

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413 and 419

[HCFA-1005-IFC]

RIN 0938-AI56

Medicare Program; Prospective Payment System for Hospital
Outpatient Services: Revisions to Criteria to Define New or
Innovative Medical Devices, Drugs, and Biologicals Eligible
for Pass-Through Payments and Corrections to the Criteria
for the Grandfather Provision for Certain Federally
Qualified Health Centers.

AGENCY: Health Care Financing Administration (HCFA), HHS

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period changes one criterion and postpones the effective date for two other criteria that a new device, drug, or biological must meet in order for its cost to be considered "not insignificant" for purposes of determining its eligibility for transitional pass-through payments. It also changes the transitional pass-through payment policy to include new single use medical devices that come in contact with human tissue and that are surgically implanted or inserted in a patient whether or not the devices remain with the patient after the patient is released from the hospital outpatient

department. These policies represent a departure from those presented in the April 7, 2000 **Federal Register** final rule with comment period entitled, "Prospective Payment System for Hospital Outpatient Services".

This interim final rule with comment period also corrects a trigger date for grandfathering of provider-based Federally Qualified Health Centers (FQHCs) to conform with the intent not to disrupt existing FQHCs with longstanding provider-based treatment that we discussed in the April 2000 final rule. Under the criteria in the April 2000 final rule with comment period, FQHCs are treated as departments of a provider without regard to the criteria for provider-based status in that document if they meet other criteria and were designated as FQHCs before 1995. Under this correction, facilities that meet those other criteria and were designated as FQHCs or "look-alikes" on or before April 7, 2000 would continue to be treated as provider-based. In addition, we are clarifying how the requirement for prior notice to beneficiaries is to be applied in emergency situations. Also, we are clarifying the protocols for off-campus departments in emergency situations.

DATES: *Effective date:* This interim final rule is effective August 1, 2000, except the amendments to § 413.65(m) that are effective October 10, 2000.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on [OFR--please insert 30 days after the date of publication in the **Federal Register**].

ADDRESSES: Mail an original and 3 copies of written comments to the following address only:

Health Care Financing Administration,

Department of Health and Human Services,

Attention: HCFA-1005-IFC,

P.O. Box 8013,

Baltimore, MD 21244-8013

Since comments must be received by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver your written comments by courier (1 original and 3 copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201 or

Room C5-14-03,
7500 Security Boulevard,
Baltimore, MD 21244.

Comments mailed to the two above addresses may be delayed and received too late to be considered.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1005-IFC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 445-G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT:

Vivian Braxton, (410)786-4571 (for information related to transitional payment policy changes).

George Morey, (410)786-4653 (for information related to the grandfathering of Federally Qualified Health Centers and "look-alikes", the requirement for notice to beneficiaries of cost-sharing liability, and the protocols for off-campus departments).

SUPPLEMENTARY INFORMATION:

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The Website address is: <http://www.access.gpo.gov/nara/index.html>.

I. Background

On April 7, 2000, we published in the **Federal Register** (65 FR 18434) a final rule with comment for implementation of a new prospective payment system (PPS) for hospital outpatient services. The new system establishes payment rates for each PPS covered service using ambulatory payment classification (APC) groups. On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing our decision to delay the effective date of the outpatient PPS from July 1, 2000 as set forth in the April 7, 2000 final rule until August 1, 2000. We stated in the June 30, 2000 notice that we are delaying the effective date because we have to make a major change to the current claims processing system to implement the new PPS. We further stated that the 1 month postponement would give us additional time to test and refine the complex software programs needed to operate the PPS and would give hospitals the additional time they require to prepare and train for

the new system. Therefore, the PPS provisions incorporated in the April 7, 2000 final rule are effective August 1, 2000 and the provider-based provisions included in that rule are effective October 10, 2000.

Among the provisions of the April 7, 2000 final rule are those implementing section 1833(t)(6) of the Social Security Act (the Act), which was added by section 201(b) of the Balanced Budget Refinement Act of 1999 (BBRA 1999). This section provides for temporary additional payments, termed "transitional pass-through payments," for certain drugs, biologicals, and devices. The provision requires the Secretary to make additional payments to hospitals for at least 2 but no more than 3 years for specific items. The items designated by the law are the following: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; current radiopharmaceutical drugs and biological products; and new medical devices, drugs, and biologic agents, in instances in which the item was not being paid for as a hospital outpatient service as of December 31, 1996, and when the cost of the item is "not insignificant" in relation to the hospital outpatient PPS payment amount. For those drugs, biologicals, and devices

referred to as "current," the transitional payment begins on the first date the new PPS is implemented, as required by section 1833(t)(6)(B)(i) of the Act.

In the April final rule, we established three criteria that a new device, drug, or biological must meet to determine whether its cost are not insignificant relative to the APC payment with which the item is associated. We stated that all of the following cost criteria must be satisfied in order for a new device, drug, or biological to be eligible for transitional pass-through payments:

- (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 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 department fee schedule amount determined to be associated with the item exceed 10 percent of the applicable hospital outpatient department fee schedule amount.

In this interim final rule, we are revising the first criterion and delaying the effective date of the other two criteria.

Our plans for implementation of section 1833(t)(6) of the Act are discussed in the April 2000 final rule (65 FR 18478). This section, along with other sections implementing BBRA 1999 provisions that were included in the April 2000 final rule have not previously been subject to public comment were subject to comment until June 6, 2000. We explained in the April 2000 final rule that we found good cause to waive the customary procedure for prior notice and comment with respect to these BBRA 1999 provisions and the final rule provides a 60-day period for the public to comment on these provisions. (For a full discussion of the waiver of proposed rulemaking, refer to Section XI of the April 2000 final rule (65 FR 18535).)

The transitional pass-through payments provide a way for ensuring appropriate payment for new items for which the use and costs are not adequately represented in the 1996 base year claims data on which the hospital outpatient prospective payment system is based. Although individual items will receive transitional pass-through payments for 2 to 3 years from either the first date the PPS is implemented

or on the first date payment is initiated for the specific item, the underlying provision is permanent and provides an on-going mechanism for new items to qualify for 2 to 3 years pass-through payments in the future.

Another provision of the April 2000 final rule (65 FR 18477) describes the payment approach for new technology services by defining a special category of APCs referred to as "new technology APCs." Services, such as new surgical techniques (for example, transurethral microwave thermotherapy) or items not eligible for transitional pass-through payments can be paid as a part of these new technology APCs. At a later stage, once data about the actual hospital costs incurred to furnish a new technology service are available, we expect to move payment for these services or items to other, APCs with services that are comparable clinically and with respect to resources. As explained in the April 2000 final rule, if we cannot move the new technology service to an existing APC because it is dissimilar clinically and, with respect to resource costs, from all other APCs, we will create a separate APC for the service. As stated in our April 2000 final rule, the timeframe for treating a service or item as new technology will be consistent with that for pass-through payments; that is at least 2 but no more than 3 years.

In the April 2000 final rule (65 FR 18480), we established eight specific criteria that new or innovative medical devices must meet to be considered eligible for pass-through payments under section 1833(t)(6) of the Act. We stated in the final rule that new or innovative medical devices must meet all of the following criteria to be considered eligible for transitional pass-through payments:

- a. They were not recognized for payment as a hospital outpatient service prior to 1997.
- b. They have been approved/cleared for use by the Food and Drug Administration.
- c. They are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act. We recognize that some investigational devices are refinements of existing technologies or replications of existing technologies and may be considered reasonable and necessary. We will consider devices for coverage under the outpatient PPS if they have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices. (See §§ 405.203 (FDA

categorization of investigational devices) to 405.215 (Confidential commercial and trade secret information).) However, in accordance with § 405.209 (Payment for a non-experimental/investigational (Category B) device), payment for a nonexperimental investigational device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

- d. They are an integral and subordinate part of the procedure performed, are used for one patient only, are surgically implanted or inserted, and remain with that patient after the patient is released from the hospital outpatient department.
- e. The associated cost is not insignificant in relation to the APC payment for the service in which the innovative medical equipment is packaged. (For the definition of "not insignificant," see the April 2000 final rule (65 FR 18480).)
- f. They are not equipment, instruments, apparatuses, implements, or such items for which depreciation

and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (HCFA Pub. 15-1). (As discussed in the April 2000 final rule, these costs are considered overhead expenses that are and will continue to be factored into the APC payment.)

- g. They are not materials and supplies such as sutures, clips, or customized surgical kits furnished incident to a service or procedure.
- h. They are not materials such as biologicals or synthetics that may be used to replace human skin.

Note that devices that meet criteria "b" and "c" but not one of the others, though they are not eligible for transitional pass-through payments under section 1833(t)(6) of the Act, are paid through the usual payments for the associated APC. These payment levels will be updated over time to reflect the use of new items and services.

Three of the criteria, "c", "d", and "g," are the focus of the transitional pass-through payment changes contained in this interim final rule. In criterion "c", we stated that devices cleared by the FDA with IDE Category B status would be considered for transitional pass-through payment. We further stated that we would limit such payment to the

amount that would be paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA. In criterion "d," we stated our intent to interpret the new device transitional pass-through payment provision in a way that would limit these payments to those devices that are implantable in the sense that they are surgically inserted in a patient and remain with that patient after the patient is released from the hospital outpatient department. In criterion "g" we expressed our intent to treat all "clips" equally as though they function solely as tools and supplies that are necessary for the surgeon to perform a surgical procedure without considering other functions that may qualify some as candidates for pass-through consideration.

In Addendum K of the April 2000 final rule, we published a preliminary list of those particular items and services for which we expect to make payment based on either the pass-through or new technology provision effective August 1, 2000. A slightly different version of this list was posted on our web site, www.hcfa.gov, on March 9, 2000. (A separate notice published elsewhere in the April 7, 2000 **Federal Register** (65 FR 18341) specifically identified this web site posting.) The April 2000 final rule and the web

site posting contain instructions about how interested parties may apply for transitional pass-through or new technology payment status for items or services. On May 12, 2000, we updated our web site posting to reflect additional items approved for pass-through and new technology payments on implementation of the new system; that is, August 1, 2000. In addition, on June 22, 2000 we posted updated instructions and announced the application deadline of July 14, 2000 for transitional pass-through and new technology payments effective October 1, 2000.

The April 2000 final rule also specified a number of criteria that facilities or organizations must meet to be considered, for purposes of Medicare payment, to be "provider-based." We adopted these criteria in an attempt to ensure that only appropriately qualified facilities and organizations receive the higher payment levels typically associated with this status. The criteria for provider-based status are set forth in § 413.65 (Requirements for a determination that a facility or an organization has provider-based status) of the April 2000 final rule (65 FR 18538).

In the April 2000 final rule, we included a special grandfathering provision applicable to FQHCs and "look-alikes" (facilities that are structured like FQHCs and

meet all the requirements for grant funding but have not actually received these grants). The provision stated that a facility or entity would be treated as provider-based, without regard to compliance with the provider-based criteria if it has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider and 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 based on the recommendation of the Public Health Service (PHS), was determined by HCFA before 1995 to meet the requirements for receiving such a grant. We included this provision in response to comments suggesting that application of provider-based criteria to FQHCs and "look-alikes" could interfere with the continuity of care to patients served by these health centers. We also were concerned that application of the criteria could adversely affect access to care for the patients served by these facilities. Therefore, we indicated that we were accepting the comments and had crafted the criteria to give effect to these concerns.

The April 2000 final rule (65 FR 18540) also contained a requirement, in new § 413.65(g)(7) (Obligations of hospital outpatient departments and hospital-based entities), that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than a rural health clinic) that is not located on the main provider's campus, the hospital has a duty to furnish written notice to the beneficiary, before 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 furnished, before the delivery of services, to the beneficiary's authorized representative.

In addition, the April 2000 final rule amended § 489.24 (Special responsibilities of Medicare hospitals in emergency cases), sometimes referred to the Emergency Medical Treatment and Active Labor Act (EMTALA) regulation. In new § 489.24(i)(2), we required that hospitals establish

protocols for handling individuals with potential emergency conditions at off-campus departments. In new § 489.24(i)(2)(ii), we further required that if the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus.

II. Provisions of the Interim Final Rule

A. *New Medical Devices, Drugs, and Biologicals*

We are revising §419.43 (e)(1)(iv) to change one criterion and to postpone the effective date for two other criteria that a new device, drug, or biological must meet in order for its cost to be considered "not insignificant". In the April 2000 final rule, (65 FR 18434), the expected reasonable cost of a device had to exceed 25 percent of the applicable fee schedule amount for the associated service in order for the cost of the device to meet the "not insignificant" test. Based on the experience that we gained by reviewing the applications submitted for approval of new devices, drugs and biologicals as pass-through items, we concluded that the 25 percent-limitation was too restrictive and could result in limiting Medicare beneficiaries' access to new products. In order to ensure that Medicare beneficiaries will continue to have access to the latest technologies, we are changing that criterion. We will now require that the expected reasonable cost of a new device must exceed 10 percent of the applicable fee schedule amount for the associated service.

The additional two criteria, proposed in the April 2000 rule, for determining whether a new device, drug, or

biological cost is "not insignificant" will be postponed and will apply to devices, drugs, and biologicals for which a transitional pass-through payment is first made on or after January 1, 2003. The delay in effective date for these criteria is necessary so that we will have sufficient time to gather and analyze data needed to determine the current portion of the fee schedule amounts associated with a device, drug, or biological, which is an essential factor in applying these criteria.

B. Revision to Criteria to Define New or Innovative Medical Devices Eligible for Pass-through Payments.

In criterion "c", we stated that devices cleared by the FDA with IDE Category B status would be considered for transitional pass-through payment. We further stated that we would limit pass-through payment for the eligible IDE Category B device to the amount that would be paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA. This approach was taken based on the regulations requirement set forth in § 405.209 that limits payment for the IDE Category B device in the manner described. Since publishing our April 2000 final rule, we have reviewed this policy and now believe that it would be more appropriate to provide that

the payment amount for IDE Category B items that qualify for transitional pass-through payments be determined in the same manner as other pass-through items (that is, no cap). Since IDE Category B devices are subjected to the same eligibility requirements as any other device applying for pass-through status and since pass-through payments for a specific device are temporary, we believe that, for purposes of making outpatient PPS pass-through payments, it is more appropriate to not impose a payment cap on eligible IDE Category B devices. Therefore, we are revising criterion "c" by removing the cost limitation provision for IDE Category B devices that qualify for transitional pass-through payments.

In addition, since publication of the April 2000 final rule, we have been processing a large number of applications for transitional pass-through payment status for new medical devices. It has become apparent that our attempt to distinguish implantable devices using the procedure we had outlined in the April 2000 final rule had practical limitations. For example, a significant number of applications received were for devices that consist of more than one component in which one component would be implantable according to the new medical device definition stated in the April 2000 final rule (65 FR 18480) while

other components, such as catheters, guidewires, or certain clips would not meet this definition.

Distinguishing these components of a single product and pricing them separately appears unnecessarily cumbersome.

In some instances, a particularly expensive catheter that is surgically inserted, removed, and disposed of in the course of a procedure may be used in one of a number of procedures.

In this instance the new medical device is implanted temporarily rather than permanently as indicated in our original policy published in the April 2000 final rule.

However, we did not intend for our policy to exclude new medical devices that are implanted or inserted during a procedure but also may be removed during that procedure so that the patient leaves the hospital without the device.

Rather, we believe that these devices should be considered for pass-through payments because they also are implantables.

In other instances, it became apparent that some clips are expensive and function other than as tools or supplies necessary for a surgeon to perform a surgical procedure.

Some clips are radiological site or tissue markers that are implanted and may be used months after implantation to locate an area for imaging and later removed. We did not

intend to exclude such clips from consideration for pass-through payments.

Separating components of a single product and pricing them separately could require the establishment of a number of new payment groups consisting of just one product as a result of introduction of a single, high-priced item. Industry representatives also indicated significant concerns about our way of proceeding.

Therefore, we are modifying our interpretation of which devices are eligible for transitional pass-through payments to include new medical devices that are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted in a patient during a procedure but may also be removed during that procedure so that the patient leaves the hospital without the device. Our revised interpretation also includes clips that are used as radiological site or tissue markers.

In addition, we are clarifying our interpretation of criterion "g" to include as supplies pharmacological imaging and stressing agents other than radiopharmaceuticals (for which payment under the transitional pass-through provision is established by section 1833(t)(6)(A) of the Act). Also, in criterion "g" we have become aware of the need, based on our review of pass-through applications, to clarify that

supplies include contrast media and stressing agents, excluding radiopharmaceuticals, that are used in imaging procedures. We are revising criteria "c", "d" and "g" of the eight criteria for defining new medical devices for pass-through payments that were discussed in the preamble of the April 2000 final rule to reflect this change. These three revised criteria are as follows:

- Criterion - c. They are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act. Some investigational devices are refinements of existing technologies or replications of existing technologies and may be considered reasonable and necessary. If such devices have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices in accordance with sections §§ 405.203 to 405.215 of this chapter, excluding § 405.209, they will be considered for coverage under the hospital outpatient prospective payment system.

- Criterion - d. They are an integral and subordinate part of the procedure performed, are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted, whether or not they

remain with the patient when the patient is released from the hospital outpatient department.

- Criterion - g. They are not materials and supplies such as sutures, customized surgical kits, clips (other than radiological site or tissue markers), or furnished incident to a service or procedure. Supplies include pharmacological imaging and stressing agents other than radiopharmaceuticals (for which transitional pass-through payment is authorized under section 1833(t)(6)(A) of the Act).

Also, we are revising § 419.43(e)(4) (Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals) to include all eight criteria to define new or innovative medical devices eligible for pass-through payments.

The policies discussed above represent a change from the policies stated in the April 2000, final rule. This interim final rule with comment, thus, supersedes the relevant aspects of the previous rule. Comments on our revised policy will be considered if received by [OFR== please insert 30 days after date of publication].

C. Revision to Grandfather Provision for Certain FQHCs and Look-Alikes.

Since publication of the April 2000 final rule, we have become aware that, as currently worded, the rule would not fulfill its intended purpose in that the continuity of care and access to care for patients of some health centers could be jeopardized. This is because those centers meet other criteria for grandfathering but were not designated as FQHCs or "look-alikes" before 1995. To meet our original policy intent of helping to ensure that the new criteria do not disrupt the delivery of services to patients of these facilities, we are correcting § 413.65(m) to state that a facility or entity would be treated as provider-based, without regard to compliance with the provider-based criteria, if it has since April 7, 1995 furnished only services that were billed as if they had been furnished by a department of a provider and received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act; or based on the recommendation of the PHS, was determined by HCFA on or before April 7, 2000 to meet the requirements for

receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements. We are making this change to clarify that grandfathering under § 413.65 is based on continued status as a section 330 of the Public Health Service Act grantee or a "look-alike" facility.

III. Clarification Issues

A. Clarification of Transitional Pass-Through/New Technology Codes

We wish to clarify that the "C" codes assigned to many items shown in the May 12, 2000 web site posting are temporary HCFA Common Procedure Coding System (HCPCS) codes that are to be used exclusively to bill pass-through and new technology items paid under the hospital outpatient PPS. These codes cannot be used to bill other Medicare payment systems, for example, the durable medical equipment fee schedule. Assignment of the "C" category of HCPCS codes for use in the hospital outpatient PPS is intended to expedite the processing of requests for pass-through and new technology status and to ensure beneficiaries timely access to new and appropriate technologies. Therefore, applicants may submit a single application as detailed in the April 2000 final rule (65 FR 18481) for such items that do not have an established HCPCS code to ATTN: PPS New

Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850. HCPCS applications unrelated to the pass-through and new technology provisions should continue to follow the regular HCPCS application process found on the Internet at <http://www.hcfa.gov/medicare/hcpcs.htm>.

As stated in the April 2000 final rule, if the item for which pass-through or new technology status is requested requires approval/clearance by the Food and Drug Administration (FDA), submit a copy of the FDA approval/clearance letter. Products may be considered for pass-through status as soon as they are approved/cleared by the FDA without a specified period of marketing experience. This approach reflects our policy on assigning "C" codes since the creation of these codes under the HCPCS.

B. Clarification of Notice of Beneficiary Cost-Sharing Liability

Following publication of the April 2000 final rule, some hospitals and their representatives have asked whether it is our intent that the beneficiary notice requirement in new § 413.65(g)(7) be followed in cases when the prohibition on patient dumping requirements in § 489.24, sometimes referred to as the Emergency Medical Treatment and Active

Labor Act (EMTALA) requirements, apply. The concern expressed is that, in such cases, it would not be appropriate to delay mandated screening and stabilization services to deliver a notice of patient financial liability. Questions also have arisen as to whether hospitals can reasonably be expected to furnish an exact statement of the patient's financial liability, since the exact scope of services needed may not be known at the time notice must be given.

We understand this concern and wish to confirm that in EMTALA cases the requirements of § 489.24 continue to apply, so that hospitals are not required to deliver the notices before screening and stabilizing a patient with an emergency medical condition. We further understand the concerns that have been expressed regarding estimates of financial liability. We are clarifying that when the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains the fact that the beneficiary will incur a coinsurance liability to the hospital that they would not incur if the facility were not provider-based. The hospital may furnish an estimate based on typical or average charges for visits to the facility or organization, while stating that the patients actual liability will depend upon the actual services furnished by

the hospital. We are developing a separate proposed rule that will further revise and clarify the notice requirements and will issue that proposed rule for public comment as soon as possible.

C. Clarification of Protocols for Off-Campus Departments

Following publication of the April 2000 final rule, some hospitals and their representatives have asked whether it is our intent that the staff of off-campus departments described in new § 489.24(i)(2)(ii), such as physical therapy, radiology, or other facilities not routinely staffed with physicians, RNs, or LPNs, be required to contact emergency personnel at the main hospital campus (as described in new § 489.24(i)(3)(ii) before arranging an appropriate transfer to a medical facility other than the main hospital. This question refers to cases in which an appropriate transfer is necessary 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 the time needed to move the individual to the main hospital campus would significantly jeopardize the individual's life or health.

We understand this concern and do not intend that new § 489.24(i)(2)(ii) be interpreted in a way that could delay

an appropriate transfer. Therefore, we are clarifying that in any case arising in an off-campus department, of the kind described in new § 489.24(i)(2)(ii), the contact with emergency personnel at the main hospital campus should be made either after or concurrently with, the actions needed to arrange an appropriate transfer under new § 489.24(i)(3)(ii) if doing otherwise would significantly jeopardize the individual's life or health. We note that this clarification does not relieve the off-site department of the responsibility for making this contact, but only clarifies that the contact may be delayed in specific cases when doing otherwise would endanger a patient subject to EMTALA protection.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs

agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). This interim final rule is not a major rule because we have determined that the economic impact will be negligible for the revisions related to the transitional pass-through payments for new or innovative medical devices and the grandfathering of FQHCs and "look-alikes."

In addition, the budget impact related to the transitional pass-through provision has already been addressed in the April 2000 final rule (65 FR 18530). As stated in that rule, the pass-through provision is budget neutral as required by section 1833(t)(2)(E) of the Act as amended by section 201(c) of the BBRA. Section 1833(t)(6)(D) of the Act caps the projected additional payments annually at 2.5 percent of the total projected payments for hospital outpatient services each year before calendar year 2004 and no more than 2.0 percent in year 2004

and in subsequent years. Under this provision, we have the authority to reduce pro rata the amount of the additional payments, if before the beginning of a year, we estimate that these payments would otherwise exceed the caps. We advised, in the April 2000 final rule, that it is extremely difficult for us to estimate projected pass-through expenditures as required by law because we do not have claims data available for most items that would be eligible for pass-through payments and because many eligible items would be added after the new system is implemented. For these reasons, in the April 2000 final rule, we stated that there would be no uniform reduction applied to the pass-through payments for calendar years 2000 and 2001. The pass-through change incorporated in this interim final rule does not alter these circumstances.

Also, the budgetary impact related to the grandfathering provision was already calculated in the April 2000 final rule (65 FR 18530) as if these providers were designated before April 7, 2000.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit

organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all FQHCs and "look-alikes" are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with not more than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the prospective payment system, we classify these hospitals as urban hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. This interim final rule will not have a significant economic effect on these governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule will not have a substantial effect on States or local governments.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

VI. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Waiver of Proposed Rulemaking and Waiver of the 30-Day Delay in the Effective Date

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 substances 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 issued. For the reasons set forth below, we find good cause to waive the requirement for notice and comment procedures for the refinement of rules concerning provider based status for FQHCs (including "look-alike" facilities).

We believe that implementing the provider-based provisions contained in the April 2000 final rule without the refinements incorporated in this document could jeopardize continuity of care at certain facilities currently treated as provider-based FQHCs, and consequently disrupt care for Medicare beneficiaries served in those facilities. It would have been impracticable to complete notice-and-comment procedures by August 1, 2000. Given the limited timeframe and the time required to complete notice-and-comment procedures (to develop proposed policies, draft the proposed rule, provide a 60-day public comment period, consider public comments, develop final policies, and draft a final rule), it would not have been possible to issue this document as a proposed rule and issue a final rule by August 1, 2000. Therefore we find that notice and

comment procedures on this issue would be impracticable and contrary to the public interest.

With respect to outpatient PPS, this rule revises a policy reflected in the April 7 final rule with comment period. The April 7 rule provided a waiver of notice and comment procedures for, among other things, the outpatient PPS policy revised herein.

We find the circumstances surrounding this interim final rule make it impracticable and contrary to the public interest to allow a 30-day delay in its effective date with respect to outpatient PPS. This interim final rule refines policies set forth in the April 2000 final rule including the definition of new medical devices, drugs, and biologicals eligible for pass-through payments. The provisions contained in the April 2000 final rule regarding the transitional pass-through payments will be implemented on August 1, 2000, while the provider-based provisions will be implemented on October 10, 2000. We do not believe that it would be feasible or desirable to implement pass-through provisions contained in the April 2000 final rule without the refinements incorporated in this document. We believe that it would be impracticable and contrary to the public

interest to have an effective date for the policy revisions in this document relating to devices that differs from the effective date for the rest of outpatient PPS. If we allow a 30-day delay in the effective date of this rule, hospitals and fiscal intermediaries will be placed at greater risks to make additional changes soon after implementing major systems changes; will find it cumbersome; and will consider it an inefficient use of resources.

Therefore, we find good cause to waive the 30-day delay in the effective date.

List of Subjects42 CFR Part 413

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

42 CFR Part 419

Health facilities, Hospitals, Medicare.

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

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

A. 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 E--Payments to Providers

2. In § 413.65, paragraph (m) is revised to read as follows:

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

* * * * *

(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 on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with the recipient of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

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

* * * * *

PART 419--PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

B. Part 419 is amended as set forth below:

1. The authority citation continues to read as follows:

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

Subpart D--Payments to Hospitals

2. Section 419.43 is amended by:

- A. Revising paragraphs (e)(1)(iv).
- B. Redesignating paragraph (e)(4) as paragraph (e)(5).
- C. Adding new paragraph (e)(4).

The revision and addition reads as follows:

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

* * * * *

(e) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals--

* * *

(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) and(D)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) In the case of a new device, drug, or biological for which a transitional pass-through payment is first made before January 1, 2003, the cost of the device, drug, or biological is considered not insignificant if its expected reasonable cost exceeds 10 percent of the applicable fee schedule amount for the associated service.

(D)In the case of a new device, drug, or biological for which a transitional pass-through payment is first made on or after January 1, 2003, 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 10 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.

* * * * *

(4) Criteria to Define New or Innovative Medical Devices Eligible for Pass-through Payments. HCFA makes pass-through payment for new or innovative medical devices that meet all of the following criteria:

(i) They were not recognized for payment as a hospital outpatient service prior to 1997.

(ii) They have been approved/cleared for use by the FDA.

(iii) They are determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act. Some investigational devices are refinements of existing technologies or replications of existing technologies and

may be considered reasonable and necessary. If such devices have received an FDA investigational device exemption (IDE) and are classified by the FDA as Category B devices in accordance with sections §§ 405.203 to 405.215 of this chapter, excluding § 405.209, they will be considered for coverage under the hospital outpatient prospective payment system.

(iv) They are an integral and subordinate part of the procedure performed, are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted whether or not they remain with the patient when the patient is released from the hospital outpatient department.

(v) The associated cost is not insignificant, as determined under paragraph (e)(1)(iv) of this section, in relation to the APC payment for the service in which the related medical device is packaged.

(vi) They are not equipment, instruments, apparatuses, implements, or such items for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (HCFA Pub. 15-1).

(vii) They are not materials and supplies such as sutures, customized surgical kits, or clips, other than radiological site markers, furnished incident to a service or procedure. Supplies include pharmacological imaging and stressing agents other than radiopharmaceutical (for which transitional pass-through payment is authorized under section 1833(t)(6)(A) of the Act).

(viii) They are not materials such as biologicals or synthetics that may be used to replace human skin.

* * * * *

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

Dated: _____

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

Approved: _____

Donna E. Shalala,
Secretary.

BILLING CODE 4120-01-P)