded depreciation account funds were available at the time of the borrowing. Available funds in the funded depreciation account, to the extent of the unnecessary borrowing, are called "tainted" funds. Interest expense incurred on borrowing for a capital purpose is not an allowable cost to the extent that funded depreciation account funds were available at the time of the borrowing.

(iii) A provider can remove the "unnecessary" characterization of borrowing, and thereby cure tainted funded depreciation, by using the tainted funds for a proper purpose described in paragraph (e)(3)(i) of this section. However, any funded depreciation that existed at the time of the unnecessary borrowing and is not classified as tainted must be used before any of the tainted funds.

(iv) When only a portion of the borrowing is considered unnecessary under paragraph (e)(2)(ii) of this section, subsequent repayments of such borrowing from general funds are applied first to the allowable portion of the borrowing and then, when all of the allowable borrowing is repaid, to the unallowable portion of the borrowing. When funds from the funded depreciation account are used for the repayment of the unnecessary borrowing, an equivalent amount of tainted funds is cured with-

out regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section. Similarly, where general funds are used to pay for the unallowable borrowing after the necessary borrowing has been repaid, an equivalent amount of tainted funded depreciation is cured without regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section.

(3) *Withdrawals of funded depreciation*—(i) *Proper withdrawals.* (A) Withdrawals from funded depreciation are considered proper if made either for the acquisition or replacement of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(B) *First-in, first-out basis.* Proper withdrawals from funded depreciation are made on a first-in, first-out basis.

(C) *Exception.* If CMS determines that a borrowing is unnecessary because of the existence of available funded depreciation, and additional deposits have been made to funded depreciation after the occurrence of the unnecessary borrowing, withdrawals made after the date of the additional deposits are deemed to be made on a last-in, first-out basis.

(ii) *Improper withdrawals.* (A) Withdrawals from funded depreciation that do not meet the requirements for proper withdrawals under the provisions in paragraph (e)(3)(i)(A) of this section are considered improper withdrawals.

(B) Improper withdrawals from funded depreciation are made on a last-in, first-out basis. If improper withdrawals are made, interest expense is reduced in accordance with section § 413.153(c)(3).

(C) Improper withdrawals will result in the offset of otherwise allowable interest expense under the offset provisions in § 413.153(c)(3).

(4) *Loans from funded depreciation.* (i) When the general fund of the provider borrows from the funded depreciation to obtain working capital for normal operating expenses to furnish patient care, interest incurred by the general fund is an allowable operating cost only if the interest expense is supported by documents that evidence that the funds were borrowed and that payment of interest and repayment of the funds are required, is separately

identified in the provider's accounting records, and meets the necessary and proper tests described in §§413.153(b)(2) and (b)(3). However, if the general fund of the provider borrows from the funded depreciation account to acquire depreciable assets used in furnishing patient care, or for other capital purposes related to patient care, interest expense paid by the general fund to the funded depreciation account is not an allowable cost. Providers are expected to use the funded depreciation for these purposes.

(ii) Loans from funded depreciation to the general fund are considered investments of funded depreciation, but do not have to meet the readily marketable test described in paragraph (e) of this section. Loans made from funded depreciation are subject to the requirement that funded depreciation must be available for the acquisition of depreciable assets used to furnish patient care, or for other capital purposes related to patient care. Costs incurred to secure lines of credit from lending institutions to ensure such availability are not allowable costs.

(iii) Funding of depreciation from general funds will not be recognized to the extent of any outstanding loans from the funded depreciation account to the general fund. Deposits from the general fund into the funded depreciation account must be first applied to reduce any loans outstanding from the funded depreciation to the general fund. When the loans are repaid in full, general funds deposited in the funded depreciation account are considered as repayments of the general fund. Therefore, any subsequent interest expense of the general fund paid to the funded depreciation fund is not an allowable cost.

(iv) A provider may loan its funded depreciation to a related organization for any purpose subject to the following conditions:

(A) Authorization for such a loan by the provider's appropriate managing body of the provider, such as Board of Trustees or Board of Directors, must be on file.

(B) The funded depreciation loaned must remain available, as specified in paragraph (e)(2) of this section, to the provider making the loan. Costs in-

curred for lines of credit to assure such availability are not allowable costs. During the period of time that the loan is outstanding, if the provider making the loan resorts to outside borrowing for a purpose for which its funded depreciation should have been used, interest expense on an amount of the outside borrowing up to the amount of the funded depreciation that should have been available would be disallowed as unnecessary.

(C) Such loans shall be considered investments of the provider's funded depreciation, but the requirement that funded depreciation be invested in readily marketable investments as required in paragraph (e) of this section is waived for such loans.

(D) The funded depreciation account must earn interest on such loans at a rate that does not exceed the rate that would be charged for a comparable loan from an independent lending institution. This investment income will not be used to reduce the provider's interest expense if all the other conditions in paragraph (e) of this section are met. If the entity borrowing the funds is another provider participating in the Medicare program, the interest expense incurred on such loans would be allowable if the loan meets all of the interest expense requirements specified in §413.153. (For purposes of §413.153(b)(3)(ii), such loans are not considered to be with a related lender.)

(f) *Gains and losses on disposal of assets*—(1) *General*. Depreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty.

(i) *Disposal of an asset before December 1, 1997*. If disposal of a depreciable asset, including the sale or scrapping of an asset before December 1, 1997, results in a gain or loss, an adjustment is necessary in the provider's allowable cost.

(A) The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs.

(B) The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program.

(C) The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (6) of this section.

(D) The gain or loss on the disposition of depreciable assets has no retroactive effect on a proprietary provider's equity capital for years prior to the year of disposition.

(ii) *Disposal of an asset on or after December 1, 1997.* No gain or loss is recognized on either the sale or scrapping of an asset that occurs on or after December 1, 1997, regardless of whether the asset is sold incident to a provider's change of ownership, or otherwise sold or scrapped as an asset of a Medicare participating provider. Gains or losses on dispositions other than sales or scrapping are recognized to the same extent as prior to December 1, 1997.

(2) *Bona fide sale or scrapping before December 1, 1997.* For the bona fide sale or scrapping of depreciable assets before December 1, 1997, the following apply:

(i) Except as specified in paragraph (f)(3) of this section, gains and losses realized from the bona fide sale or scrapping of depreciable assets are included in the determination of allowable cost only if the sale or scrapping occurs while the provider is participating in Medicare. The extent to which such gains and losses are included is calculated by prorating the basis for depreciation of the asset in accordance with the proportion of the asset's useful life for which the provider participated in Medicare. For purposes of this paragraph (f)(2)(i), scrapping refers to the physical removal from the provider's premises of tangible personal properties that are no longer useful for their intended purpose and are only salable for their scrap or junk value.

(ii) If the total amount of gains or losses realized from bona fide sales or scrapping does not exceed \$5,000 within the cost reporting period or if the provider's cumulative utilization under the Medicare program is less than 5 percent, the net amount of gains or losses realized from sale or scrapping will be allowed as a depreciation adjustment in the period of disposal. For purposes of this paragraph (f)(2)(ii), the provider's cumulative Medicare utiliza-

tion percentage is determined by comparing the cumulative total of the Medicare inpatient days for all reporting periods in which depreciation on the asset disposed of was claimed under the Medicare program to the cumulative total of inpatient days of the participating provider for the same reporting periods.

(iii) If the conditions specified in paragraph (f)(2)(ii) of this section are not met, the adjustment to reimbursable cost in the reporting period of asset disposition is calculated as follows:

(A) The total amount of gains or losses shall be allocated to all reporting periods under the Medicare program, based on the ratio of the depreciation allowed on the assets in each reporting period to the total depreciation allowed under the Medicare program.

(B) The results of this allocation are multiplied by the ratio of Medicare reimbursable cost to total allowable cost for each reporting period.

(C) The results of this multiplication are then added.

(D) Effective for cost reporting periods beginning on or after October 1, 1991, no adjustment will be made for the portion of gains or losses allocated to inpatient hospital services for which the hospital was paid under the fully prospective payment methodology as described in § 412.340 of this chapter or under the hold-harmless methodology based on the Federal rate as described in § 412.344(a)(1) of this chapter for new capital costs or in § 412.344(a)(2) of this chapter.

(iv) If a provider sells more than one asset for a lump sum sales price, the gain or loss on the sale of each depreciable asset must be determined by allocating the lump sum sales price among all the assets sold, in accordance with the fair market value of each asset as it was used by the provider at the time of sale. If the buyer and seller cannot agree on an allocation of the sales price, or if they do agree but there is insufficient documentation of the current fair market value of each asset, the contractor for the selling provider will require an appraisal by an independent appraisal expert to establish the fair market value of each asset

and will make an allocation of the sales price in accordance with the appraisal.

(3) *Sale within 1 year after termination.* Gains and losses realized from a bona fide sale of depreciable assets within 1 year immediately following the date on which the provider terminates participation in the Medicare program are also included in the determination of allowable cost, in accordance with the procedure specified in paragraph (f)(2) of this section. However, if several assets are sold for a lump sum sales price, the determination of fair market value must be based on the appraised value of the assets as they were last used by the provider while participating in the Medicare program.

(4) *Exchange, trade-in or donation.* Gains or losses realized from the exchange, trade-in, or donation of depreciable assets are not included in the determination of allowable cost. When the disposition of an asset is by means of exchange or trade-in, the historical cost of the new asset is the sum of the undepreciated cost of the asset disposed of and the additional cash or other assets transferred (or to be transferred) to acquire the new asset. However, if the asset disposed of was acquired by the provider before its participation in the Medicare program and the sum of the undepreciated cost and the cash or other assets transferred (or to be transferred) exceed the list price or fair market value of the new asset, the historical cost of the new asset is limited to the lower of its list price or fair market value.

(5) *Demolition or abandonment.* (i) For purposes of this section, the term "abandonment" means the permanent retirement of an asset for any future purpose, not merely the provider's ceasing to use the asset for patient care purposes. To claim an abandonment under the Medicare program, the provider must have relinquished all rights, title, claim, and possession of the asset with the intention of never reclaiming it or resuming its ownership, possession, or enjoyment.

(ii) If losses resulting from the demolition or abandonment of depreciable assets do not exceed \$5,000 within the cost-reporting period, the losses are to be allowed in the period of disposal.

(iii) If losses exceed \$5,000 and, at the date of disposition, the demolished or abandoned assets are at least 80 percent depreciated as computed under the straight-line method, such losses are includable in the determination of allowable cost under the Medicare program in the period of disposal and the procedure provided in paragraph (f)(2)(iii) of this section must be used in determining the adjustment to reimbursable cost.

(iv) Losses in excess of \$5,000 resulting from the demolition or abandonment of assets, which at the date of disposition are not 80 percent depreciated as computed under the straight-line method, must be capitalized as a deferred charge and amortized as follows:

(A) If the State Health Planning and Development Agency (SHPDA) designated under section 1521 of the Public Health Service Act approves the demolition or abandonment of a depreciable asset as being consistent with the health systems plan of the health service area in which the provider is located, the net loss realized shall be capitalized as a deferred charge and amortized over the remaining life of the demolished or abandoned asset, or at the rate of \$5,000 per year, whichever is greater. If no SHPDA exists or if such agency is unable or unwilling to perform this function, the provider must submit a request for approval to the contractor. The contractor, after reviewing this request and before issuing the approval, will submit the request along with its recommendation to the appropriate Regional Office for its approval.

(B) If a provider fails to obtain approval as specified in paragraph (f)(5)(iv)(A) of this section, a loss is not allowable unless the demolished or abandoned asset is replaced. If the asset is replaced, the loss resulting from the unapproved demolition or abandonment must be capitalized as a deferred charge and amortized over the estimated useful life of the replacement asset or at the rate of \$5,000 per year, whichever is greater.

(v) If a loss resulting from the demolition or abandonment is deferred and amortized and the provider terminates

its participation in the Medicare program or ceases to use a replacement asset in the provision of patient care services, the unamortized deferred charge remaining at that time must not be included in determining allowable cost under the Medicare program.

(vi) Losses on demolition must include the demolition cost incurred by the provider for razing and removal of the asset, less any salvage value recovered by the provider. However, if a provider demolishes a depreciable asset for the purpose of preparing land for future sale, the net demolition cost incurred by the provider (razing and removal costs less salvage recovered) is considered a capital expenditure and added to the historical basis of the land.

(vii) If a provider purchases land on which there is a building, no depreciation will be allowed under the Medicare program unless the building is used in providing patient care. If the building is demolished, the entire purchase price and demolition cost shall be considered the historical cost of the land. If the building is used for patient care, but demolished within 5 years of purchase, the entire purchase price, less allowed depreciation, plus demolition cost will be considered the historical cost of the land.

(6) *Involuntary conversion.* (i) Losses resulting from the involuntary conversion of depreciable assets, such as condemnation, fire, theft, or other casualty, are generally included in the determination of allowable cost on a deferred basis if the asset is restored or replaced. However, losses resulting from a provider's imprudent management of its depreciable assets, such as the failure to obtain proper insurance coverage, are not included in the determination of allowable cost.

(ii) The net allowable loss from involuntary conversion must consist of the undepreciated cost of unrecovered book value of the asset, less amounts received from insurance proceeds gifts, and grants received from local, State, or Federal government, or any other source as a result of the involuntary conversion.

(iii) If the asset is replaced and the net allowable loss in any cost-reporting period does not exceed \$5,000, the entire amount must be included in allowable

cost in the period in which the loss is incurred. If the asset is replaced and the net allowable loss in any cost-reporting period exceeds \$5,000, the loss must be capitalized as a deferred charge and amortized over the useful life of the replacement or restored asset. If a replaced or restored asset ceases to be used in the provision of patient care services or the provider terminates its participation in the Medicare program, the unamortized deferred charge remaining at that time will not be included in determining allowable cost under the Medicare program.

(iv) If the provider fails to replace or restore an involuntarily converted asset, the loss is not included in determining allowable cost. However, if the provider intends to replace or restore the asset but is unable to do so because the designated SHPDA finds such replacement or restoration to be inconsistent with the health systems plan of the provider's health service area, the loss is allowable so long as the provider continues to participate in Medicare. In this case, the loss must be capitalized as a deferred charge and amortized over the remaining life of the involuntarily converted asset, or at the rate of \$5,000 per year, whichever is greater.

(v) If a gain is realized from an involuntary conversion of depreciable assets, the net amount realized reduces the basis of the restored or replacement asset. If the asset is not restored or replaced, the gain is to be treated in accordance with paragraph (f)(2) of this section.

(7) *Effect on equity capital.* The unrecovered loss entered on the books of the provider as a deferred charge, in accordance with paragraphs (f) (5) and (6) of this section, is not includable in the computation of equity capital under § 413.157.

(8) *Sale of replacement or restored assets.* If a provider sells a replacement or restored asset while participating in the Medicare program or within 1 year immediately following the date on which it terminates its participation in the Medicare program, the unrecovered loss entered on the books of the provider as a deferred charge in accordance with paragraphs (f) (5) and (6) of

this section will not be included in determining the gain or loss realized from the sale of the replacement or restored asset. However, if the sale of such asset is made to a related organization, as defined in §413.17, and the purchasing organization continues as a provider in the Medicare program, the remaining deferred charge representing the unrecovered depreciable basis of the demolished, abandoned or destroyed asset must continue to be amortized over the remaining expected useful life of the replacement or restored asset. If the sale is made to an unrelated organization, further amortization of the deferred charge is not allowed.

(g) *Establishment of cost basis on purchase of facility as an ongoing operation*—(1) *Assets acquired after July 1, 1966 and before August 1, 1970.* The cost basis for the assets of a facility purchased as an ongoing operation after July 1, 1966, and before August 1, 1970, is the lowest of the—

(i) Total price paid for the facility by the purchaser, as allocated to the individual assets of the facility;

(ii) Total fair market value of the facility at the time of the sale, as allocated to the individual assets; or

(iii) Combined fair market value of the individually identified assets at the time of the sale.

(2) *Assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984.* For depreciable assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984, in addition to the limitations specified in paragraph (g)(1) of this section, the cost basis of the depreciable assets may not exceed the current reproduction cost depreciated on a straight-line basis over the life of the asset to the time of the sale.

(3) *Assets acquired by hospitals and SNFs on or after July 18, 1984 and not subject to an enforceable agreement entered into before that date.* Subject to paragraphs (b)(1)(ii) (B) through (G) and (b)(1)(iii) of this section, historical cost may not exceed the lowest of the following:

(i) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset

not in existence as of July 18, 1984, the first owner of record of the asset);

(ii) The acquisition cost to the new owner; or

(iii) The fair market value of the asset on the date of acquisition.

(4) *Assets acquired by all providers on or after December 1, 1997.* Subject to the provisions of paragraph (b)(1)(i)(A) of this section, the historical cost may not exceed the historical cost of the asset, as recognized under the Medicare program, less depreciation allowed, to the owner of record as of August 5, 1997 (or for an asset not in existence as of August 5, 1997, the first owner of record after August 5, 1997).

(5) *Transactions other than bona fide.* If the purchaser cannot demonstrate that the sale was bona fide, in addition to the limitations specified in paragraph (g)(1), (2), and (3) of this section, the purchaser's cost basis may not exceed the seller's cost basis, less accumulated depreciation.

(h) *Sale and leaseback agreements and other lease transactions.* (1) For sale and leaseback agreements for all providers, and for sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992, a provider may include in its allowable costs incurred rental charges, as specified in a sale and leaseback agreement with a non-related purchaser involving plant facilities or equipment, only if—

(i) The rental charges are reasonable based on consideration of rental charges of comparable facilities and market conditions in the area; the type, expected life, condition, and value of the facilities or equipment rented; and other provisions of the rental agreement;

(ii) Adequate alternate facilities or equipment that would serve the purpose are not or were not available at lower cost; and

(iii) The leasing was based on economic and technical considerations.

(2) If the conditions of paragraph (h)(1) of this section are not met, the amount a provider may include in its allowable costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or

equipment such as interest expense on mortgages, taxes, depreciation, and insurance costs.

(3) For hospitals and SNFs entering into sale and leaseback agreements on or after October 23, 1992, the amount a provider may include in its allowable costs as rental or lease expense may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership). This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the costs of ownership the provider may include in allowable costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in allowable costs may not exceed the aggregate costs of ownership that would have been included in allowable costs over the useful life of the asset had the provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in allowable costs in the early years of the lease due to the costs of ownership limitation, and include these amounts in allowable costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership. In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iii) In the aggregate, the amount of rental or lease costs included in allowable costs may not exceed the amount

of the costs of ownership that the provider could have included in allowable costs had the provider retained legal title to the asset.

(4) For lease transactions of all providers entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(5)(i) If a lease is a virtual purchase under paragraph (h)(4) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and must be capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time

at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(6) For lease transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is 75 percent or more of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (that is, payments to be made during the lease term, including bargain purchase option, guaranteed residual value, or penalties for failure to renew) equals 90 percent or more of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. The present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is less than the lessee's incremental borrowing rate, in which case, the interest rate implicit in the lease is used.

(7)(i) If a lease is a virtual purchase under paragraph (h)(6) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the costs of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost as described in this paragraph, a provider may not include accelerated depreciation in its allowable costs.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and is cap-

italized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the amount considered as depreciation, for the purpose of having computed the limitation expressed in paragraph (h)(7)(i) of this section, must be used in calculating the limitation on adjustments to depreciation for the purpose of determining any gain or loss upon disposal of an asset under paragraph (f) of this section.

(i) *Intergovernmental transfer of facilities.* The basis for depreciation of assets transferred under appropriate legal authority from one governmental entity to another is as follows:

(1) The historical cost incurred by the present owner in acquiring the asset under a bona fide sale. The historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase of fair market value at the time of the purchase.

(2) The fair market value at the time of donation under a bona fide donation of the asset (subject to the limitations set forth under paragraph (i) of this section). An asset is considered donated when a governmental entity acquires the asset without assuming the functions for which the transferor used the asset or making any payment for it in the form of cash, property, or services.

(3) If neither paragraph (h) (1) nor (2) of this section applies, for example, the transfer was solely to facilitate administration or to reallocate jurisdictional responsibility, or the transfer constituted a taking over in whole or in part of the function of one governmental entity by another governmental entity, the basis for depreciation is—

(i) With respect to an asset on which the transferor has claimed depreciation under the Medicare program, the transferor's basis under the Medicare program prior to the transfer. The method of depreciation used by the transferee may be the same as that used by the transferor, or the transferee may change the method, as permitted under paragraph (d)(2) of this section; or

(ii) With respect to an asset on which the transferor has not claimed depreciation under the Medicare program, the cost incurred by the transferor in acquiring the asset (not to exceed the basis that would have been recognized had the transferor participated in the Medicare program) less depreciation calculated on the straight-line basis over the life of the asset to the time of transfer.

(j) *Basis of assets donated to a provider*—(1) Assets not used or depreciated under the Medicare program. If an asset has never been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the fair market value of the asset at the time of donation.

(2) *Assets used or depreciated under the Medicare program*. If an asset has been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the lesser of—

(i) The fair market value at the time of donation; or

(ii) The net book value in the hands of the owner last participating in the Medicare program.

(3) *Transfers of State hospitals to nonprofit corporations without monetary consideration*. If a State transfers a hospital to a nonprofit corporation without monetary consideration on or after July 18, 1984, the depreciable basis of

the assets to the new owner is the net book value of the assets as recorded on the State's books at the time of the transfer. For purposes of this section, monetary consideration includes cash, new debt, and assumed debt.

(k) *Transactions involving a provider's capital stock*—(1) *Acquisition of capital stock of a provider*. If the capital stock of a provider is acquired, the provider's assets may not be revalued. For example, if Corporation A purchases the capital stock of Corporation B, the provider, Corporation B continues to be the provider after the purchase and Corporation A is merely the stockholder. Corporation B's assets may not be revalued.

(2) *Statutory merger*. A statutory merger is a combination of two or more corporations under the corporation laws of the State, with one of the corporations surviving. The surviving corporation acquires the assets and liabilities of the merged corporation(s) by operation of State law. The effect of a statutory merger upon Medicare reimbursement is as follows:

(i) *Statutory merger between unrelated parties*. If the statutory merger is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the merged corporation(s) acquired by the surviving corporation may be revalued in accordance with paragraph (g) of this section. If the merged corporation was a provider before the merger, then it is subject to the provisions of paragraphs (d)(3) and (f) of this section concerning recovery of accelerated depreciation and the realization of gains and losses. The basis of the assets owned by the surviving corporation are unaffected by the transaction. An example of this type of transaction is one in which Corporation A, a nonprovider, and Corporation B, the provider, are combined by a statutory merger, with Corporation A being the surviving corporation. In such a case the assets of Corporation B acquired by Corporation A may be revalued in accordance with paragraph (g) of this section.

(ii) *Statutory merger between related parties*. If the statutory merger is between two or more related corporations (as specified in § 413.17), no revaluation of assets is permitted for those assets

acquired by the surviving corporation. An example of this type of transaction is one in which Corporation A purchase the capital stock of Corporation B, the provider. Immediately after the acquisition of the capital stock of Corporation B, there is a statutory merger of Corporation B and Corporation A, with Corporation A being the surviving corporation. Under these circumstances, at the time of the merger the transaction is one between related parties and is not a basis for revaluation of the provider's assets.

(3) *Consolidation.* A consolidation is the combination of two or more corporations resulting in the creation of a new corporate entity. If at least one of the original corporations is a provider, the effect of a consolidation upon Medicare reimbursement for the provider is as follows:

(i) *Consolidation between unrelated parties.* If the consolidation is between two or more corporations that are unrelated (as specified in §413.17), the assets of the provider corporation(s) may be revalued in accordance with paragraph (g) of this section.

(ii) *Consolidation between related parties.* If the consolidation is between two or more related corporations (as specified in §413.17), no revaluation of provider assets is permitted.

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43456, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992; 57 FR 39830, Sept. 1, 1992; 57 FR 43919, Sept. 23, 1992; 58 FR 17528, Apr. 5, 1993; 59 FR 45401, Sept. 1, 1994; 63 FR 1382, Jan. 9, 1998; 65 FR 8662, Feb. 22, 2000; 82 FR 38515, Aug. 14, 2017]

§413.139 Depreciation: Optional allowance for depreciation based on a percentage of operating costs.

(a) *Principle.* With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the provider's 1965 operating costs or the provider's current year's allowable costs, whichever are the lower. The percentage to be applied is 5 percent starting with the year 1966-67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets ac-

quired after 1965; however, if the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the straight-line depreciation on assets acquired after 1965 (including the estimated depreciation on assets held on a rental basis during the current year) may not exceed 6 percent of the provider's allowable cost for the current year.

(b) *Definitions*—(1) *Operating costs.* Operating costs are the total costs incurred by the provider in operating the institution or facility.

(2) *Allowable costs.* Allowable costs are the costs of a provider that are includable under the principles for cost reimbursement. Through application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost that is attributable to covered services for beneficiaries is determined.

(c) *Application.* If a provider has inadequate historical cost records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has records of the cost of pre-1966 depreciable assets currently in use.

(d) *Allowance based on a percentage of operating costs.* (1) The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles or the current year's allowable operating costs, whichever is lower. The percentage to be applied is five for the reporting period that starts before or during 1966-67, four and one-half for the reporting period that begins during 1967-68, and continues to decline annually by equal amounts to become zero in 1976-77.

(2) If used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs,

§ 413.139

42 CFR Ch. IV (10-1-24 Edition)

or return on equity capital. Such exclusions are to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs of services furnished to Medicare beneficiaries during the reporting period.

(e) *Change to actual depreciation.* (1) A provider that elects this allowance may at any time before 1976 change to actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

(2) If the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost may be made through appropriate means involving expert consultation with the determination being subject to review and approval by the contractor.

(f) *Determination of optional allowance based on percentage of operating costs illustrated.* The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Example No. 1. The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets. The current year's allowable cost also does not include any allowance in lieu of specific recognition of other costs or return on equity capital.

YEAR 1966	
Current year's allowable cost	\$1,100,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance	5
Allowance	\$50,000

¹ 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

YEAR 1967	
Current year's allowable cost	\$1,200,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance ²	5

YEAR 1967—Continued

Allowance	\$50,000
¹ 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.	
² Since the reporting period began during the year 1966–1967 (July 1, 1966–June 30, 1967) 5 percent is the percentage to be used.	

YEAR 1968

Operating cost for 1965	\$1,000,000
Current year's allowable cost ¹	\$900,000
Percent for determining the allowance ²	4½
Allowance	\$40,500

¹ The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

² Since the reporting period began during the year 1967–1968 (July 1, 1967–June 30, 1968) 4½ percent is the percentage to be used.

Example No. 2. When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation, allowance in lieu of specific recognition of other costs, or return on equity capital. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

YEAR 1966	
Adjusted current year's allowable cost	\$1,100,000
Adjusted operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance	5
Allowance	\$50,000
Less estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966	\$3,000
Adjusted allowance	\$47,000

¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

(g) *Limitation on depreciation if optional allowance is used.* This optional allowance only is subject to a limitation based on the provider's total allowable operating cost for the current year. To determine this limitation, compute the sum of the actual depreciation claimed, the allowance based on a percentage of operating costs, and the estimated straight-line depreciation on depreciable-type assets rented after 1965. If this sum exceeds six percent of the provider's current year's allowable cost (exclusive of any actual

depreciation claimed, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital), the allowance for depreciation based on a percentage of operating costs is reduced by the amount of excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis, it must be converted to a straight-line basis only for use in calculating this limitation. It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation of six percent, as it affects the availability of the allowance, is designed as a safeguard if the presumption is not borne out. If the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the six percent limitation.

Example No. 1. The following illustration demonstrates how this limitation would be determined.

YEAR 1966

[The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation, the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.]

Adjusted operating cost for 1965	\$1,000,000
Percent for determining the allowance	5
In 1966 assets were acquired which produce a straight-line depreciation of	\$18,000
Estimated depreciation on assets rented in 1966	\$2,000
Adjusted allowable operating cost for 1966	\$1,100,000
CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS	
Gross allowance	
5 percent times adjusted 1965 operating costs (\$1,000,000)	\$50,000
Estimated depreciation on assets rented in 1966	2,000
Straight-line depreciation on post-1965 assets	18,000
Total	70,000
6 percent of adjusted 1966 allowable operating cost	66,000
Reduction in allowance	4,000
Allowance	50,000
Reduction	4,000
Adjusted allowance	46,000
Total depreciation allowance for 1966 (\$18,000 actual depreciation plus \$46,000 allowance based on operating cost)	64,000

Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was \$3,500. In that case, it would include in its 1966 allowable cost not only the \$46,000 allowance based on operating costs but also \$36,000 (in this instance $2 \times$ straight-line rate is used) in actual depreciation and the rental expense of \$3,500—or a total of \$85,500 covering all its depreciable assets.

§413.144 Depreciation: Allowance for depreciation on fully depreciated or partially depreciated assets.

(a) *Principle.* Depreciation on assets being used by a provider at the time it enters into the Medicare program is allowed. This principle applies even though such assets may be fully or partially depreciated on the provider's books.

(b) *Application.* Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the contractor. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method (§413.139), in which case the correction should be made at the time of discontinuing the use of that method. If an asset has become fully depreciated under Medicare, further depreciation is not appropriate or allowable, even though the asset may continue in use.

(c) *Example of an allowance for a fully-depreciated asset.* For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use

that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost.

(d) *Corrections to depreciation.* If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life. Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the contractor.

§ 413.149 Depreciation: Allowance for depreciation on assets financed with Federal or public funds.

(a) *Principle.* Depreciation is allowed on assets financed with Hill-Burton or other Federal or public funds.

(b) *Application.* Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in furnishing services. It is the function of payment of depreciation to provide funds that make it possible to maintain the assets and preserve the capital employed in the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the program, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation is not treated as a reduction of allowable interest expense under § 413.153(a).

§ 413.153 Interest expense.

(a)(1) *Principle.* Necessary and proper interest on both current and capital indebtedness is an allowable cost. However, interest costs are not allowable if incurred as a result of—

(i) Judicial review by a Federal court (as described in § 413.64(j));

(ii) An interest assessment on a determined overpayment (as described in § 405.377 of this chapter); or

(iii) Interest on funds borrowed to repay an overpayment (as described in § 413.64(j) or § 405.378 of this chapter), up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(2) *Exception.* In those cases of administrative or judicial reversal, interest paid on funds borrowed to repay an overpayment is an allowable cost, in accordance with this section.

(b) *Definitions.*—(1) *Interest.* Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

(2) *Necessary.* Necessary interest is interest that meets the following requirements:

(i) It is incurred on a loan made to satisfy a financial need of the provider. Loans that result in excess funds or investments are not considered necessary.

(ii) It is incurred on a loan made for a purpose reasonably related to patient care.

(iii) It is reduced by investment income except income from—

(A) Gifts, grants, and endowments, whether held separately or pooled with other funds;

(B) Funded depreciation that meets the program's qualifying criteria;

(C) The provider's qualified pension funds;

(D) The provider's deferred compensation funds that meet the program's qualifying criteria; and

(E) The provider's self-insurance trust funds that meet the program's qualifying criteria.

(iv) It is not reduced by interest received as a result of judicial review by

a Federal court (as described in §413.64(j)).

(3) *Proper*. Proper requires that interest be—

(i) Incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made; and

(ii) Paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds, the funded depreciation account, or the provider's qualified pension fund.

(4) *Zero coupon bonds*. Zero coupon bonds are issued by government agencies, corporations, and banks at a price substantially below the face value. The difference between the purchase price and the face value reflects the actual amount of interest and is neither a discount nor an adjustment to the interest rate as with other bonds. Interest is paid at maturity when the bond is redeemed at face value.

(c) *Borrower-lender relationship*. (1) Except as described in paragraph (c)(2) of this section, to be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the "bargaining" process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary loans. Loans should be made under terms and conditions that a prudent borrower would make in arm'slength transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable. Thus, interest paid by the provider to partners, stockholders, or related organizations of the provider would not be allowable. If the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds. Therefore, if interest on loans by partners, stockholders, or related organizations is disallowed as a cost solely because of the relationship factor, the principal of such loans is

treated as invested funds in the computation of the provider's equity capital under §413.157.

(2) Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Interest on loans to providers by partners, stockholders, or related organizations made prior to July 1, 1966, is allowable as cost, provided that the terms and conditions of payment of such loans have been maintained in effect without modification subsequent to July 1, 1966. If the general fund of a provider "borrows" from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment is accorded interest paid by the general fund on money "borrowed" from the funded depreciation account of the provider or from the provider's qualified pension fund. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

(3) If funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment is accorded deposits in the provider's qualified pension fund if such deposits are used for other than the purpose for which the fund was established.

(d) *Loans not reasonably related to patient care*. (1) The following types of loans are not considered to be for a purpose reasonably related to patient care:

(i) For loans made to finance acquisition of a facility, that portion of the cost that exceeds—

(A) Historical cost as determined under §413.134(b); or

(B) The cost basis determined under §413.134(g); and

(ii) Loans made to finance capital stock acquisitions, mergers, or consolidations for which revaluation of assets is not allowed under §413.134(k).

(2) In determining whether a loan was made for the purpose of acquiring

a facility, we apply any owner's investment or funds first to the tangible assets, then to the intangible assets other than goodwill, and lastly to the goodwill. If the owner's investment or funds are not sufficient to cover the cost allowed for tangible assets, we apply funds borrowed to finance the acquisition to the portion of the allowed cost of the tangible assets not covered by the owner's investment, then to the intangible assets other than goodwill, and lastly to the goodwill. Repayments of the funds borrowed are applied first to the borrowing related to the tangible assets, then to the borrowing related to the intangible assets other than goodwill, and lastly to the borrowing related to the goodwill.

(3) When a provider borrows funds, but only some of the funds are necessary, repayments of the loan (principal and interest portions) are applied first to pay for the necessary portion of the loan. Only after all of the necessary portion of the loan (principal and interest) has been repaid are any repayments applied to the unnecessary portion of the loan. Repayments toward non-allowable borrowing pertaining to assets or activities not related to patient care are considered investments, and the provisions of paragraph (b)(2)(iii) of this section are applied.

(e) *Zero coupon bonds*—(1) *Interest on bonds issued on or after August 15, 1996.* For zero coupon bonds issued on or after August 15, 1996, interest expense incurred to provide funds for patient care-related costs is an allowable expense, and interest income earned for investment purposes is an allowable offset, in the cost reporting period in which the interest accrues.

(2) *Interest income offset.* Interest income from zero coupon bonds must be offset against allowable interest expense as prescribed in paragraph (b)(2) of this section and in § 413.130(g)(2). If zero coupon bonds are purchased with the proceeds of an advanced refunding of debt, offset of the investment income is required under § 413.153(b)(2)(iii), but the investment income is not prorated under § 413.130(g)(2).

(3) *Use of effective interest method.* (i) Interest expense and interest income

from zero coupon bonds that are reported as they accrue must be amortized using the effective interest method. This method recognizes the actual accrual of interest expense or income for each interest computation period (as specified by the bond instrument) throughout the life of the bond.

(ii) A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period.

(iii) If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period shall be apportioned to each cost reporting period.

(iv) An example of the computation of interest using the effective interest method follows:

Facts

Life of zero coupon bond: 15 years.

Value at maturity: \$50,000.

Bondholder pays \$6,996 for the bond.

Annual interest rate is 13.5506% compounded semi-annually.

From the table below, interest for the first year would be \$980.11 (\$474.00 plus \$506.11).

Col 1 Six-month periods	Col 2 Book value beginning of period	Col. 3 Effective interest*	Col. 4 Book value end of period (columns 2 + 3)
1	\$6,996.00	\$474.00	\$7,470.00
2	7,470.00	506.11	7,976.11
3	7,976.11	540.40	8,516.51
4	8,516.51	577.02	9,093.53
29	43,855.94	2,971.37	46,827.31
30	46,827.31	3,172.69	50,000.00

*Computed by multiplying the book value at the beginning of each period (Column 2) by 6.7753% (the annual interest rate of 13.5506% \div 2 = 6.7753%).

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43457, Aug. 30, 1991; 59 FR 45402, Sept. 1, 1994; 61 FR 37014, July 16, 1996; 61 FR 63748, 63479, Dec. 2, 1996; 65 FR 8662, Feb. 22, 2000]

§ 413.157 Return on equity capital of proprietary providers.

(a) *Definitions.* For purposes of this section—

Proprietary provider means a provider that is organized and operated with the expectation of earning a profit for its

owners (as distinguished from a provider that is organized and operated on a nonprofit basis). Proprietary providers may be sole proprietorships, partnerships, or corporations. Effective for cost reporting periods beginning on or after July 6, 1987, the term applies only to proprietary hospitals and SNFs.

(b) *General rule.* A reasonable return on equity capital invested and used in the provision of patient care is paid as an allowance in addition to the reasonable cost of covered services furnished to beneficiaries by proprietary providers.

(1) *Rate of return applicable to proprietary providers for cost reporting periods beginning before July 6, 1987.* Except as provided in paragraphs (b)(2), (b)(3), and (b)(4) of this section, the amount allowable on an annual basis, for cost reporting periods beginning before July 6, 1987, is determined by multiplying the provider's equity capital by a percentage equal to one and one-half times the average of the rates of interest on special issues of public debt obligations issued for purchase by the Medicare Part A Trust Fund for each of the months during the provider's reporting period or portion thereof covered under the program.

(2) *Rate of return for inpatient hospital services furnished by proprietary hospitals.* The rate used in determining the return for inpatient hospital services is a percentage of the average of the rates of interest described in paragraph (b)(1) of this section. The percentages applicable to inpatient hospital services are as follows:

(i) 150 percent for cost reporting periods beginning before April 20, 1983.

(ii) 100 percent for cost reporting periods beginning on or after April 20, 1983 and before October 1, 1986.

(iii) 75 percent for cost reporting periods beginning on or after October 1, 1986 and before October 1, 1987.

(iv) 50 percent for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988.

(v) 25 percent for cost reporting periods beginning on or after October 1, 1988 and before October 1, 1989.

(vi) Zero percent for cost reporting periods beginning on or after October 1, 1989.

(3) *Rate of return related to proprietary SNFs.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for SNF services furnished before October 1, 1993, is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for SNF services furnished on or after October 1, 1993.

(4) *Rate of return related to outpatient hospital services.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for outpatient hospital services furnished before January 1, 1988 is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for outpatient hospital services furnished on or after January 1, 1988.

(5) *Rate of return for proprietary services of all nonhospital and non-SNF providers.* (i) For cost reporting periods beginning on or after October 1, 1985, but before July 6, 1987, the rate used in determining the return for services of all nonhospital and non-SNF providers is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) For cost reporting periods beginning on or after July 6, 1987, there is no allowance for return on equity capital for nonhospital and non-SNF providers.

(c) *Application—(1) Computation of equity capital.* For purposes of computing the allowable return, the provider's equity capital means—

(i) The provider's investment in plant, property, and equipment related to patient care (net of depreciation) and funds deposited by a provider who leases plant, property, or equipment related to patient care and is required by the terms of the lease to deposit such funds (net of noncurrent debt related to such investment or deposited funds); and

(ii) Net working capital maintained for necessary and proper operation of patient care activities. However, debt representing loans from partners, stockholders, or related organizations on which interest payments would be

§ 413.157

allowable as costs but for the provisions of § 413.153(b)(3)(ii), is not subtracted in computing the amount of equity capital in order that the proceeds from such loans be treated as part of the provider's equity capital. In computing the amount of equity capital upon which a return is allowable, investment in facilities is recognized on the basis of the historical cost, or other basis, used for depreciation and other purposes under Part A of Medicare.

(2) *Acquisitions after July 1970.* With respect to a facility or any tangible assets of a facility acquired on or after August 1, 1970, the excess of the price paid for such facility or such tangible assets over the historical cost, as defined in § 413.134(b), or the cost basis, as determined under § 413.134(g) (whichever is appropriate), is not includable in equity capital, and loans made to finance such excess portion of the cost of such acquisitions (see § 413.153(d)) are excluded in computing equity capital.

(3) *Acquisitions prior to August 1970.* With respect to a facility or any tangible assets of a facility acquired before August 1970, the excess of the price paid for such facility or assets over the fair market value of tangible assets at the time of purchase is includable in equity capital to the extent that it is reasonable except that the cumulative allowable return for such excess may not exceed 100 percent of such excess. For purposes of this section, the cumulative allowable return means the sum of the allowable rate of return on equity capital for all months starting from August 1, 1970. For example, if the allowable rates of return on equity capital for a provider are 9 percent for the first year (and such year started August 1, 1970), 8.5 percent for the second year, and 10.5 percent for the third year, the cumulative allowable return at the end of the third year would be 28 percent. After the cumulative allowable return equals 100 percent, the inclusion in equity capital of the excess is no longer allowable.

(4) *Computation of return on equity capital.* For purposes of computing the allowable return, the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to

42 CFR Ch. IV (10-1-24 Edition)

time based upon interest rates in accordance with this principle, is determined by CMS and communicated through contractors. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs.

Example of calculation of cumulative allowable return. X purchased a provider on July 1, 1969, paying \$100,000 in excess of the fair market value of the assets acquired. Provider X files its cost report on a calendar-year basis. The allowable rate of return on equity capital for August 1, 1970-December 31, 1970 (4.538 percent), is obtained by multiplying the allowable rate of return for the period ending December 31, 1970 (10.891) by $\frac{5}{12}$ (a fraction of which the numerator is the number of months from August 1, 1970, to the end of the cost-reporting period and the denominator is the number of months in the cost-reporting period). The cumulative allowable return for Provider X for the period August 1, 1970-December 31, 1973, (32.367 percent) is computed as follows:

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The \$100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the \$100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 26960, May 25, 1994]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

SOURCE: 62 FR 43668, Aug. 15, 1997, as amended at 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

§ 413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in § 413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 of this chapter and meets the

supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 and § 410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered “renal dialysis services,” and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

[75 FR 49198, Aug. 12, 2010]

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in §414.313.

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in §414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in §405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biologicals furnished by independent ESRD facilities is based on the methodology specified in §414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in §413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates estab-

lished by CMS in §413.230 and separate payment will no longer be provided.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 69935, Nov. 19, 2008; 75 FR 49198, Aug. 12, 2010; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015]

§413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

[75 FR 49199, Aug. 12, 2010]

§413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under §413.171, except for those renal dialysis services furnished during payment year 2022, in the case of an ESRD facility that does not earn enough points under the program described at §413.178 to meet or exceed the minimum total performance score (as defined at §413.178(a)(8)) established by CMS for a payment year (as defined at §413.178(a)(10)), payments otherwise made to the facility under §413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

(1) For every 10 points that the total performance score (as defined at §413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

(2) [Reserved]

(b) Any payment reduction will apply only to the payment year involved and will not be taken into account in computing the single payment amount

§ 413.178

42 CFR Ch. IV (10–1–24 Edition)

under this subpart for services provided in a subsequent payment year.

[76 FR 646, Jan. 5, 2011, as amended at 83 FR 57068, Nov. 14, 2018; 86 FR 62020, Nov. 8, 2021]

§ 413.178 ESRD quality incentive program.

(a) *Definitions.* As used in this section:

(1) *Achievement threshold* means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.

(2) *Baseline period* means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.

(3) *Benchmark* means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment year.

(4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (e)(1)(i) through (v) of this section.

(5) *End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)* means the program authorized under section 1881(h) of the Social Security Act.

(6) *ESRD facility* means an ESRD facility as defined in § 413.171.

(7) *Improvement threshold* means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

(9) *Payment reduction* means the reduction, as specified by CMS, to each

payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.

(10) *Payment year* means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.

(11) *Performance period* means the time period during which data are collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment year.

(12) *Performance standards* are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) *Reporting measure* means a measure that is scored for a payment year using the methodology described in paragraph (e)(1)(vi) of this section.

(14) *Total performance score (TPS)* means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment year.

(b) *Applicability of the ESRD QIP.* The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number (CCN) effective date.

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule.* Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception.* CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (<https://qualitynet.cms.gov>) and listserv announcements.

(4) *Measure retention.* All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among the majority of ESRD facilities is so high and unvarying that meaning-

ful distinctions in improvements or performance can no longer be made.

(B) *Factor 2.* Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3.* A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4.* A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5.* A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure—

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the FEDERAL REGISTER.

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3)

and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold. The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet website (<https://www.qualitynet.org/>), to CMS via email to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Facilities must provide the following information on the form:

- (i) Facility CCN.
- (ii) Facility name.
- (iii) CEO name and contact information.
- (iv) Additional contact name and contact information.
- (v) Reason for requesting an exception.
- (vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied with the requirements in paragraph (d)(4) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) With the exception of first and second quarter 2020 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility. With respect to fourth quarter 2019 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility is deemed to have met the requirements of this paragraph if the facility actually submitted the data by the March 31, 2020 submission deadline but did not notify CMS that it would do so.

(e) *Performance scoring under the ESRD QIP.* (1) CMS will award points to an ESRD facility based on its performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree

to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment year.

(i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark specified for that measure.

(ii) CMS will award 0 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period falls below the achievement threshold specified for that measure.

(iii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iv) CMS will award 0 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period is below the improvement threshold specified for that measure.

(v) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

(vi) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.

(2) CMS calculates the TPS for an ESRD facility for a payment year as follows:

(i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (e)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.

(ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the payment year.

(f) *Public availability of ESRD QIP performance information.* (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (f)(1) of this section available to the public, CMS will provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(g) *Limitation on review.* There is no administrative or judicial review of the following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

(3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.

(4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.

(h) *Special rule for payment year 2022.*

(1) CMS will calculate a measure rate for all measures specified by CMS under paragraph (c) of this section for the PY 2022 ESRD QIP but will not score facility performance on any of

those measures or calculate a TPS for any facility under paragraph (e) of this section.

(2) CMS will not establish a mTPS for PY 2022.

(i) *Special rules for payment year 2023.*

(1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, Standardized Fistula Rate clinical measure, ICH CAHPS clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

[83 FR 57068, Nov. 14, 2018, as amended at 84 FR 60803, Nov. 8, 2019; 85 FR 54872, Sept. 2, 2020; 86 FR 62020, Nov. 8, 2021; 87 FR 67302, Nov. 7, 2022; 88 FR 76504, Nov. 6, 2023]

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a pediatric ESRD facility projects on the basis of prior year costs and utilization trends that it has an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable to one or more of the factors in § 413.182,

the facility may request, in accordance with paragraph (e) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.

(d) *Payment rate exception request.* Effective October 1, 2002, CMS may approve exceptions to a pediatric ESRD facility's updated prospective payment rate, if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002. A pediatric ESRD facility may request an exception to its payment rate at any time after it is in operation for at least 12 consecutive months.

(e) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(f) *Completion of requirements and criteria.* The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in §413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(g) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its contractor.

(h) *Determination of an exception request.* In determining the facility's payment rate under the exception process, CMS excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(i) *Period of approval: Payment exception request.* A prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its contractor until 30 days after the contractor's receipt of the facility's letter notifying the contractor of the facility's request to give up its exception rate and be subject to the basic case-mix adjusted composite payment rate methodology. ESRD facilities electing to retain their nonpediatric or pediatric exception rates (including self-dialysis training) do not need to notify their contractors. Once a facility notifies its contractor in writing that it cannot retain its current exception rate, that decision cannot be subsequently reversed.

(j) *Denial of an exception request.* CMS denies exception requests submitted without the documentation specified in §413.182 and the applicable regulations cited there.

(k) *Criteria for refiling a denied exception request.* A pediatric ESRD facility that was denied an exception request may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its composite payment rate for isolated essential facilities, self dialysis training

costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (1)(3), is no longer granted any new exception to the composite payment rate as defined in §413.180(1).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in §413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its composite payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in §413.239 of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are used as the payment amount in place of the composite rate, and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with §413.239(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under §413.220, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005; 75 FR 49199, Aug. 12, 2010]

§413.182 Criteria for approval of exception requests.

(a) CMS may approve exceptions to a pediatric ESRD facility's prospective payment rate if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002.

(b) The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

§ 413.184

(1) Pediatric patient mix, as specified in § 413.184.

(2) Self-dialysis training costs in pediatric facilities, as specified in § 413.186.

[70 FR 70331, Nov. 21, 2005]

§ 413.184 Payment exception: Pediatric patient mix.

(a) *Qualifications.* To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate that—

(1) At least 50 percent of its patients are individuals under 18 years of age;

(2) Its nursing personnel costs are allocated properly between each mode of care;

(3) The additional nursing hours per treatment are not the result of an excess number of employees;

(4) Its pediatric patients require a significantly higher staff-to-patient ratio than typical adult patients; and

(5) These services, procedures, or supplies and their per treatment costs are clearly prudent and reasonable when compared to those of pediatric facilities with a similar patient mix.

(b) *Documentation.* (1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report (in accordance with cost reporting requirements under § 413.198) showing—

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§ 413.186 Payment exception: Self-dialysis training costs in pediatric facilities.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for the training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training

rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The pediatric ESRD facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) A pediatric ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally 3 times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had

trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

[70 FR 70331, Nov. 21, 2005]

§413.194 Appeals.

(a) *Appeals under section 1878 of the Act.* (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under §413.89(h)(3) may request review by the contractor or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R to part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with §413.180 may request review from the contractor or the PRRB if CMS has denied the request in whole or in part. In such a case, the procedure in subpart R of

§ 413.195

part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by CMS on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under § 405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the contractor or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

[62 FR 43668, Aug. 15, 1997, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the estab-

42 CFR Ch. IV (10–1–24 Edition)

lishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

[75 FR 49199, Aug. 12, 2010]

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) CMS or the facility's contractor notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the FEDERAL REGISTER without opportunity for prior comment. Revisions of the rate-setting methodology are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

[62 FR 43668, Aug. 15, 1997, as amended at 75 FR 49199, Aug. 12, 2010]

§413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in §413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with §413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size,

scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§413.13, 413.30, 413.35, 413.40, 413.74, and §§415.55 through 415.70, §415.162, and §415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

(5) Each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. Beginning January 1, 2025, the data and information must include, but is not limited to the following:

(i) Information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility;

(ii) Information reported on ESRD PPS claims about the total number of billing units (or the expected number of billing units, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in §413.217 of this chapter or oral forms of renal dialysis drugs and biological products), of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis

§ 413.200

drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount (or no discarded amount expected, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), using the JZ modifier (or any successor modifier that includes the same data).

(6) Beginning January 1, 2025, each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 87 FR 72287, Nov. 23, 2022; 88 FR 76504, Nov. 6, 2023]

§ 413.200 [Reserved]

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the con-

42 CFR Ch. IV (10–1–24 Edition)

tractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in paragraph (a) of this section, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.89(h)(3).

[75 FR 49200, Aug. 12, 2010, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

[75 FR 49200, Aug. 12, 2010]

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate

market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

[75 FR 49200, Aug. 12, 2010]

§ 413.230

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235 of this part;

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

[75 FR 49200, Aug. 12, 2010, as amended at 84 FR 60803, Nov. 8, 2019; 88 FR 76505, Nov. 6, 2023]

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to

42 CFR Ch. IV (10–1–24 Edition)

that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

[75 FR 49200, Aug. 12, 2010, as amended at 87 FR 67302, Nov. 7, 2022]

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year, except as specified in paragraph (g)(6) of this section.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) Five (5) road miles or less from the ESRD facility in question.

(d) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an

attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

(1) For payment year 2012, the attestation must be provided by January 3, 2012;

(2) For payment year 2015, the attestation must be provided by December 31, 2014;

(3) For payment year 2016, the attestation must be provided by December 31, 2015; and

(4) For payment year 2021, the attestation must be provided by December 31, 2020.

(f) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in §413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (e) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 con-

secutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(3) In the case of an ESRD facility that has changed its cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3-cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID-19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID-19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6-month period by 2.

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent

3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to one or more displaced patients. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 days after the end of the cost reporting year, whichever is later, for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume

adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests—

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting

years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraph (e) of this section and this paragraph (g).

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015; 83 FR 57069, Nov. 23, 2018; 85 FR 71485, Nov. 9, 2020; 88 FR 76505, Nov. 6, 2023]

§ 413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

[80 FR 69077, Nov. 6, 2015]

§ 413.234 Drug designation process.

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

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described

in paragraphs (c)(3) and (g) of this section, referred to as the post-transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

(2) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new renal dialysis drug or biological product is used to treat or manage;

(ii) The new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable

time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

(1) A new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment for 2 years.

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

(2) A new renal dialysis drug or biological product that is not considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last

calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

(d) *Oral-only drug determination.* An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

(e) *Exclusion criteria for the transitional drug add-on payment adjustment.* A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) Type 3 NDA—New Dosage Form.

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA*, as described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) Type 5 NDA—New Formulation or Other Differences.

(i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(1) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(2) Requires safety or effectiveness testing because of novel inactive ingredients; or

(3) Requires full safety or effectiveness testing because it is:

(i) Subject to exclusivity held by another applicant, or

(ii) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(iii) A crude natural product, or

(iv) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(4) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the

active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in paragraph (e)(2) of this section.

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA*, as described in paragraph (e)(2) of this section, would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) *Type 7 NDA—Previously Marketed But Without an Approved NDA.*

(i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. Regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) *Type 8 NDA—Prescription to Over-the-Counter (OTC).*

(i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA*.

(5) *Combination of Type 3 NDA.* *Type 3 NDA*, as described in paragraph (e)(1) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, or in combination with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section;

(i) *Type 2 NDA—New Active Ingredient.*

(A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the

unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA*.

(ii) *Type 4 NDA—New Combination.*

(A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA*, as described in paragraph (e)(5)(ii)(B)(1) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME, but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section.

(1) *Type 1 NDA—New Molecular Entity.*

(i) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer

or a racemic mixture is an NME only when neither has been previously approved or marketed.

(ii) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA*.

(iii) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA*, as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(iv) An active moiety in a radiopharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(v) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new combination* and the NDA would thus be classified as a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA.* *Type 5 NDA*, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8. A*

Type 9 NDA, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3* NDA as described in paragraph (e)(1) of this section or a *Type 5* NDA as described in paragraph (e)(2) of this section or *Type 7* NDA as described in paragraph (e)(3) of this section or a *Type 8* NDA as described in paragraph (e)(4) of this section.

(i) *Type 9* NDA—New Indication or Claim, Drug Not to be Marketed under *Type 9* NDA after Approval.

(A) A *Type 9* NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the “parent NDA”), and the applicant does not intend to market this drug product under the *Type 9* NDA after approval. Generally, a *Type 9* NDA is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*.

(B) When the *Type 9* NDA is submitted, it will be given the same NDA classification as the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9* NDA, FDA will “administratively close” the *Type 9* NDA and thereafter only accept submissions to the “parent” NDA.

(ii) [Reserved]

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment.* Beginning January 1, 2021, payment for calcimimetics is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for the third and fourth quarters

of calendar year 2018 and for the full calendar year 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in the third and fourth quarter of calendar year 2018 and the full calendar year 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or

negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in §413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the latest available forecast of annual growth in the ESRD bundled market basket composite price proxy for pharmaceuticals.

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under §413.235.

[80 FR 69077, Nov. 6, 2015, as amended at 83 FR 57070, Nov. 14, 2018; 84 FR 60803, Nov. 8, 2019; 85 FR 71485, Nov. 9, 2020; 88 FR 76506, Nov. 6, 2023]

EFFECTIVE DATE NOTE: At 87 FR 67302, Nov. 7, 2022, §413.234 paragraph (a) was amended by adding the word "functional" before the word "equivalent" in the definition of "Oral-only drug", effective Jan. 1, 2025.

§413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body

mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under §413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010, as amended at 88 FR 76506, Nov. 6, 2023]

§413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset new) that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under § 413.171;

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and an-

nounce the results in the FEDERAL REGISTER as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a per treatment amount for use in calculating the pre-adjusted per treatment amount by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(iii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by subtracting the average per treatment offset amount (as determined using the data sources and methodology specified in paragraphs (f)(2) and (3) of this section, respectively, of this section) from the per treatment amount (as determined in paragraph (f)(1)(ii) of this section) to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own.

(2) The methodology specified in paragraph (f)(3) of this section for determining the average per treatment offset amount uses the following data sources:

(i) Dialysis machine and equipment cost, total cost across all dialysis mo-

dalities, the number of hemodialysis-equivalent home dialysis treatment counts, and the number of hemodialysis-equivalent total treatment counts are obtained from renal facility cost reports (CMS form 265-11) and hospital cost reports (CMS form 2552-10) using calendar years 2017-2019 cost reports.

(A) Dialysis machine and equipment costs are obtained by summing lines 8.01 through 17.02 from Worksheet B, Column 4 for renal facility cost reports, and by summing lines 2 through 11 from Worksheet I-2 for hospital cost reports.

(B) Total cost across all dialysis modalities are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 2 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I-4, Column 2 for the hospital cost reports.

(C) Hemodialysis-equivalent total treatment counts are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I-4, Column 1 for the hospital cost reports.

(D) Hemodialysis-equivalent home dialysis treatment counts are obtained by summing lines 14.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 7 through 10 from Worksheet I-4, Column 1 for the hospital cost reports. In both renal facility and hospital cost reports, home Continuous Ambulatory Peritoneal Dialysis and home Continuous Cyclic Peritoneal Dialysis are reported as patient weeks, so a conversion factor of 3 is applied to obtain hemodialysis-equivalent treatment counts.

(ii) [Reserved]

(3) CMS uses the following methodology to calculate the average per treatment offset amount for home dialysis machines that is subtracted from the per treatment amount as determined in paragraph (f)(1)(ii) of this section to determine the pre-adjusted per treatment amount specified in paragraph (f)(1)(iii) of this section:

(i) Calculates annualized values for calendar year 2018 at the ESRD facility

level for the metrics specified in paragraph (f)(2)(i) of this section by dividing the numbers of days the cost report spanned to compute a per-day metric, then multiplying the resulting value by the number of days in 2018 the cost report covered to compute the metrics attributable to the period covered by the cost report in 2018. Next, for ESRD facilities with multiple cost reports covering 2018 the resulting metrics are aggregated. Finally, each ESRD facility's aggregated metrics are annualized to cover the full calendar year 2018. The annualization factor for an ESRD facility is the total number of days in 2018 divided by the total days in 2018 covered by the ESRD facility's cost report(s).

(ii) Calculates an estimated home dialysis machine and equipment cost for each ESRD facility by multiplying the annualized dialysis machine and equipment cost determined in paragraph (f)(3)(i) of this section by the ESRD facility's hemodialysis-equivalent home dialysis treatment percentage. The hemodialysis-equivalent home dialysis treatment percentage for each facility is calculated by dividing annualized hemodialysis-equivalent home treatment count determined in paragraph (f)(3)(i) of this section by annualized hemodialysis-equivalent treatment count across all modalities determined in paragraph (f)(3)(i) of this section.

(iii) Calculates an average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 by dividing the sum of the estimated home dialysis machine and equipment cost in paragraph (f)(3)(ii) of this section across all ESRD facilities by the sum of annualized hemodialysis-equivalent home treatment counts determined in paragraph (f)(3)(i) of this section across all facilities.

(iv) Calculates the amount subtracted from the pre-adjusted treatment amount determined in paragraph (f)(1)(iii) of this section by inflating the average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 determined in paragraph (f)(3)(iii) to calendar year 2021. The average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 is inflated to calendar year

2021 by multiplying this value by the payment rate update factor required under section 1881(b)(14)(F)(i) of the Social Security Act for calendar years 2019, 2020, and 2021. This value is then divided by a scaling factor to be converted to the ESRD PPS payment scale. The scaling factor is calculated by dividing the calendar year 2018 total cost per treatment inflated to calendar year 2021 by the average ESRD PPS payment per treatment projected for calendar year 2021.

(v) Effective January 1, 2022, CMS annually updates the amount determined in paragraph (f)(3)(iv) of this section by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

[84 FR 60805, Nov. 8, 2019, as amended at 85 FR 71486, Nov. 9, 2020; 88 FR 76506, Nov. 6, 2023]

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle:

(i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel

are excluded from the definition of outlier services.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage*: This term has the meaning set forth in §413.220(b)(4).

(b) *Eligibility for outlier payments*—(1) *Adult beneficiaries*. An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries*. An ESRD facility will receive an outlier payment for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for

ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount*: CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed dollar loss amount, as applicable.

[75 FR 49201, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69077, Nov. 6, 2015; 84 FR 60806, Nov. 8, 2019; 85 FR 71487, Nov. 9, 2020]

§413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment*. ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under §413.230 of this part, will be paid a per-treatment payment amount for renal dialysis services (as defined in §413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31,

§ 413.241

42 CFR Ch. IV (10–1–24 Edition)

2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b) (12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010. Requests received by the MAC after November 1, 2010, will not be accepted regardless of postmarks, or delivered dates. MACs will establish the manner in which an ESRD facility will indicate their intention to be excluded from the transition and paid entirely based on payment under the ESRD PPS. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by their MAC by November 1, 2010, payments to the ESRD facility for items and services

provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in § 413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated MAC of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in § 413.171, furnished during the transition period, new ESRD facilities as defined in § 413.171, are paid based on the per-treatment payment amount determined under § 413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the transition, CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

[75 FR 49201, Aug. 12, 2010]

§ 413.241 Pharmacy arrangements.

Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis service drugs and biologicals to patients in a timely manner.

[75 FR 49202, Aug. 12, 2010]

Subpart I—Prospectively Determined Payment Rates for Low-Volume Skilled Nursing Facilities, for Cost Reporting Periods Beginning Prior to July 1, 1998

SOURCE: 60 FR 37594, July 21, 1995, unless otherwise noted.

§ 413.300 Basis and scope.

(a) *Basis.* This subpart implements section 1888(d) of the Act, which provides for optional prospectively determined payment rates for qualified SNFs.

(b) *Scope.* This subpart sets forth the eligibility criteria an SNF must meet to qualify, the process governing election of prospectively determined payment rates, and the basis and methodology for determining prospectively determined payment rates.

§ 413.302 Definitions.

For purposes of this subpart—

Area wage level means the average wage per hour for all classifications of employees as reported by health care facilities within a specified area.

Census region means one of the 9 census divisions, comprising the 50 States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

Routine capital-related costs means the capital-related costs, allowable for Medicare purposes (as described in subpart G of this part), that are allocated to the SNF participating inpatient routine service cost center as reported on the Medicare cost report.

Routine operating costs means the cost of regular room, dietary, and nursing services, and minor medical and surgical supplies for which a separate charge is not customarily made. It does not include the costs of ancillary services, capital-related costs, or, where appropriate, return on equity.

Rural area means any area outside an urban area in a census region.

Urban area means—

(1) Prior to October 1, 2004, a Metropolitan Statistical Area (MSA), or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as listed in § 412.62(f)(1)(ii)(B) of this chapter.

(2) Effective October 1, 2004, a Metropolitan Statistical Area (MSA), as defined by the Office of Management and Budget, or a New England county

deemed to be an urban area as specified under § 412.64.

[60 FR 37594, July 21, 1995, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.304 Eligibility for prospectively determined payment rates.

(a) *General rule.* An SNF is eligible to receive a prospectively determined payment rate for a cost reporting period if it had fewer than 1,500 Medicare covered inpatient days as reported on a Medicare cost report in its immediately preceding cost reporting period. This criterion applies even if the SNF received a prospectively determined payment rate during the preceding cost reporting period.

(b) *Less than a full cost reporting period.* If the cost reporting period that precedes an SNF's request for prospectively determined payment is not a full cost reporting period, the SNF is eligible to receive prospectively determined payment rates only if the average daily Medicare census for the period (Medicare inpatient days divided by the total number of days in the cost reporting period) is not greater than 4.1.

(c) *Newly-participating SNFs.* An SNF is eligible to receive prospectively determined payment rates for its first cost reporting period for which it is approved to participate in Medicare.

§ 413.308 Rules governing election of prospectively determined payment rates.

(a) *Requirements.* An SNF must notify its contractor at least 30 calendar days before the beginning of the cost reporting period for which it requests to receive such payment that it elects prospectively determined payment rates. A separate request must be made for each cost reporting period for which an SNF seeks prospectively determined payment. A newly participating SNF with no preceding cost reporting period must make its election within 30 days of its notification of approval to participate in Medicare.

(b) *Contractor notice.* After evaluating an SNF's request for prospectively determined payment rates, the contractor notifies the SNF in writing as to whether the SNF meets any of the eligibility criteria described in § 413.304 and the timely election requirements

§ 413.310

under § 413.308(a). The contractor must notify the SNF of its initial and final determinations within 10 working days after it receives all the data necessary to make each determination. The contractor's determination is limited to one cost reporting period.

(c) *Prohibition against revocation.* An SNF may not revoke its request after it has received the initial determination of eligibility from the contractor and the cost reporting period has begun.

(d) *Revocation by contractor.* If an SNF is given tentative approval to receive a prospectively determined payment rate, and, after the start of the applicable cost reporting period, the contractor determines that the SNF does not meet the eligibility criteria, the contractor must revoke the prospectively determined payment option.

§ 413.310 Basis of payment.

(a) *Method of payment.* Under the prospectively determined payment rate system, a qualified SNF receives a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. Each SNF's routine per diem payment rate is determined according to the methodology described in § 413.312 and is based on various components of SNF costs.

(b) *Payment in full.* The payment rate represents payment in full for routine services as described in § 413.314 (subject to applicable coinsurance as described in subpart G of part 409 of this title), and for routine capital costs. Payment is made in lieu of payment on a reasonable cost basis for routine services and for routine capital costs.

§ 413.312 Methodology for calculating rates.

(a) *Data used.* (1) To calculate the prospectively determined payment rates, CMS uses:

(i) The SNF cost data that were used to develop the applicable routine service cost limits;

(ii) A wage index to adjust for area wage differences; and

(iii) The most recent projections of increases in the costs from the SNF market basket index.

(2) In the annual schedule of rates published in the FEDERAL REGISTER

42 CFR Ch. IV (10–1–24 Edition)

under the authority of § 413.320, CMS announces the wage index and the annual percentage increases in the market basket used in the calculation of the rates.

(b) *Calculation of per diem rate—(1) Routine operating component of rate—(i) Adjusting cost report data.* The SNF market basket index is used to adjust the routine operating cost from the SNF cost report to reflect cost increases occurring between cost reporting periods represented in the data collected and the midpoint of the initial cost reporting period to which the payment rates apply.

(ii) *Calculating a per diem cost.* For each SNF, an adjusted routine operating per diem cost is computed by dividing the adjusted routine operating cost (see paragraph (b)(1)(i) of this section) by the SNF's total patient days.

(iii) *Adjusting for wage levels.* (A) The SNF's adjusted per diem routine operating cost calculated under paragraph (b)(1)(ii) of this section is then divided into labor-related and nonlabor-related portions.

(B) The labor-related portion is obtained by multiplying the SNF's adjusted per diem routine operating cost by a percentage that represents the labor-related portion of cost from the market basket. This percentage is published when the revised rates are published as described in § 413.320.

(C) The labor-related portion of each SNF's per diem cost is divided by the wage index applicable to the SNF's geographic location to arrive at the adjusted labor-related portion of routine cost.

(iv) *Group means.* SNFs are grouped by urban or rural location by census region. Separate means of adjusted labor-related and nonlabor routine operating costs for each SNF group are established in accordance with the SNF's region and urban or rural location. For each group, the mean labor-related and mean nonlabor-related per diem routine operating costs are multiplied by 105 percent.

(2) *Computation of routine capital-related cost.* (i) The SNF routine capital-related cost for both direct and indirect capital costs allocated to routine services, as reported on the Medicare

cost report, is obtained for each SNF in the data base.

(ii) For each SNF, the per diem capital-related cost is calculated by dividing the SNF's routine capital costs by its inpatient days.

(iii) SNFs are grouped by urban and rural location by census region, and mean per diem routine capital-related cost is determined for each group.

(iv) Each group mean per diem capital-related cost is multiplied by 105 percent.

(3) *Computation of return on owner's equity for services furnished before October 1, 1993.* (i) Each proprietary SNF's Medicare return on equity is obtained from its cost report and the portion attributable to the routine service cost is determined as described in §413.157.

(ii) For each proprietary SNF, per diem return on equity is calculated by dividing the routine cost related return on equity determined under paragraph (b)(3)(i) of this section by the SNF's total Medicare inpatient days.

(iii) Separate group means are computed for per diem return on equity of proprietary SNFs, based on regional and urban or rural classification.

(iv) Each group mean is multiplied by 105 percent.

§413.314 Determining payment amounts: Routine per diem rate.

(a) *General rule.* An SNF that elects to be paid under the prospectively determined payment rate system, and qualifies for such payment, is paid a per diem rate for inpatient routine services. This rate is adjusted to reflect area wage differences and the cost reporting period beginning date (if necessary) and is subject to the limitation specified in paragraph (d) of this section.

(b) *Per diem rate.* The prospectively determined payment rate for each urban and rural area in each census region is comprised of the following:

(1) A routine operating component, which is divided into:

(i) A labor-related portion adjusted by the appropriate wage index; and
(ii) A nonlabor-related portion.

(2) A routine capital-related cost portion.

(3) For proprietary SNFs only, a portion that is based on the return on

owner's equity related to routine cost, applicable only for services furnished before October 1, 1993.

(c) *Adjustment for cost reporting period.*

(1) If a facility has a cost reporting period beginning after the beginning of the Federal fiscal year, the contractor increases the labor-related and nonlabor-related portions of the prospective payment rate that would otherwise apply to the SNF by an adjustment factor. Each factor represents the projected increase in the market basket index for a specific 12-month period. The factors are used to account for inflation in costs for cost reporting periods beginning after October 1. Adjustment factors are published in the annual notice of prospectively determined payment rates described in §413.320.

(2) If a facility uses a cost reporting period that is not 12 months in duration, the contractor must obtain a special adjustment factor from CMS for the specific period.

(d) *Limitation of prospectively determined payment rate.* The per diem prospectively determined payment rate for an SNF, excluding capital-related costs and excluding return on equity for services furnished prior to October 1, 1993, may not exceed the individual SNF's routine service cost limit. Under §413.30, the routine service cost limit is the limit determined without regard to exemptions, exceptions, or retroactive adjustments, and is the actual limit in effect when the provider elects to be paid a prospectively determined payment rate.

§413.316 Determining payment amounts: Ancillary services.

Ancillary services are paid on the basis of reasonable cost in accordance with section 1861(v)(1) of the Act and §413.53.

§413.320 Publication of prospectively determined payment rates or amounts.

At least 90 days before the beginning of a Federal fiscal year to which revised prospectively determined payment rates are to be applied, CMS publishes a notice in the FEDERAL REGISTER:

§ 413.321

(a) Establishing the prospectively determined payment rates for routine services; and

(b) Explaining the basis on which the prospectively determined payment rates are calculated.

§ 413.321 Simplified cost report for SNFs.

SNFs electing to be paid under the prospectively determined payment rate system may file a simplified cost report. The cost report contains a simplified method of cost finding to be used in lieu of cost methods described in § 413.24(d). This method is specified in the instructions for Form CMS-2540S, contained in sections 3000-3027.3 of Part 2 of the Provider Reimbursement Manual. This form may not be used by hospital-based SNFs or SNFs that are part of a health care complex. Those SNFs must file a cost report that reflects the shared services and administrative costs of the hospital and any other related facilities in the health care complex.

Subpart J—Prospective Payment for Skilled Nursing Facilities

SOURCE: 63 FR 26309, May 12, 1998, unless otherwise noted.

§ 413.330 Basis and scope.

(a) *Basis.* This subpart implements section 1888(e) of the Act, which provides for the implementation of a prospective payment system for SNFs for cost reporting periods beginning on or after July 1, 1998.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for SNFs, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules.

§ 413.333 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the resident classification system.

Market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods

42 CFR Ch. IV (10-1-24 Edition)

and services included in covered skilled nursing services.

Resident classification system means a system for classifying SNF residents into mutually exclusive groups based on clinical, functional, and resource-based criteria. For purposes of this subpart, this term refers to the current version of the resident classification system, as set forth in the annual publication of Federal prospective payment rates described in § 413.345.

Rural area means, for services provided on or after July 1, 1998, but before October 1, 2005, an area as defined in § 412.62(f)(1)(iii) of this chapter. For services provided on or after October 1, 2005, *rural area* means an area as defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means, for services provided on or after July 1, 1998, but before October 1, 2005, an area as defined in § 412.62(f)(1)(ii) of this chapter. For services provided on or after October 1, 2005, *urban area* means an area as defined in §§ 412.64(b)(1)(ii)(A) and 412.64(b)(1)(ii)(B) of this chapter.

[63 FR 26309, May 12, 1998; 63 FR 53307, Oct. 5, 1998, as amended at 73 FR 46440, Aug. 8, 2008; 82 FR 36633, Aug. 4, 2017]

§ 413.335 Basis of payment.

(a) *Method of payment.* Under the prospective payment system, SNFs receive a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. The per diem payments are made on the basis of the Federal payment rate described in § 413.337 and, during a transition period, on the basis of a blend of the Federal rate and the facility-specific rate described in § 413.340. These per diem payment rates are determined according to the methodology described in §§ 413.337 and 413.340.

(b) *Payment in full.* (1) The payment rates represent payment in full (subject to applicable coinsurance as described in subpart G of part 409 of this chapter) for all costs (routine, ancillary, and capital-related) associated with furnishing inpatient SNF services to Medicare beneficiaries other than costs associated with approved educational activities as described in § 413.85.

(2) In addition to the Federal per diem payment amounts, SNFs receive payment for bad debts of Medicare beneficiaries, as specified in §413.89 of this part.

[63 FR 26309, May 12, 1998, as amended at 73 FR 46440, Aug. 8, 2008]

§413.337 Methodology for calculating the prospective payment rates.

(a) *Data used.* (1) To calculate the prospective payment rates, CMS uses—

(i) Medicare data on allowable costs from freestanding and hospital-based SNFs for cost reporting periods beginning in fiscal year 1995. SNFs that received “new provider” exemptions under §413.30(e)(2) are excluded from the data base used to compute the Federal payment rates. In addition, allowable costs related to exceptions payments under §413.30(f) are excluded from the data base used to compute the Federal payment rates;

(ii) An appropriate wage index to adjust for area wage differences;

(iii) The most recent projections of increases in the costs from the SNF market basket index;

(iv) Resident assessment and other data that account for the relative resource utilization of different resident types; and

(v) Medicare Part B SNF claims data reflecting amounts payable under Part B for covered SNF services (other than those services described in §411.15(p)(2) of this chapter) furnished during SNF cost reporting periods beginning in fiscal year 1995 to individuals who were residents of SNFs and receiving Part A covered services.

(b) *Methodology for calculating the per diem Federal payment rates—*(1) *Determining SNF costs.* In calculating the initial unadjusted Federal rates applicable for services provided during the period beginning July 1, 1998 through September 30, 1999, CMS determines each SNF’s costs by summing its allowable costs for the cost reporting period beginning in fiscal year 1995 and its estimate of Part B payments (described in paragraphs (a)(1)(i) and (a)(1)(v) of this section).

(2) *Use of market basket index.* The SNF market basket index is used to adjust the SNF cost data to reflect cost increases occurring between cost re-

porting periods represented in the data and the initial period (beginning July 1, 1998 and ending September 30, 1999) to which the payment rates apply. For each year, the cost data are updated by a factor equivalent to the annual market basket index percentage minus 1 percentage point.

(3) *Calculation of the per diem cost.* For each SNF, the per diem cost is computed by dividing the cost data for each SNF by the corresponding number of Medicare days.

(4) *Standardization of data for variation in area wage levels and case-mix.* The cost data described in paragraph (b)(2) of this section are standardized to remove the effects of geographic variation in wage levels and facility variation in case-mix.

(i) The cost data are standardized for geographic variation in wage levels using the wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in §413.333.

(ii) Starting on October 1, 2022, CMS applies a cap on decreases to the wage index such that the wage index applied to a SNF is not less than 95 percent of the wage index applied to that SNF in the prior FY.

(iii) The cost data are standardized for facility variation in case-mix using the case-mix indices and other data that indicate facility case-mix.

(5) *Calculation of unadjusted Federal payment rates.* CMS calculates the national per diem unadjusted payment rates by urban and rural classification in the following manner:

(i) By computing the average per diem standardized cost of freestanding SNFs weighted by Medicare days.

(ii) By computing the average per diem standardized cost of freestanding and hospital-based SNFs combined weighted by Medicare days.

(iii) By computing the average of the amounts determined under paragraphs (b)(5)(i) and (b)(5)(ii) of this section.

(c) *Calculation of adjusted Federal payment rates for case-mix and area wage levels.* The Federal rate is adjusted to account for facility case-mix using a resident classification system and associated case-mix indices that account for the relative resource utilization of

different patient types. This classification system utilizes the resident assessment instrument completed by SNFs as described at § 483.20 of this chapter, according to the assessment schedule described in § 413.343(b). The Federal rate is also adjusted to account for geographic differences in area wage levels using an appropriate wage index.

(d) *Annual updates of Federal unadjusted payment rates.* CMS updates the unadjusted Federal payment rates on a fiscal year basis.

(1) *Update formula.* The unadjusted Federal payment rate shall be updated as follows:

(i) For the initial period beginning on July 1, 1998, and ending on September 30, 1999, the unadjusted Federal payment rate is equal to the rate computed under paragraph (b)(5)(iii) of this section increased by a factor equal to the SNF market basket index percentage change for such period minus 1.0 percentage point.

(ii) For fiscal year 2000, the unadjusted Federal payment rate is equal to the rate computed for the initial period described in paragraph (d)(1)(i) of this section increased by a factor equal to the SNF market basket index percentage change for that period minus 1.0 percentage point.

(iii) For fiscal year 2001, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year.

(iv) For fiscal years 2002 and 2003, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved minus 0.5 percentage points.

(v) For each subsequent fiscal year, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved, except as provided in paragraphs (d)(1)(vi) and (vii) of this section.

(vi) For fiscal year 2018, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF

market basket index percentage change of 1 percent (after application of paragraphs (d)(2) and (3) of this section).

(vii) For fiscal year 2019, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF market basket index percentage change of 2.4 percent (after application of paragraphs (d)(2) and (3) of this section).

(2) *Forecast error adjustment.* Beginning with fiscal year 2004, an adjustment to the annual update of the previous fiscal year's rate will be computed to account for forecast error. The initial adjustment (in fiscal year 2004) to the update of the previous fiscal year's rate will take into account the cumulative forecast error between fiscal years 2000 and 2002. Subsequent adjustments in succeeding fiscal years will take into account the forecast error from the most recently available fiscal year for which there is final data. The forecast error adjustment applies whenever the difference between the forecasted and actual percentage change in the SNF market basket index exceeds the following threshold:

(i) 0.25 percentage points for fiscal years 2004 through 2007; and

(ii) 0.5 percentage points for fiscal year 2008 and subsequent fiscal years.

(3) *Multifactor productivity (MFP) adjustment.* For fiscal year 2012 and each subsequent fiscal year, the SNF market basket index percentage change for the fiscal year (as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section) shall be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The reduction of the market basket index percentage change by the MFP adjustment may result in the market basket index percentage change being less than zero for a fiscal year, and may result in the unadjusted Federal payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

(4) *Penalty for failure to report quality data.* For fiscal year 2018 and subsequent fiscal years—

(i) In the case of a SNF that does not meet the requirements in § 413.360, for a

fiscal year, the SNF market basket index percentage change for the fiscal year (as specified in paragraph (d)(1)(v) of this section, as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section, reduced by the MFP adjustment specified in paragraph (d)(3) of this section, and as specified for FY 2018 in section 1888(e)(5)(B)(iii) of the Act), is further reduced by 2.0 percentage points.

(ii) The application of the 2.0 percentage point reduction specified in paragraph (d)(4)(i) of this section to the SNF market basket index percentage change may result in such percentage being less than zero for a fiscal year, and may result in payment rates for that fiscal year being less than such payment rates for the preceding fiscal year.

(iii) Any 2.0 percentage point reduction applied pursuant to paragraph (d)(4)(i) of this section will apply only to the fiscal year involved and will not be taken into account in computing the payment amount for a subsequent fiscal year.

(e) Pursuant to section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) as revised by section 314 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), using the best available data, the Secretary will issue a new regulation with a newly refined case-mix classification system to better account for medically complex patients. Upon issuance of the new regulation, the temporary increases in payment for certain high cost patients will no longer be applicable.

(f) *Adjustments to payment rates under the SNF Value-Based Purchasing Program.* Beginning with payment for services furnished on October 1, 2018, the adjusted Federal per diem rate (as defined in § 413.338(a)) otherwise applicable to a SNF for the fiscal year is reduced by the applicable percent (as defined in § 413.338(a)). The resulting amount is then adjusted by the value-based incentive payment amount (as defined in § 413.338(a)) based on the SNF

performance score calculated for the SNF for that fiscal year under § 413.338.

[63 FR 26309, May 12, 1998, as amended at 66 FR 39600, July 31, 2001; 68 FR 46070, Aug. 4, 2003; 76 FR 48539, Aug. 8, 2011; 82 FR 36633, Aug. 4, 2017; 83 FR 39289, Aug. 8, 2018; 87 FR 47616, Aug. 3, 2022; 89 FR 64160, Aug. 6, 2024]

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) *Definitions.* As used in this section:

Achievement threshold (or achievement performance standard) means the 25th percentile of SNF performance on a measure during the baseline period for a fiscal year.

Adjusted Federal per diem rate means the payment made to SNFs under the skilled nursing facility prospective payment system (as described under section 1888(e)(4)(G) of the Act).

Applicable percent means for FY 2019 and subsequent fiscal years, 2.0 percent.

Baseline period means the time period used to calculate the achievement threshold, benchmark, and improvement threshold that apply to a measure for a fiscal year.

Benchmark means, for a fiscal year, the arithmetic mean of the top decile of SNF performance on a measure during the baseline period for that fiscal year.

Eligible stay means, for purposes of the SNF readmission measure, an index SNF admission that would be included in the denominator of that measure.

Health equity adjustment (HEA) bonus points means the points that a SNF can earn for a fiscal year based on its performance and proportion of SNF residents who are members of the underserved population.

Improvement threshold (or improvement performance standard) means an individual SNF's performance on a measure during the applicable baseline period for that fiscal year.

Logistic exchange function means the function used to translate a SNF's performance score into a value-based incentive payment percentage.

Low-volume SNF means a SNF with fewer than 25 eligible stays included in the SNF readmission measure denominator during the performance period

for each of fiscal years 2019 through 2022.

Measure performance scaler means, for a fiscal year, the sum of the points assigned to a SNF for each measure on which the SNF is a top tier performing SNF.

Performance period means the time period during which SNF performance on a measure is calculated for a fiscal year.

Performance standards are the levels of performance that SNFs must meet or exceed to earn points on a measure under the SNF VBP Program for a fiscal year.

Ranking means the ordering of SNFs based on each SNF's performance score under the SNF VBP Program for a fiscal year.

SNF performance score means the numeric score ranging from 0 to 100 awarded to each SNF based on its performance under the SNF VBP Program for a fiscal year.

SNF readmission measure means, prior to October 1, 2027, the SNF 30-Day All-Cause Readmission Measure (SNFRM) specified under section 1888(g)(1) of the Social Security Act. Beginning October 1, 2027, the term SNF readmission measure means the SNF Within-Stay Potentially Preventable Readmission (SNF WS PPR) Measure specified under section 1888(g)(2) of the Social Security Act.

SNF Value-Based Purchasing (VBP) Program means the program required under section 1888(h) of the Act.

Top tier performing SNF means a SNF whose performance on a measure during the applicable fiscal year meets or exceeds the 66.67th percentile of SNF performance on the measure during the same fiscal year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable fiscal year.

Underserved population means Medicare beneficiaries who are SNF residents in a Medicare Part A stay who

are also dually eligible, both partial and full, for Medicaid.

Value-based incentive payment adjustment factor is the number that will be multiplied by the adjusted Federal per diem rate for services furnished by a SNF during a fiscal year, based on its performance score for that fiscal year, and after such rate is reduced by the applicable percent.

Value-based incentive payment amount is the portion of a SNF's adjusted Federal per diem rate that is attributable to the SNF VBP Program.

(b) *Applicability of the SNF VBP Program.* The SNF VBP Program applies to SNFs, including facilities described in section 1888(e)(7)(B) of the Act. Beginning with fiscal year 2023, the SNF VBP Program does not include a SNF, with respect to a fiscal year, if:

(1) The SNF does not have the minimum number of cases that applies to each measure for the fiscal year, as specified by CMS; or

(2) The SNF does not have the minimum number of measures for the fiscal year, as specified by CMS.

(c) *Process for reducing the adjusted Federal per diem rate and applying the value-based incentive payment adjustment factor under the SNF VBP Program—*(1) *General.* CMS will make value-based incentive payments to each SNF based on its performance score for a fiscal year under the SNF VBP Program under the requirements and conditions specified in this paragraph.

(2) *Value-based incentive payment amount—*(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs under paragraph (d)(3) of this section. Beginning with the FY 2023 SNF VBP, the total amount available for value-based incentive payments for a fiscal year is 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS. Beginning with the FY 2027 SNF VBP, the total amount available

for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the application of the Health equity adjustment bonus points as calculated under paragraph (k) of this section.

(ii) *Calculation of the value-based incentive payment amount.* The value-based incentive payment amount is calculated by multiplying the adjusted Federal per diem rate by the value-based incentive payment adjustment factor, after the adjusted Federal per diem rate has been reduced by the applicable percent.

(iii) *Calculation of the value-based incentive payment adjustment factor.* The value-based incentive payment adjustment factor is calculated by estimating Medicare spending under the skilled nursing facility prospective payment system to estimate the total amount available for value-based incentive payments, ordering SNFs by their SNF performance scores, then assigning an adjustment factor value for each performance score subject to the limitations set by the exchange function.

(iv) *Reporting of adjustment to SNF payments.* CMS will inform each SNF of the value-based incentive payment adjustment factor that will be applied to its adjusted Federal per diem rate for services furnished during a fiscal year at least 60 days prior to the start of that fiscal year.

(d) *Performance scoring under the SNF VBP Program (applicable, as described in this paragraph, to fiscal year 2019 through and including fiscal year 2025).* (1) CMS will award points to SNFs based on their performance on the SNF readmission measure applicable to a fiscal year during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 99 points for achievement to each SNF whose performance meets or exceeds the achievement threshold but is less than the benchmark.

(ii) CMS will award from 0 to 90 points for improvement to each SNF whose performance exceeds the im-

provement threshold but is less than the benchmark.

(iii) CMS will award 100 points to a SNF whose performance meets or exceeds the benchmark.

(iv) CMS will not award points for improvement to a SNF that has fewer than 25 eligible stays during the baseline period.

(2) The highest of the SNF's achievement, improvement and benchmark score will be the SNF's performance score for the fiscal year.

(3) If, with respect to a fiscal year beginning with fiscal year 2019 through and including fiscal year 2022, CMS determines that a SNF is a low-volume SNF, CMS will assign a performance score to the SNF for the fiscal year that, when used to calculate the value-based incentive payment amount (as defined in paragraph (a)(17) of this section), results in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate (as defined in paragraph (a)(2) of this section) that would apply to the SNF for the fiscal year without application of §413.337(f).

(e) *Performance scoring under the SNF VBP Program beginning with fiscal year 2026.* (1) *Points awarded based on SNF performance.* CMS will award points to SNFs based on their performance on each measure for which the SNF reports the applicable minimum number of cases during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 9 points for achievement to each SNF whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold for that measure but is less than the benchmark for that measure.

(ii) CMS will award 10 points for achievement to a SNF whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(iii) CMS will award from 0 to 9 points for improvement to each SNF whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(iv) CMS will not award points for improvement to a SNF that does not meet the case minimum for a measure for the applicable baseline period.

(v) The highest of the SNF's achievement and improvement score for a given measure will be the SNF's score on that measure for the applicable fiscal year.

(2) *Calculation of the SNF performance score for fiscal year 2026.* The SNF performance score for FY 2026 is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year to calculate the SNF's point total.

(ii) CMS will normalize the point total such that the resulting SNF performance score is expressed as a number of points earned out of a total of 100.

(3) *Calculation of the SNF performance score beginning with fiscal year 2027.* The SNF performance score for a fiscal year is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year.

(ii) CMS will normalize the SNF's point total such that the resulting point total is expressed as a number of points earned out of a total of 100.

(iii) CMS will add to the SNF's point total under paragraph (e)(3)(ii) of this section any applicable health equity adjustment bonus points calculated under paragraph (k) of this section such that the resulting point total is the SNF Performance Score for the fiscal year, except that no SNF Performance Score may exceed 100 points.

(f) *Confidential feedback reports and public reporting.*

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on each measure specified for the fiscal year. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, CMS calculates the measure rates included in those reports using data that are current as of a specified date as follows:

(i) For the SNFRM, the specified date is 3 months after the last index SNF

admission in the applicable baseline period or performance period.

(ii) For the Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization ("SNF HAI"), Discharge to Community—Post-Acute Care Measure for Skilled Nursing Facilities ("DTC PAC SNF"), and Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions ("SNF WS PPR") measure, the specified date is 3 months after the last SNF discharge in the applicable baseline period or performance period.

(iii) For the Number of Hospitalizations per 1,000 Long Stay Residents ("Long Stay Hospitalization") measure, the specified date is 3 months after the last day of the final quarter of the applicable baseline period or performance period.

(iv) For the Total Nursing Hours per Resident Day Staffing ("Total Nurse Staffing") measure and the Total Nursing Staff Turnover ("Nursing Staff Turnover") measure, the specified date is 45 days after the last day of each quarter of the applicable baseline period or performance period.

(v) For the Discharge Function Score for SNFs ("DC Function measure") and Percent of Residents Experiencing One of More Falls with Major Injury (Long Stay) ("Falls with Major Injury (Long Stay)") measure, the specified date is the February 15th that is approximately 4.5 months after the last day of the applicable baseline period or performance period.

(2) Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides in each of these reports to review and submit corrections to the measure rate calculations contained in that report. The underlying data used to calculate the measure rates are not subject to review and correction under this paragraph (f)(2). Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's name;

(iii) The correction requested; and

(iv) The reason for requesting the correction, including any available evidence to support the request.

(3) Beginning not later than 60 days prior to each fiscal year, CMS will provide reports to SNFs on their performance under the SNF VBP Program for a fiscal year. SNFs will have the opportunity to review and submit corrections to their SNF performance scores and ranking contained in these reports for 30 days following the date that CMS provides the reports. Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's name;

(iii) The correction requested; and

(iv) The reason for requesting the correction, including any available evidence to support the request.

(4) CMS will publicly report the information described in paragraphs (f)(2) and (3) of this section on the Nursing Home Compare website or a successor website. Beginning with information publicly reported on or after October 1, 2019, and ending with information publicly reported on September 30, 2022 the following exceptions apply:

(i) If CMS determines that a SNF has fewer than 25 eligible stays during the baseline period for a fiscal year but has 25 or more eligible stays during the performance period for that fiscal year, CMS will not publicly report the SNF's baseline period SNF readmission measure rate and improvement score for that fiscal year;

(ii) If CMS determines that a SNF is a low-volume SNF with respect to a fiscal year and assigns a performance score to the SNF under paragraph (d)(3) of this section, CMS will not publicly report the SNF's performance period SNF readmission measure rate, achievement score or improvement score for the fiscal year; and

(iii) If CMS determines that a SNF has zero eligible cases during the performance period with respect to a fiscal year, CMS will not publicly report any information for that SNF for that fiscal year.

(5) Beginning with the information publicly reported on or after October 1, 2022, the following exceptions apply:

(i) If a SNF does not have the minimum number of cases during the base-

line period that applies to a measure for a fiscal year, CMS will not publicly report the SNF's baseline period measure rate for that particular measure, although CMS will publicly report the SNF's performance period measure rate and achievement score if the SNF had the minimum number of cases for the measure during the performance period of the same program year;

(ii) If a SNF does not have the minimum number of cases during the performance period that applies to a measure for a fiscal year, CMS will not publicly report any information with respect to the SNF's performance on that measure for the fiscal year;

(iii) If a SNF does not have the minimum number of measures during the performance period for a fiscal year, CMS will not publicly report any data for that SNF for the fiscal year.

(g) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the value-based incentive payment percentage and the amount of the value-based incentive payment under section 1888(h)(5) of the Act.

(2) The determination of the amount of funding available for value-based incentive payments under section 1888(h)(5)(C)(ii)(III) of the Act and the payment reduction under section 1888(h)(6) of the Act.

(3) The establishment of the performance standards under section 1888(h)(3) of the Act and the performance period.

(4) The methodology developed under section 1888(h)(4) of the Act that is used to calculate SNF performance scores and the calculation of such scores.

(5) The ranking determinations under section 1888(h)(4)(B) of the Act.

(h) *Special rules for the FY 2022 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2022, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF,

with the exception of those SNFs qualifying for the low-volume scoring adjustment described in paragraph (d)(3) of this section.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section. CMS will then apply low-volume scoring adjustment described in paragraph (d)(3) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (e)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (e)(3) of this section.

(i) *Special rules for the FY 2023 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2023, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (f)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (f)(3) of this section.

(j) *Validation.* (1) Beginning with the FY 2023 program year, for the SNFRM measure, and beginning with the FY 2026 program year for all other claims-based measures, the information reported through claims are validated for

accuracy by Medicare Administrative Contractors (MACs).

(2) Beginning with the FY 2026 program year, for all measures that are calculated using Payroll-Based Journal System data, information reported through the Payroll-Based Journal system is validated for accuracy by CMS and its contractors through quarterly audits.

(3) Beginning October 1, 2026, for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. CMS will request medical records as follows:

(i) On an annual basis, a CMS contractor will randomly select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if the SNF submitted at least one MDS record in the calendar year that is 3 years prior to the applicable fiscal year or was included in the SNF VBP Program in the year prior to the applicable fiscal year.

(ii) For each SNF selected under paragraph (j)(3)(i) of this section, the CMS contractor will request in writing up to 10 medical records.

(iii) A SNF that receives a request for medical records under paragraph (j)(3)(ii) of this section must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request as documented on the request.

(k) *Calculation of the Health equity adjustment (HEA) bonus points.* CMS calculates the number of HEA bonus points that are added to a SNF's point total calculated under paragraph (e)(3)(iii) of this section by:

(1) Determining for each measure whether the SNF is a top tier performing SNF and assigning two points to the SNF for each such measure;

(2) Summing the points calculated under paragraph (k)(1) of this section to calculate the measure performance scaler;

(3) Calculating the underserved multiplier for the SNF; and

(4) Multiplying the measure performance scaler calculated under paragraph (k)(2) of this section by the underserved multiplier calculated under paragraph (k)(3) of this section.

(l) *Measure selection, retention, and removal policy.* (1) The SNF VBP measure

set for each fiscal year includes the SNF readmission measure CMS has specified under section 1888(g) of the Social Security Act for application in the SNF VBP Program.

(2) Beginning with FY 2026, the SNF VBP measure set for each fiscal year may include up to nine additional measures specified by CMS. Each of these measures remains in the measure set unless CMS removes or replaces it based on one or more of the following factors:

(i) SNF performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(ii) Performance or improvement on a measure do not result in better resident outcomes.

(iii) A measure no longer aligns with current clinical guidelines or practices.

(iv) A more broadly applicable measure for the particular topic is available.

(v) A measure that is more proximal in time to the desired resident outcomes for the particular topic is available.

(vi) A measure that is more strongly associated with the desired resident outcomes for the particular topic is available.

(vii) The collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the Program.

(3) Upon a determination by CMS that the continued requirement for SNFs to submit data on a measure specified under paragraph (1)(2) of this section raises specific resident safety concerns, CMS may elect to immediately remove the measure from the SNF VBP Program. Upon removal of the measure, CMS will provide notice to SNFs and the public, along with a statement of the specific patient safety concern that would be raised if SNFs continued to submit data on the measure. CMS will also provide notice of the removal in the FEDERAL REGISTER.

(4) CMS uses rulemaking to make substantive updates to the specifications of measures used in the SNF VBP Program. CMS makes technical meas-

ure specification updates in a sub-regulatory manner and informs SNFs of measure specification updates through postings on the CMS website, listservs, and other educational outreach efforts to SNFs.

(m) *Extraordinary circumstances exception policy.* (1) A SNF may request and CMS may grant exceptions to the SNF Value-Based Purchasing Program's requirements under this section for one or more calendar months when there are certain extraordinary circumstances beyond the control of the SNF.

(2) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred. Prior to FY 2025, the request must be submitted in the form and manner specified by CMS on the SNF VBP website at <https://www.cms.gov/Medicare/Quality/Nursing-Home-Improvement/Value-Based-Purchasing/Extraordinary-Circumstance-Exception> and include a completed Extraordinary Circumstances Request form (available on <https://qualitynet.cms.gov/>) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients including, but not limited to, photographs and media articles. Beginning with FY 2025, a SNF may request an extraordinary circumstances exception by sending an email with the subject line "SNF VBP Extraordinary Circumstances Exception Request" to the SNF VBP Program Help Desk with the following information:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's business name and business address;

(iii) Contact information for the SNF's chief executive officer (CEO) or CEO-designated personnel, including all applicable names, email addresses, telephone numbers, and the SNF's physical mailing address (which cannot be a P.O. Box);

(iv) A description of the event, including the dates and duration of the extraordinary circumstance;

(v) Available evidence of the impact of the extraordinary circumstance on the care the SNF provided to its residents or the SNF's ability to report

§ 413.340

42 CFR Ch. IV (10–1–24 Edition)

SNF VBP data, including, but not limited to, photographs, media articles, and any other materials that would aid CMS in determining whether to grant the exception; and

(vi) A date proposed by the SNF for when it will again be able to fully comply with the SNF VBP Program's requirements and a justification for the proposed date.

(3) Except as provided in paragraph (m)(4) of this section, CMS will not consider an exception request unless the SNF requesting such exception has complied fully with the requirements in paragraph (m)(2) of this section.

(4) CMS may grant exceptions to SNFs without a request if it determines that an extraordinary circumstance affected an entire region or locale.

(5) CMS will calculate a SNF performance score for a fiscal year for a SNF for which it has granted an exception request that does not include its performance on a quality measure during the calendar months affected by the extraordinary circumstance.

(n) *SNF VBP performance standards.*

(1) CMS announces the performance standards for each measure no later than 60 days prior to the start of the performance period that applies to the measure for the fiscal year.

(2) Beginning with FY 2021, if CMS discovers an error in the performance standard calculations subsequent to publishing their numerical values for a fiscal year, CMS will update the numerical values to correct the error. If CMS subsequently discovers one or more other errors with respect to the fiscal year, CMS will not further update the numerical values for that fiscal year.

(3) Beginning with FY 2025, CMS may update the numerical values of the performance standards for a measure if, between the time that CMS announced the performance standards for the measure for that fiscal year and the time that CMS calculates SNF performance on the measure at the conclusion of the performance period for that measure for that fiscal year, CMS has made technical updates to the

specifications for the measure that affect the measure rate calculations.

[82 FR 36633, Aug. 4, 2017, as amended at 83 FR 39289, Aug. 8, 2018; 85 FR 47633, Aug. 5, 2020; 86 FR 42524, Aug. 4, 2021; 87 FR 47616, Aug. 3, 2022; 88 FR 53346, Aug. 7, 2023; 89 FR 64160, Aug. 6, 2024]

§ 413.340 Transition period.

(a) *Duration of transition period and proportions for the blended transition rate.* Beginning with an SNF's first cost reporting period beginning on or after July 1, 1998, there is a transition period covering three cost reporting periods. During this transition phase, SNFs receive a payment rate comprising a blend of the adjusted Federal rate and a facility-specific rate. For the first cost reporting period beginning on or after July 1, 1998, payment is based on 75 percent of the facility-specific rate and 25 percent of the Federal rate. For the subsequent cost reporting period, the rate is comprised of 50 percent of the facility-specific rate and 50 percent of the Federal rate. In the final cost reporting period of the transition, the rate is comprised of 25 percent of the facility-specific rate and 75 percent of the Federal rate. For all subsequent cost reporting periods, payment is based entirely on the Federal rate.

(b) *Calculation of facility-specific rate for the first cost reporting period.* The facility-specific rate is computed based on the SNF's Medicare allowable costs from its fiscal year 1995 cost report plus an estimate of the amounts payable under Part B for covered SNF services (other than those services described in § 411.15(p)(2) of this chapter) furnished during fiscal year 1995 to individuals who were residents of SNFs and receiving Part A covered services. Allowable costs associated with exceptions, as described in § 413.30(f), are included in the calculation of the facility-specific rate. Allowable costs associated with exemptions, as described in § 413.30(e)(2), are included in the calculation of the facility-specific rate but only to the extent that they do not exceed 150 percent of the routine cost limit. Low Medicare volume SNFs that were paid a prospectively determined rate under § 413.300 for their cost reporting period beginning in fiscal year 1995 will utilize that rate as the basis

for the allowable costs of routine (operating and capital-related) expenses in determining the facility-specific rate. Each SNF's allowable costs are updated to the first cost reporting period to which the payment rates apply using annual factors equal to the SNF market basket percentage minus 1 percentage point.

(c) *SNFs participating in the Multistate Nursing Home Case-Mix and Quality Demonstration.* SNFs that participated in the Multistate Nursing Home Case-Mix and Quality Demonstration in a cost reporting period that began in calendar year 1997 will utilize their allowable costs from that cost reporting period, including prospective payment amounts determined under the demonstration payment methodology.

(d) *Update of facility-specific rates for subsequent cost reporting periods.* The facility-specific rate for a cost reporting period that is subsequent to the first cost reporting period is equal to the facility-specific rate for the first cost reporting period (described in paragraph (a) of this section) updated by the market basket index.

(1) For a subsequent cost reporting period beginning in fiscal years 1998 and 1999, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage minus one percentage point.

(2) For a subsequent cost reporting period beginning in fiscal year 2000, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage.

(e) *SNFs excluded from the transition period.* SNFs that received their first payment from Medicare, under present or previous ownership, on or after October 1, 1995, are excluded from the transition period, and payment is made according to the Federal rates only.

§413.343 Resident assessment data.

(a) *Submission of resident assessment data.* SNFs are required to submit the resident assessment data described at §483.20 of this chapter in the manner necessary to administer the payment rate methodology described in §413.337.

This provision includes the frequency, scope, and number of assessments required.

(b) *Assessment schedule.* In accordance with the methodology described in §413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of an initial Medicare assessment with an assessment reference date that is set for no later than the 8th day of posthospital SNF care, and such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.

(c) *Noncompliance with assessment schedule.* CMS pays a default rate for the Federal rate when a SNF fails to comply with the assessment schedule in paragraph (b) of this section. The default rate is paid for the days of a patient's care for which the SNF is not in compliance with the assessment schedule.

[63 FR 26309, May 12, 1998, as amended at 64 FR 41682, July 30, 1999; 84 FR 38832, Aug. 7, 2019]

§413.345 Publication of Federal prospective payment rates.

CMS publishes information pertaining to each update of the Federal payment rates in the FEDERAL REGISTER. This information includes the standardized Federal rates, the resident classification system that provides the basis for case-mix adjustment, and the factors to be applied in making the area wage adjustment. This information is published before May 1 for the fiscal year 1998 and before August 1 for the fiscal years 1999 and after.

[82 FR 36634, Aug. 4, 2017]

§413.348 Limitation on review.

Judicial or administrative review under sections 1869 or 1878 of the Act or otherwise is prohibited with regard to the establishment of the Federal rates. This prohibition includes the methodology used in the computation of the Federal standardized payment rates, the case-mix methodology, and the development and application of the wage index. This prohibition on judicial and

§ 413.350

42 CFR Ch. IV (10–1–24 Edition)

administrative review also extends to the methodology used to establish the facility-specific rates but not to determinations related to reasonable cost in the fiscal year 1995 cost reporting period used as the basis for these rates.

§ 413.350 Periodic interim payments for skilled nursing facilities receiving payment under the skilled nursing facility prospective payment system for Part A services.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, SNFs receiving payment under the PPS for Part A services do not receive interim payments during the cost reporting year, and receive payment only following submission of a bill. Paragraph (d) of this section provides for accelerated payments in certain circumstances.

(b) *Periodic interim payments.* (1) An SNF receiving payment under the prospective payment system may receive periodic interim payments (PIP) for Part A SNF services under the PIP method subject to the provisions of § 413.64(h). To be approved for PIP, the SNF must meet the qualifying requirements in § 413.64(h)(3). Moreover, as provided in § 413.64(h)(5), contractor approval is conditioned upon the contractor's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* The contractor estimates an SNF's prospective payments net of estimated beneficiary coinsurance and makes biweekly payments equal to $\frac{1}{26}$ of the total estimated amount of payment for the year. If an SNF has payment experience under the prospective payment system, the contractor estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP—(i) Request by the SNF.* An SNF receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the contractor.* An contractor terminates PIP if the SNF no longer meets the requirements of § 413.64(h).

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the contractor determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to $\frac{1}{26}$ of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Accelerated payments—(1) General rule.* Upon request, an accelerated payment may be made to an SNF that is receiving payment under the prospective payment system and is not receiving PIP under paragraph (b) of this section if the SNF is experiencing financial difficulties because of the following:

(i) There is a delay by the contractor in making payment to the SNF.

(ii) Due to an exceptional situation, there is a temporary delay in the SNF's preparation and submittal of bills to the contractor beyond its normal billing cycle.

(2) *Approval of payment.* An SNF's request for an accelerated payment must be approved by the contractor and CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by

recoupment as SNF bills are processed or by direct payment by the SNF.

[64 FR 41682, July 30, 1999]

§413.355 Additional payment: QIO reimbursement for cost of sending records electronically or by photocopy and mailing.

An additional payment is made to a skilled nursing facility in accordance with §476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

[85 FR 59025, Sept. 18, 2020]

§413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the SNF as operating in the CMS designated data submission system. For purposes of this section, a program year is the fiscal year in which the market basket percentage described in §413.337(d) is reduced by two percentage points if the SNF does not report data in accordance with paragraph (b) of this section.

(b) *Data submission requirement.* (1) Except as provided in paragraph (c) of this section, and for a program year, SNFs must submit to CMS data on measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Social Security Act and standardized resident assessment data in accordance with section 1899B(b)(1) of the Social Security Act, in the form and manner, and at a time, specified by CMS.

(2) CMS may remove a quality measure from the SNF QRP based on one or more of the following factors:

(i) Measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better resident outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired resident outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired resident outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

(c) *Exception and extension requests.* (1) A SNF may request and CMS may grant exceptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the SNF.

(2) A SNF may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to SNFQRPreconsiderations@cms.hhs.gov that contains all of the following information:

(i) SNF CMS Certification Number (CCN).

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) SNF's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the SNF believes it will be able to again submit SNF QRP data and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS will not consider an exception or extension request

unless the SNF requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to SNFs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a SNF to submit data in accordance with paragraph (b) of this section.

(d) *Reconsideration.*

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests must be submitted to CMS by sending an email to

SNFQRPreconsiderations@cms.hhs.gov containing all of the following information:

(i) SNF CCN.

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) CMS identified reason(s) for non-compliance stated in the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider a reconsideration request unless the SNF has complied fully with the requirements in paragraph (d)(2) of this section.

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the

United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

(e) *Appeals.* A SNF that is dissatisfied with CMS' decision on a request for reconsideration may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(f) *Data completion threshold.*

(1) SNFs must meet or exceed the following data completeness thresholds with respect to a program year:

(i) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the Minimum Data Set (MDS) on at least 80 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2018 through FY 2025 program years.

(ii) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2026 and for all subsequent payment updates.

(iii) The threshold set at 100 percent for measures data collected and submitted through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for FY 2023 and for all subsequent payment updates.

(iv) If selected for the data validation process under paragraph (g) of this section, the threshold set at 100 percent submission of medical charts.

(2) These thresholds apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

(3) A SNF must meet or exceed each applicable threshold described in paragraph (f)(1) of this section to avoid receiving the applicable penalty for failure to report quality data set forth in § 413.337(d)(4).

(g) *Data validation process.* (1) Beginning with the FY 2027 payment year: for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. The process by which CMS will request medical

records and by which SNFs must submit the requested medical records is as follows:

(i) On an annual basis, a CMS contractor will select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if it submitted at least one MDS record to CMS in the fiscal year that is 2 years prior to the applicable program year, and if the SNF has been randomly selected for a periodic audit for the same year under §413.338.

(ii) For each SNF selected under this paragraph (g)(1), the CMS contractor will request up to 10 medical records. Each SNF selected will only be required to submit records once in a fiscal year, for a maximum of 10 records for each SNF selected. Each requested medical record must be the same medical record that has been requested for submission by the SNF for the same year under §413.338. CMS will submit its request in writing to the selected SNF.

(iii) A SNF that receives a request for medical records under this paragraph (g)(1) must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request.

(2) Beginning with the FY 2027 payment year: the information reported through claims for all claims-based measures are validated for accuracy by Medicare Administrative Contractors (MACs).

[82 FR 36634, Aug. 4, 2017, as amended at 83 FR 39290, Aug. 8, 2018; 84 FR 38832, Aug. 7, 2019; 87 FR 47618, Aug. 3, 2022; 88 FR 53346, Aug. 7, 2023; 89 FR 64162, Aug. 6, 2024]

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

SOURCE: 81 FR 77965, Nov. 4, 2016, unless otherwise noted.

§413.370 Scope.

This subpart implements section 1834(r) of the Act by setting forth the principles and authorities under which CMS is authorized to establish a payment amount for renal dialysis services furnished to beneficiaries with an acute kidney injury in or under the supervision of an ESRD facility that meets the conditions of coverage in

part 494 of this chapter and as defined in §413.171.

§413.371 Definition.

For purposes of the subpart, the following definition applies:

Individual with acute kidney injury. The term individual with acute kidney injury means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

§413.372 AKI dialysis payment rate.

The amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for such year under section 1881(b)(14), that is, the ESRD base rate as set forth in §413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in §413.196(d)(1), adjusted for wages as set forth in §413.231, and adjusted by any other amounts deemed appropriate by the Secretary under §413.373.

§413.373 Other adjustments to the AKI dialysis payment rate.

The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

§413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act.

(b) Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in §413.171, but that are related to their dialysis treatment as a result of their AKI, would be separately payable, that is, drugs, biologicals, laboratory services, and

§ 413.375

42 CFR Ch. IV (10–1–24 Edition)

supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

§ 413.375 Notification of changes in rate-setting methodologies and payment rates.

(a) Changes to the methodology for payment for renal dialysis services furnished to beneficiaries with AKI as well as any adjustments to the AKI payment rate other than wage index will be adopted through notice and comment rulemaking.

(b) Annual updates in the AKI dialysis payment rate as described in § 413.372 that do not include those changes described in paragraph (a) of this section are announced by notice published in the FEDERAL REGISTER without opportunity for public comment.

(c) Effective for cost reporting periods beginning on or after January 1, 2017, on an annual basis CMS updates the AKI dialysis payment rate.

Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals. Organ Procurement Organizations, and Histocompatibility Laboratories

SOURCE: 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

§ 413.400 Definitions.

As used in this subpart:

Histocompatibility laboratory means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

Independent organ procurement organization (IOPO) means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

(1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.

(2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

Organ, for Medicare organ acquisition payment purposes, means:

(1) A human kidney, liver, heart, lung, pancreas, or intestine (or multi-visceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Organ procurement organization (OPO) means an organization defined in § 486.302 of this chapter. OPOs can be independent or hospital based.

Standard acquisition charge (SAC) means a charge as defined in § 413.404 of this chapter.

Transplant hospital (TH) means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

Transplant program means an organ-specific transplant program within a TH (as defined in this section).

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72287, Nov. 23, 2022]

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those

organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH.

(b) *Types of costs.* Organ acquisition costs are as follows:

(1) Tissue typing, including tissue typing furnished by independent laboratories.

(2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

(5) Organ preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

(7) Surgeons' fees for excising deceased organs (currently limited to \$1,250 for kidneys).

(8) Transportation of the:

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

(c) *Living donor complications.* (1) *Living kidney donor complications.* Living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report.

(A) Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary.

(B) Living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

(2) *Living non-renal donor complications.* Hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report.

(A) Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary.

(B) Hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the Medicare cost report, and paid through the cost report on a reasonable cost basis.

(d) *Costs not related to organ acquisition.* (1) Items or services that are not related or reasonable to acquire an organ for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered organ acquisition costs.

(2) Examples of items or services that are not organ acquisition costs include, but are not limited to the following:

- (i) Donor burial and funeral expenses.
- (ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.
- (iii) Transportation costs for a living donor.
- (iv) Fees or in-center payments for donor referrals.
- (v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)).
- (vi) Unreasonable costs incurred for administrator's duties associated with professional organizations.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

§ 413.404 Standard acquisition charge.

(a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.

(3) When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organ.

(b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).

(2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.

(i) *Living donor SAC for THs—(A) Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC.—*

(1) *Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

(i) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(ii) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(1)(i) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

(2) *Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

(i) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) Dividing the costs in paragraph (b)(3)(i)(C)(2)(i) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

(1) Costs of tissue typing services, including those furnished by independent laboratories.

(2) Costs of physician pre-admission transplant evaluation services.

(3) Registry fees as specified at § 413.402(b)(6) of this subpart.

(4) Costs for donor and recipient evaluations and workups furnished prior to admission for transplantation.

(5) Other costs associated with procurement, for example, general routine and special care services (for example, intensive care unit or critical care unit services), related to the donor.

(6) Costs of operating room and other inpatient ancillary services related to the donor.

(7) Organ preservation and perfusion costs.

(8) Transportation costs of the excised organ as specified in § 413.402(b)(8)(i) of this subpart.

(ii) *Deceased donor SAC for TH/HOPOs—(A) Definition.* The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC—(1)—Initial deceased donor SAC.* A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(i) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(ii) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(1)(i) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(2) *Subsequent deceased donor SAC.* A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(i) By using the TH's actual organ acquisition costs for the deceased donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) By dividing the costs in paragraph (b)(3)(ii)(B)(2)(i) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC.* Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(1) Costs of organs acquired from other THs or OPOs.

(2) Costs of transportation as specified in §413.402(b)(8).

(3) Surgeons' fees for excising deceased donor organs (currently limited to \$1,250 for kidneys).

(4) Costs of tissue typing services, including those furnished by independent laboratories.

(5) Organ preservation and perfusion costs.

(6) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(7) Operating room and other inpatient ancillary service costs.

(c) *Independent OPO SACs—(1) Non-renal SAC.* An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

(iii) An IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

(2) *Kidney SAC.* (i) *General.* An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year.* The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in §413.420(d)(1).

(iv) *SAC adjustments.* The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses

§ 413.406

42 CFR Ch. IV (10–1–24 Edition)

its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

§ 413.406 Acquisition of pancreata for islet cell transplant.

(a) Medicare only covers and pays for reasonable costs of acquisition on or after October 1, 2004, of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(b) Pancreata procured under paragraph (a), for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

§ 413.408 [Reserved]

§ 413.410 [Reserved]

§ 413.412 Intent to transplant, intent for research, counting en bloc, and unusable organs.

(a) *Principles for organs intended for transplant for organ acquisition payment purposes.* (1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type. These costs include the costs associated with an organ intended for transplant, but subsequently determined unsuitable for transplant and furnished for research.

(3) An organ intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs.

(4) Subject to paragraph (a)(4)(iii) of this section, OPOs and THs must re-

duce total organ acquisition costs, when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research, as follows:

(i) By deducting the costs to furnish organs for research from total organ acquisition costs; or

(ii) By offsetting the total organ acquisition costs by the revenue received for these organs.

(iii) In no event may the reduction in total organ acquisition costs as a result of application of paragraph (a)(4) of this section exceed the costs incurred to furnish organs for research.

(5) When the costs to furnish organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, no offset is necessary.

(b) *Principles for organs intended for research for organ acquisition payment purposes.* (1) An organ is intended for research when the OPO or TH designates it for research

prior to the time the donor enters the hospital's operating room for surgical removal of the organ.

(2) Medicare does not share in the acquisition costs of an organ intended for research and costs to procure these organs must not be included in organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(3) An organ intended for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(c) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count -

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For

each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(d) *Unusable organs.* (1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a physician determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

[87 FR 72289, Nov. 23, 2022]

§413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant

and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72289, Nov. 23, 2022]

§413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are

matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

(1) All costs must be reasonable and necessary.

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs -

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) Donor's procurement occurs at recipient TH. In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]

§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services

attributable to a deceased donor or a donor whose death is imminent. These services must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team, must be authorized by the OPO, and are included as organ acquisition costs when:

(1) There is consent to donate; and

(2) Declaration of death has been made, or if a declaration of death has not been made, death is imminent and it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant.

(b) *Amounts billed for organ acquisition costs.* When a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in paragraph (a) of this section, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

[87 FR 72290, Nov. 23, 2022]

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* Definitions relevant to this section can be found in § 413.400.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with §413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's

or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in §413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to determine the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) *Retroactive adjustment.* A retroactive adjustment in the amount paid under the interim rate is made in accordance with §413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements.* For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals.* If the amount in controversy is \$1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance

§ 413.420

42 CFR Ch. IV (10–1–24 Edition)

with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]