

X. Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this final rule will not have any negative impact on the rights, roles, and responsibilities of State, local or Tribal governments.

XI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule. We find that the circumstances surrounding this rule make it impracticable to pursue a process of notice-and-comment rulemaking before the provisions of this rule take effect.

The BBRA 1999 was enacted on November 29, 1999. This final rule incorporates the following hospital outpatient PPS provisions in the BBRA 1999: outlier adjustment for high cost cases; transitional pass-through payment adjustments for additional costs (over the payments for APCs otherwise made) for new medical devices, drugs, and biologicals; definition of APCs so that the variation of costs of items within an APC is subject to certain limits; establishment of "transitional corridors" for the first 3½ years of the new system that limit losses hospitals might otherwise face; payment for implantable devices under the hospital outpatient PPS, rather than under the Durable Medical Equipment Fee Schedule; limitation of the copayment on an outpatient procedure to the amount of the inpatient hospital deductible; requirement to review annually the APC groups, relative weights, and wage and other adjustments; and calculation of the conversion factor in a budget-neutral manner, eliminating the 5.7 percent reduction indicated in the proposed rule.

As discussed earlier in this rule, July 1, 2000 is the earliest date on which we can feasibly implement the PPS. The provisions of the BBRA 1999, enacted on November 29, 1999, made numerous refinements to the PPS. With respect to the BBRA 1999 provisions, it would

have been impracticable to complete notice and comment procedures by July 1, 2000. Given the limited timeframe, given the nature and scope of the BBRA 1999 refinements, and given the time required to complete notice and comment rulemaking (to develop proposed policies, draft the proposed rule, provide a 60-day public comment period, consider public comments, develop final policies, draft a final rule), it would not have been possible to issue this document as a proposed rule and issue a final rule by July 1.

In addition, it would not be feasible to implement the hospital outpatient PPS *without* the BBRA 1999 provisions, not only because of the nature of the BBRA 1999 provisions, but also because section 201(m) of the BBRA 1999 states: "Except as provided in this section, the amendments made by this section shall be effective as if included in the enactment of BBA." Therefore, if we undertook prior notice and comment procedures with respect to the BBRA 1999 provisions, then (because such procedures could not be completed by July 1, 2000) the PPS would not be implemented by July 1, 2000.

Accordingly, we find good cause to waive the procedures for *prior* notice and comment with respect to the provisions of this document that implement the BBRA 1999 refinements to hospital outpatient PPS. We are providing a 60-day period for public comment with respect to the provisions of this final rule with comment period that implement the BBRA refinements. We are not accepting comments with respect to the other aspects of this document (for which the public has already had an extensive opportunity to comment).

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 419

Health facilities, Hospitals, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 1003

Administrative practice and procedure, Archives and records, Grant program—social programs, Maternal and Child Health, Medicaid, Medicare, Penalties.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

A. Part 409 is amended as set forth below:

1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

2. In § 409.10, paragraph (b) is revised to read as follows:

§ 409.10 Inpatient services.

* * * * *

(b) *Inpatient hospital services* does not include the following types of services:

(1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.

(2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swing-bed hospital that has an approval to furnish nursing facility services.

(3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69 of this chapter.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Part 410 is amended as set forth below:

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

2. In § 410.2, the introductory text is republished, the definition of “Community mental health center (CMHC)” is revised, and the definitions of “Encounter” and “Outpatient” are added in alphabetical order to read as follows:

§ 410.2 Definitions.

As used in this part—

Community mental health center (CMHC) means an entity that—

(1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility;

(2) Provides 24-hour-a-day emergency care services;

(3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services;

(4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; and

(5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located.

Encounter means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

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Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies

alone) directly from the hospital or CAH.

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Subpart B—Medical and Other Health Services

3. In § 410.27:

A. The section heading is revised;

B. The introductory text to paragraph (a) is revised;

C. The introductory text to paragraph (a)(1) is republished;

D. The word “and” at the end of paragraph (a)(1)(i) is removed; and

E. New paragraphs (a)(1)(iii), (e), and (f) are added to read as follows:

§ 410.27 Outpatient hospital services and supplies incident to a physician service: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to a physician service to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

* * * * *

(iii) In the hospital or at a location (other than an RHC or an FQHC) that HCFA designates as a department of a provider under § 413.65 of this chapter; and

* * * * *

(e) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(f) Services furnished at a location (other than an RHC or an FQHC) that HCFA designates as a department of a provider under § 413.65 of this chapter must be under the direct supervision of a physician. “Direct supervision” means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

4. In § 410.28, paragraph (a)(4) is removed, paragraph (c) is redesignated as paragraph (d), and new paragraphs (c) and (e) are added to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

* * * * *

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished at a facility (other than an RHC or an FQHC)

that HCFA designates as having provider-based status only when the diagnostic services are furnished under the appropriate level of physician supervision specified by HCFA in accordance with the definitions in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

5. A new § 410.42 is added to read as follows:

§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term “hospital” includes a CAH.

(b) *Exception.* The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69.

(7) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

6. In § 410.43, paragraph (b) is revised to read as follows:

§ 410.43 Partial hospitalization services: Conditions and exclusions.

* * * * *

(b) The following services are separately covered and not paid as partial hospitalization services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

C. Part 411 is amended as set forth below:

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusion of Particular Services

2. In § 411.15:

A. The introductory text is republished;

B. The section heading to paragraph (m) is revised;

C. Paragraph (m)(1) is revised;

D. Paragraph (m)(2) is redesignated as paragraph (m)(3);

E. The introductory text to newly redesignated paragraph (m)(3) is republished;

F. Newly redesignated paragraphs (m)(3)(iii), (m)(3)(iv), and (m)(3)(v) are redesignated as paragraphs (m)(3)(iv), (m)(3)(v), and (m)(3)(vi), respectively; and

G. New paragraphs (m)(2) and (m)(3)(iii) are added to read as follows:

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(m) *Services to hospital patients*—(1) *Basic rule.* Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term "hospital" includes a CAH.

(2) *Scope of exclusion.* Services subject to exclusion from coverage under the provisions of this paragraph

(m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) *Exceptions.* The following services are not excluded from coverage:

* * * * *

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

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PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

D. Part 412 is amended as set forth below:

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

2. In § 412.50, paragraphs (a) and (b) are revised to read as follows:

§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment systems, as described in subparts H and M of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter. Inpatient hospital services do not include the following types of services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(b) HCFA does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for the services

described in paragraphs (a)(1) through (a)(6) of this section.

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

E. Part 413 is amended as set forth below:

1. The authority citation for part 413 continues to read as follows:

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

Subpart A—Introduction and General Rules

§ 413.1 [Amended]

2. In § 413.1, paragraph (a)(2)(viii) is removed.

Subpart B—Accounting Records and Reports

3. In § 413.24, the heading to paragraph (d) is republished, and a new paragraph (d)(6) is added to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(d) *Cost finding methods.* * * *

(6) *Management contracts.* (i) If the main provider purchases services for a department of the provider or a provider-based entity through a management contract or otherwise directly assigns costs to the department or entity, the like costs of the main provider must be carved out to ensure that they are not allocated to the department of the provider or provider-based entity. However, if the like costs of the main provider cannot be separately identified, the costs of the services purchased through a management contract must be included in the main provider's administrative and general costs and allocated among the provider's overall statistics.

(ii) Costs of free-standing entities may not be shown in the provider's trial balance for purposes of stepping down overhead costs to these entities. The provider must develop detailed work papers showing the exact cost of the services (including overhead) provided to or by the free-standing entity and show those carved out costs as

nonreimbursable cost centers in the provider's trial balance.

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Subpart E—Payments to Providers

4. A new § 413.65 is added to read as follows:

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

(a) *Scope and definitions.* (1) *Scope.* This section applies to all facilities or organizations 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 ESRD facilities. Determinations for ESRD facilities are made under § 413.174 of this chapter.

(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 HCFA regional office, to be part of the provider's campus.

Department of a provider means a facility or organization or a physician office 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 may not be licensed to provide health care services in its own right, may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and 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 (m)(1) 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 or an FQHC 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 name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section.

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 may not be licensed to provide inpatient hospital services in its own right, and 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) *Responsibility for obtaining 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) A main provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider bills for services of the facility or organization as if the facility or organization were provider-based, or before it includes costs of those services on its cost report.

(3) A facility that is not located on the campus of a hospital and is used as a site of physician services of the kind ordinarily furnished in physician offices will be presumed to be a free-standing facility, unless it is determined by HCFA to have provider-based status.

(c) *Reporting.* (1) A main provider that creates or acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital

outpatient department or clinic, must report its acquisition of the facility or organization to HCFA if the facility or organization is located off the campus of the provider, or inclusion of the costs of the facility or organization in the provider's cost report would increase the total costs on the provider's cost report by at least 5 percent, and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status.

(2) A main provider that has had one or more facilities or organizations considered provider-based also must report to HCFA 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 could affect the provider-based status of the facility or organization.

(d) *Requirements.* An entity must meet all of the following requirements to be determined by HCFA to have provider-based status.

(1) *Licensure.* The department of the provider, remote location of a hospital, or 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, remote location of a hospital, or satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, remote location of a hospital, or 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, HCFA will determine that the facility or organization does not have provider-based status.

(2) *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 provider.

(ii) The main provider and the facility or organization seeking status as a department of the provider, remote location of a hospital, or 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 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/code of conduct), and final approval for medical staff appointments in the facility or organization.

(3) *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 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 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.

(4) *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.

(5) *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 the facility or organization are reported in a cost center of the provider, and the financial status of the facility or organization is incorporated and readily identified in the main provider's trial balance.

(6) *Public awareness.* The facility or organization seeking status as a department of a provider, remote

location of a hospital, or 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.

(7) *Location in immediate vicinity.* The facility or organization and the main provider are located on the same campus, except where the following requirements are met:

(i) 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 HCFA, 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;

(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); or

(C) If the facility or organization is unable to meet the criteria in paragraph (d)(7)(i)(A) or (d)(7)(i)(B) of this section because it was not in operation during all of the 12-month period described in the previous sentence, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in the previous sentence, accounted for at least 75 percent of the patients served by the main provider.

(ii) A facility or organization is not considered to be in the "immediate vicinity" of the main provider unless the facility or organization and the main provider are located in the same State or, where consistent with the laws of both States, adjacent States.

(iii) A rural health clinic that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criterion in this paragraph (d)(7).

(e) *Provider-based status not applicable to joint ventures.* A facility or

organization cannot be considered provider-based if the entity is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created free-standing facilities under joint venture arrangements, neither party to the joint venture arrangement can claim the free-standing facility as a provider-based entity.

(f) *Management contracts.* Facilities and organizations that otherwise meet the requirements of paragraph (d) of this section, but are operated under management contracts, must also meet all of the following criteria:

(1) The staff of the facility or organization, other than management staff, are employed by the provider or by another organization, other than the management company, which also employs the staff of the main provider.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (d)(3)(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 (b)(3)(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.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* (1) Hospital outpatient departments located either on or off the campus of the hospital that is the main provider must comply with the anti-dumping rules in §§ 489.20(l), (m), (q), and (r) and § 489.24 of this chapter. If any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, as described in § 489.24 of this chapter, the hospital must comply with the anti-dumping rules in § 489.24 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 indicator, so that applicable site-of-service reductions to physician and practitioner payment amounts can be applied.

(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 or hospital-based entity (other than an RHC) that is not located on the main provider's campus, the hospital has a duty to provide written notice to the beneficiary, prior to the delivery of services, of the amount of the beneficiary's potential financial liability (that is, of the fact that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability). The notice must be one that the beneficiary can read and understand. 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, prior to the delivery of services, to the beneficiary's authorized representative.

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

(h) *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 are furnished under arrangement.

(i) *Inappropriate treatment of a facility or organization as provider-based.* (1) *Determination and review.* If HCFA learns that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, HCFA will—

(i) Review current payments and, if necessary, take action in accordance with the rules on inappropriate billing in paragraph (j) of this section;

(ii) Investigate and determine whether the requirements in paragraph (d) of this section (or, for periods prior to October 10, 2000, the requirements in applicable program instructions) were met; and

(iii) Review all previous payments to that provider for all cost reporting periods subject to re-opening in accordance with § 405.1885 and § 405.1889 of this chapter.

(2) *Recovery of overpayments.* If HCFA finds that payments for services at the facility or organization have been made as if the facility or organization were provider-based, even though HCFA had not previously determined that the facility or organization qualified for provider-based status, HCFA will recover the difference between the amount of payments that actually were made and the amount of payments that HCFA estimates should have been made in the absence of a determination of provider-based status, except that recovery will not be made for any period prior to October 10, 2000 if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization, as described in paragraph (h)(3) of this section.

(3) *Exception for good faith effort.* HCFA determines that the management of a facility or organization has made a good faith effort to operate it as a provider-based entity if—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(6) of this section are met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, remote location of a hospital, 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.

(j) *Inappropriate billing.* If HCFA finds that a facility or organization is being treated as provider-based without having obtained a determination of provider-based status under this section, HCFA will notify the provider, adjust future payments, review previous payments, determine whether the facility or organization qualifies for provider-based status under this paragraph, and continue payments only under specific conditions, as described in paragraphs (j)(1), (j)(2), (j)(3), and (j)(4) of this section.

(1) *Notice to provider.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based

determination has been made by HCFA, HCFA will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (i) of this section, that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(2) of this section, and that a determination of provider-based status will be made.

(2) *Adjustment of payments.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will adjust future payments to the provider, the facility or organization, or both, to approximate as closely as possible the amounts that would be paid, in the absence of a provider-based determination, if all other requirements for billing were met.

(3) *Review of previous payments.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will review previous payments and, if necessary, take action in accordance with the rules on inappropriate treatment of a facility or organization as provider-based in paragraph (h) of this section.

(4) *Determination regarding provider-based status.* If HCFA finds that inappropriate billing has occurred or is occurring since no provider-based determination has been made by HCFA, HCFA will determine whether the facility or organization qualifies for provider-based status under the criteria in this section. If HCFA determines that the facility or organization qualifies for provider-based status, future payment for services at or by the facility or organization will be adjusted to reflect that determination. If HCFA determines that the facility or organization does not qualify for provider-based status, future payment for services at or by the facility or organization will be made only in accordance with the rules in paragraph (i)(5) of this section.

(5) *Continuation of payment.* The notice of denial of provider-based status sent to the provider will ask the provider to notify HCFA in writing, within 30 days of the date the notice is issued, of 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 free-standing facility. If the provider indicates that the facility, organization, or practitioners will not be seeking to enroll, or if HCFA does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (i)(5) will end as

of the 30th day after the date of notice. If the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(2) of this section for as long as is required for all billing requirements to be met (but not longer than 6 months) if the facility or organization, or its practitioners, submit a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization, or its practitioners, furnish all other information needed by HCFA to process the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, HCFA will terminate all payment to the provider, facility, or organization as of the date HCFA issues notice that necessary applications or information have not been submitted.

(k) *Correction of errors.* HCFA may review a past determination of provider-based status for a facility or organization or may review the status of a facility or organization (that is, whether the facility or organization is provider-based) if no determination regarding provider-based status has previously been made, if HCFA believes that status may be inappropriate, based on the provisions of this section. If HCFA determines that a previous determination was in error, and the entity should not be considered provider-based, HCFA notifies the main provider. Treatment of the facility or organization as provider-based ceases with the first day of the next cost report period following notification of the redetermination, but not less than 6 months after the date of notification.

(l) *Status of Indian Health Service and Tribal facilities and organizations.*

Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed 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.

(m) *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 before 1995 under section 330 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets 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 HCFA before 1995 to meet the requirements for receiving such a grant.

(n) *Effective date of provider-based status.* Provider-based status for a facility or organization is effective on the earliest date on which a request for provider-based status has been made, and all requirements of this part have been met.

Subpart F—Specific Categories of Costs

5. In § 413.118, the heading to paragraph (d) is republished, and a new paragraph (d)(5) is added to read as follows:

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

* * * * *

(d) *Blended payment amount.* * * *

(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.

* * * * *

6. In § 413.122:

A. The heading to paragraph (b) is republished

B. A new paragraph (b)(5) is added

C. The heading to paragraph (c) is republished; and

D. A new paragraph (c)(4) is added to read as follows:

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

* * * * *

(b) *Payment for hospital outpatient radiology services.* * * *

(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.* * * *

(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.

7. In § 413.124, paragraph (a) is revised to read as follows:

§ 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 the prospective payment system under part 419 of this chapter is implemented.

* * * * *

Subpart G—Capital-Related Costs

8. In § 413.130, the heading to paragraph (j) and the introductory text to paragraph (j)(1) are republished, and paragraph (j)(1)(ii) is revised to read as follows:

§ 413.130 Introduction to capital-related costs.

* * * * *

(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—

* * * * *

(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.

* * * * *

F. A new part 419, consisting of §§ 419.1, 419.2, 419.20, 419.21, 419.22, 419.30, 419.31, 419.32, 419.40, 419.41, 419.42, 419.43, 419.44, 419.50, 419.60, and 419.70, is added to read as follows:

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Subpart A—General Provisions

Sec.

419.1 Basis and scope.

419.2 Basis of payment.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

419.20 Hospitals subject to the hospital outpatient prospective payment system.

419.21 Hospital outpatient services subject to the outpatient prospective payment system.

419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

419.30 Base expenditure target for calendar year 1999.

419.31 Ambulatory payment classification (APC) system and payment weights.

419.32 Calculation of prospective payment rates for hospital outpatient services.

Subpart D—Payments to Hospitals

419.40 Payment concepts.

419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

419.42 Hospital election to reduce copayment.

419.43 Adjustments to national program payment and beneficiary copayment amounts.

419.44 Payment reductions for surgical procedures.

Subpart E—Updates

419.50 Annual updates.

Subpart F—Limitations on Review

419.60 Limitations on administrative and judicial review.

Subpart G—Transitional Corridors

419.70 Transitional adjustment to limit decline in payment.

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Subpart A—General Provisions

§ 419.1 Basis and scope.

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment.* Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Health Care Financing Administration Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is

determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Included costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to—

- (1) Use of an operating suite, procedure room, or treatment room;
- (2) Use of recovery room;
- (3) Use of an observation bed;
- (4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;
- (5) Supplies and equipment for administering and monitoring anesthesia or sedation;
- (6) Intraocular lenses (IOLs);
- (7) Incidental services such as venipuncture;
- (8) Capital-related costs;
- (9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- (10) Durable medical equipment that is implantable;
- (11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and
- (12) Costs incurred to procure donor tissue other than corneal tissue.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment rates:

- (1) Medical education costs for approved nursing and allied health education programs.
- (2) Corneal tissue acquisition costs incurred by hospitals that are paid for on a reasonable cost basis.
- (3) Costs for services listed in § 419.22.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after July 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.*

(1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a comprehensive outpatient rehabilitation facility (CORF) when they are provided outside the patient's plan (of care); or by a home health agency (HHA) to patients who are not under an HHA plan or treatment; or by a hospice program furnishing services to patients outside the hospice benefit:

- (1) Antigens.
- (2) Splints and casts.
- (3) Pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine.

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Clinical diagnostic laboratory services.

(m) Services for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital "under arrangements" but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) HCFA estimates the aggregate amount that would be payable for

hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) HCFA classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) HCFA may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, HCFA determines the median costs for the services and procedures within each APC group.

(2) HCFA assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) HCFA determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is

known as the “labor-related portion” of hospital outpatient costs.

(2) HCFA standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* HCFA calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar years 2000, 2001, and 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar years 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(2) Beginning in calendar year 2000, HCFA may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) *Budget neutrality.* HCFA adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC

group there is a predetermined beneficiary coinsurance amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) *Coinsurance percentage* is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the *greater* of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) *Program payment percentage* is calculated as the *lower* of the following: the ratio of the APC group payment rate minus the APC group unadjusted coinsurance amount, to the APC group payment rate, or 80 percent.

(3) *Unadjusted coinsurance amount* is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of coinsurance amount to inpatient hospital deductible amount.* The coinsurance amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

§ 419.41 Calculation of national beneficiary coinsurance amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted coinsurance amount for each APC group, HCFA—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary coinsurance amount for the APC group.

(b) HCFA calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted coinsurance amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital

outpatient prospective payment system, HCFA makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the coinsurance amount.

(i) The coinsurance amount for an APC cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

(ii) The coinsurance amount is computed as if the adjustments under § 419.43(d) and (e) (and any adjustment made under § 419.43(f) in relation to these adjustments) had not been paid.

(5) Adds the amount by which the coinsurance amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may *not* elect to reduce copayment for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the coinsurance amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a level that is less than that year's wage-adjusted coinsurance amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

(f) The hospital may advertise and otherwise disseminate information

concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

§ 419.43 Adjustments to national program payment and beneficiary coinsurance amounts.

(a) *General rule.* HCFA determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary coinsurance amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* HCFA determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the "labor-related portion" of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.* HCFA uses the hospital inpatient prospective payment system wage index established in accordance with part 412 of this chapter to make the adjustment referred to in paragraph (a) of this section.

(d) *Outlier adjustment—(1) General rule.* Subject to paragraph (d)(4) of this section, HCFA provides for an additional payment for each hospital outpatient service (or group of services) for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under paragraph (e) of this section.

(ii) At the option of HCFA, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by HCFA and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments—(i) In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by HCFA before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term "applicable percentage" means a percentage specified by HCFA up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, HCFA may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by HCFA), rather than for specific departments within the hospital.

(e) *Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals—(1) General rule.* HCFA provides for an additional payment under this

paragraph for any of the following that are provided as part of a hospital outpatient service (or group of services):

(i) *Current orphan drugs.* A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(ii) *Current cancer therapy drugs and biologicals and brachytherapy.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic,

a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy, if payment for the drug, biological, or device as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(iii) *Current radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this part is implemented.

(iv) *New medical devices, drugs, and biologicals.* A medical device, drug, or biological not described in paragraph (e)(1)(i), (e)(1)(ii), or (e)(1)(iii) of this section if—

(A) Payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(B) The cost of the device, drug, or biological is not insignificant (as defined in paragraph (e)(1)(iv)(C) of this section) in relation to the hospital outpatient fee schedule amount (as calculated under § 419.32(c)) payable for the service (or group of services) involved.

(C) The cost of the device, drug, or biological is considered not insignificant if it meets all of the following thresholds:

(1) Its expected reasonable cost exceeds 25 percent of the applicable fee schedule amount for the associated service.

(2) The expected reasonable cost of the new drug, biological, or device must exceed the current portion of the fee schedule amount determined to be associated with the drug, biological, or device by 25 percent.

(3) The difference between the expected reasonable cost of the item and the portion of the hospital outpatient fee schedule amount determined to be associated with the item exceeds 10 percent of the applicable hospital outpatient fee schedule amount.

(2) *Limited period of payment.* The payment under this paragraph (e) with respect to a medical device, drug, or biological applies during a period of at least 2 years, but not more than 3 years, that begins—

(i) On the first date this section is implemented in the case of a drug, biological, or device described in paragraphs (e)(2)(i), (e)(2)(ii), or (e)(2)(iii) of this section and in the case of a device, drug, or biological described

in paragraph (e)(1)(iv) of this section and for which payment under this part is made as an outpatient hospital service before the first date; or

(ii) In the case of a device, drug, or biological described in paragraph (e)(1)(iv) of this section not described in paragraph (e)(2)(i) of this section, on the first date on which payment is made under this part for the device, drug, or biological as an outpatient hospital service.

(3) *Amount of additional payment.* Subject to paragraph (e)(4)(iii) of this section, the amount of the payment under this paragraph is—

(i) In the case of a drug or biological, the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the drug or biological; or

(ii) In the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable Medicare hospital outpatient fee schedule amount that HCFA determines is associated with the device.

(4) *Limit on aggregate annual adjustment—(i) General rule.* The total of the additional payments made under this paragraph for hospital outpatient services furnished in a year, as estimated by HCFA before the beginning of the year, may not exceed the applicable percentage specified in paragraph (e)(4)(ii) of this section of the total program payments estimated to be made under this section for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (e)(4)(i) of this section, the term “applicable percentage” means—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, a percentage specified by HCFA up to (but not to exceed) 2.0 percent.

(iii) *Uniform prospective reduction if aggregate limit projected to be exceeded.* If HCFA estimates before the beginning of a year that the amount of the additional payments under this paragraph (e) for the year (or portion thereof) as determined under paragraph (e)(4)(i) of this section without regard to this paragraph (e)(4)(iii) would exceed the limit established under this paragraph (e)(4)(iii), HCFA reduces pro rata the amount of each of the additional payments under this paragraph for that

year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed the limit.

(f) *Budget neutrality.* Outlier adjustments under paragraph (d) of this section and transitional pass-through payments under paragraph (e) of this section are established in a budget-neutral manner.

§ 419.44 Payment reductions for surgical procedures.

(a) *Multiple surgical procedures.* When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Terminated procedures.* When a surgical procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts if the procedure is discontinued after the induction of anesthesia or after the procedure is started; or

(2) One-half of the full program and the beneficiary coinsurance amounts if the procedure is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced.

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, HCFA reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* HCFA will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise HCFA concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* HCFA conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

- (1) Establishment of the groups and relative payment weights;
- (2) Wage adjustment factors;
- (3) Other adjustments; and
- (4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with § 419.43(e)), the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.43(e).

Subpart G—Transitional Corridors

§ 419.70 Transitional adjustment to limit decline in payment.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the

amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions—(1) Temporary treatment for small rural hospitals.* For covered hospital outpatient services furnished in a calendar year before January 1, 2004 for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Permanent treatment for cancer hospitals.* In the case of a hospital described in § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under

this part is increased by the amount of this difference.

(e) *Prospective payment system amount defined.* In this paragraph, the term “prospective payment system amount” means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this paragraph or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined—(1) General rule.* In this paragraph, the “pre-BBA amount” means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider’s cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, HCFA shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The “base payment-to-cost ratio” for a hospital or CMHC means the ratio of—

(i) The provider’s payment under this part for covered outpatient services furnished during the cost reporting period ending in 1996, including any payment for these services through cost-sharing described in paragraph (e) of this section; and

(ii) The reasonable cost of these services for this period, without applying the cost reductions under section 1861(v)(1)(S) of the Act.

(g) *Interim payments.* HCFA makes payments under this paragraph to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this paragraph—

- (1) Are not considered an adjustment under § 419.43(f); and
- (2) Are not implemented in a budget neutral manner.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

G. Part 424 is amended as set forth below:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 424.24, the heading to paragraph (e) is republished, and a new paragraph (e)(3) is added to read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements—*

* * * * *

(3) *Recertification requirements.*

(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content.* The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

H. Part 489 is amended as set forth below:

1. The authority citation to part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Essentials of Provider Agreements

2. In § 489.20, the introductory text to the section is republished; the introductory text to paragraph (d) is revised; paragraphs (d)(3), (d)(4), and (d)(5) are redesignated as paragraphs (d)(4), (d)(5), and (d)(6), respectively; and a new paragraph (d)(3) is added to read as follows:

§ 489.20 Basic commitments.

The provider agrees to the following:

* * * * *

(d) In the case of a hospital or a CAH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services to inpatients and outpatients of a hospital or a CAH except the following:

* * * * *

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

* * * * *

3. In § 489.24, the definition for "Comes to the emergency department" in paragraph (b) is revised, and a new paragraph (i) is added to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(b) * * *

Comes to the emergency department means, with respect to an individual requesting examination or treatment, that the individual is on the hospital property. For purposes of this section, "property" means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, as well as any facility or organization that is located off the main hospital campus but has been determined under § 413.65 of this chapter to be a department of the hospital. The responsibilities of hospitals with respect to these off-campus facilities or organizations are described in paragraph (i) of this section. Property also includes ambulances owned and operated by the hospital even if the ambulance is not on hospital grounds. An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications

and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In these situations, the hospital may deny access if it is in "diversionary status," that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's instructions and transports the individual on to hospital property, the individual is considered to have come to the emergency department.

* * * * *

(i) *Off-campus departments.* If an individual comes to a facility or organization that is located off the main hospital campus but has been determined under § 416.35 of this chapter to be a department of the hospital and a request is made on the individual's behalf for examination or treatment of a potential emergency medical condition as otherwise described in paragraph (a) of this section, the hospital is obligated in accordance with the rules in this paragraph to provide the individual with an appropriate medical screening examination and any necessary stabilizing treatment or an appropriate transfer.

(1) *Capability of the hospital.* The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus department. Except for cases described in paragraph (i)(3)(ii) of this section, the obligation of a hospital under this section must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff to off-campus departments to be on standby for possible emergencies.

(2) *Protocols for off-campus departments.* The hospital must establish protocols for the handling of individuals with potential emergency conditions at off-campus departments. These protocols must provide for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services.

(i) If the off-campus department is an urgent care center, primary care center, or other facility that is routinely staffed by physicians, RNs, or LPNs, these department personnel must be trained, and given appropriate protocols, for the handling of emergency cases. At least one individual on duty at the off-campus department during its regular hours of operation must be designated

as a qualified medical person as described in paragraph (d) of this section. The qualified medical person must initiate screening of individuals who come to the off-campus department with a potential emergency medical condition, and may be able to complete the screening and provide any necessary stabilizing treatment at the off-campus department, or to arrange an appropriate transfer.

(ii) If the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and report symptoms and, if appropriate, either arrange transportation of the individual to the main hospital campus in accordance with paragraph (i)(3)(i) of this section or assist in an appropriate transfer as described in paragraphs (i)(3)(ii) and (d)(2) of this section.

(3) *Movement or appropriate transfer from off-campus departments*—(i) If the main hospital campus has the capability required by the individual and movement of the individual to the main campus would not significantly jeopardize the life or health of the individual, the personnel at the off-campus department must assist in arranging this movement. Movement of the individual to the main campus of the hospital is not considered a transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

(ii) If transfer of an individual with a potential emergency condition to a medical facility other than the main hospital campus is warranted, either because the main hospital campus does not have the specialized capability or facilities required by the individual, or because the individual's condition is deteriorating so rapidly that taking the time needed to move the individual to the main hospital campus would significantly jeopardize the life or health of the individual, personnel at the off-campus department must, in accordance with protocols established in advance by the hospital, assist in arranging an appropriate transfer of the individual to a medical facility other than the main hospital. The protocols must include procedures and agreements established in advance with other hospitals or

medical facilities in the area of the off-campus department to facilitate these appropriate transfers. Such a transfer would require—

(A) That there be either a request by or on behalf of the individual as described in paragraph (d)(1)(ii)(A) of this section or a certification by a physician or a qualified medical person as described in paragraph (d)(1)(ii)(B) or (d)(1)(ii)(C) of this section; and

(B) That the transfer comply with the requirements described in paragraph (d)(2) of this section.

(iii) If the individual is being appropriately transferred to another medical facility from the off-campus department, the requirement for the provision of medical treatment in paragraph (d)(2)(i) of this section would be met by provision of medical treatment within the capability of the transferring off-campus department.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

I. Part 498 is amended as set forth below:

1. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 498.2, the introductory text is republished, and the definition of "Provider" is revised to read as follows:

§ 498.2 Definitions.

As used in this part—

* * * * *

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and *prospective provider* means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

* * * * *

3. In § 498.3, the introductory text to paragraph (b) is republished; paragraphs (b)(2) through (b)(15) are redesignated as paragraphs (b)(3) through (b)(16), respectively; and a new paragraph (b)(2) is added to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

* * * * *

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under § 413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under § 413.65 of this chapter.

* * * * *

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

J. Part 1003 is amended as set forth below:

1. The authority citation for part 1003 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320a–7e, 1320b–10, 1395u(j), 1395u(k), 1395cc(g), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396(m), 11131(c), and 11137(b)(2).

2. Section 1003.100 is amended by revising paragraph (a), by republishing the introductory text to paragraphs (b) and (b)(1), by revising paragraphs (b)(1)(xi) and (b)(1)(xii), and by adding paragraph (b)(1)(xiii) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1128E, 1140, 1866(g), 1876(i), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Pub. L. 99–660 (42 U.S.C. 1320a–7, 1320a–7a, 1320a–7e, 1320a–7c, 1320b–10, 1395cc(g), 1395mm, 1395ss(d), 1396(m), 11131(c), and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

* * * * *

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity that, if made directly, would violate the provisions of § 411.353 of this title;

(xii) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act; or

(xiii) Knowingly and willfully present, or cause to be presented, a bill or request for payment for nonphysician services furnished to hospital patients (unless the services are furnished by the hospital, either directly or under an arrangement) in violation of sections 1862(a)(14) and 1866(a)(1)(H) of the Act.

3. Section 1003.102 is amended by republishing the introductory text to paragraph (b), by adding and reserving paragraphs (b)(12) through (b)(14), and by adding a new paragraph (b)(15) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(15) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under the Medicare or another Federal health care program, if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act, or violates the requirements for such an arrangement.

4. Section 1003.103 is amended by revising paragraph (a), by adding and reserving paragraphs (i) and (j), and by adding a new paragraph (k) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) and (d) through (k) of this section,

the OIG may impose a penalty of not more than \$10,000 for each item or service that is subject to a determination under § 1003.102.

(k) For violations of section 1862(a)(14) of the Act and § 1003.102(b)(15), the OIG may impose a penalty of not more than \$2,000 for each bill or request for payment for items and services furnished to a hospital patient.

5. Section 1003.105 is amended by republishing the introductory text to paragraph (a)(1) and by revising paragraph (a)(1)(i) to read as follows:

§ 1003.105 Exclusion from participation in Medicare, Medicaid and other Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, in lieu of or in addition to any penalty or assessment, the OIG may exclude from participation in Medicare, Medicaid and other Federal health care programs the following persons for a period of time determined under § 1003.107—

(i) Any person who is subject to a penalty or assessment under § 1003.102(a), (b)(1) through (b)(4), or (b)(15).

(Catalog of Federal Domestic Assistance 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 3, 2000.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Dated: March 28, 2000.

June G. Brown,
Inspector General, Department of Health and Human Services.

Approved: March 29, 2000.

Donna E. Shalala,
Secretary.

Note: The following addenda will not appear in the Code of Federal Regulations.

Note to Addenda A, B, C, E and F: Addenda A, B, and C have a number of errors in the following columns: APC, status indicator, payment rate, and national unadjusted coinsurance and minimum unadjusted coinsurance. We identified these errors too late in preparing this rule for publication to correct them. Some of the errors are related to the status codes assigned to the HCPCS codes and APCs.

Some errors affect addenda B, C, and E. Several of these errors involve procedures incorrectly identified as inpatient procedures, and one inpatient procedure incorrectly identified as an outpatient procedure. Certain PET scan codes and other codes are shown in incorrect APCs. Screening sigmoidoscopy and colonoscopy APCs have the wrong HCPCS codes and incorrect payment rates and coinsurance amounts. Certain dental codes were inadvertently identified as errors, so their correct APC assignments, payment rate and coinsurance amounts were not shown in the addenda. Two breath tests are subject to the clinical diagnostic lab fee schedule. We have listed below the corrections that have payment implications.

Addendum F does not include status indicators G and H which identify items that are eligible for pass-through payments. (See section III.B.3 of the preamble for a complete description of all status indications used in conjunction with this final rule.)

We also note that the word "proposed" should not appear on any Addenda contained in this final rule such as on Addendum A or C.

The fiscal intermediaries will receive the necessary changes to process outpatient PPS claims correctly. We will post the corrected Addendum B on our Website and publish a correction document in the **Federal Register**.

Our Website address is <http://www.hcfa.gov/medicare/hopsmain.htm>.

LIST ACCOMPANYING NOTE TO ADDENDA A, B, C, E AND F

CPT/ HCPCS	HOPD Status Indicator	Description	APC	Relative Weight	Proposed Payment Rate	National Unadjusted Coinsurance	Minimum Unadjusted Coinsurance
20979	E	US bone stimulation.					
31375	C	Partial removal of larynx.					
35481	T	Atherectomy, open	0081	19.36	\$938.71	\$434.25	\$187.74
61795	S	Brain surgery using computer	0302	8.21	\$398.08	\$216.55	\$79.62
61886	T	Implant neurostim arrays	0222	25.48	\$1,235.45	\$780.07	\$247.09
75945	S	Intravascular us	0267	2.72	\$131.88	\$80.06	\$26.38
75946	S	Intravascular us add-on	0267	2.72	\$131.88	\$80.06	\$26.38
78267	A	Breath test attain/anal, c-14.					
78268	A	Breath test analysis, c-14.					
92978	S	Intravasc us, heart add-on	0267	2.72	\$131.88	\$80.06	\$26.38
92979	S	Intravasc us, heart add-on	0267	2.72	\$131.88	\$80.06	\$26.38
96570	T	Photodynamic Tx, 30 min	0973	5.16	\$250.19		\$50.04
96571	T	Photodynamic Tx, addl 15 min	0973	5.16	\$250.19		\$50.04
D0277	S	Vert bitewings-sev to eight	0330	1.51	\$73.22	\$14.64	\$14.64
D0472	S	Gross exam, prep & report	0330	1.51	\$73.22	\$14.64	\$14.64