

the end of each calendar year, or within 30 days following the end of each six month period, if appropriate. Written reports of excess emissions or exceedances of process or control system parameters shall include all information required in § 63.10(c)(5) through (13) of subpart A of this part as applicable in Table 1 of § 63.560 and information from any calibration tests in which the monitoring equipment is not in compliance with PS 8 or other methods used for accuracy testing of temperature, pressure, or flow monitoring devices. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no excess emissions or exceedances have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. This information will be kept for a minimum of 5 years and made readily available to the Administrator or delegated State authority upon request.

(5) If the total duration of excess emissions or control system parameter exceedances for the reporting period is less than 5 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 10 percent of the total operating time for the reporting period, only the summary report of § 63.10(e)(3)(vi) of subpart A of this part shall be submitted, and the full excess emissions and continuous monitoring system performance report of paragraph (e)(4) of this section need not be submitted unless required by the Administrator.

(6) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is 5 percent or greater of the total operating time for the reporting period, or the total CMS downtime for the reporting period is 10 percent or greater of the total operating time for the reporting period, both the summary report of § 63.10(e)(3)(vi) of subpart A of this part and the excess emissions and continuous monitoring system performance report of paragraph (e)(4) of this section shall be submitted.

(f) *Vapor collection system of the terminal.* Each owner or operator of an affected source shall submit with the initial performance test and maintain in an accessible location on site an engineering report describing in detail the vent system, or vapor collection system, used to vent each vent stream to a control device. This report shall include all valves and vent pipes that could vent the stream to the atmosphere, thereby bypassing the

control device, and identify which valves are car-sealed opened and which valves are car-sealed closed.

(g) If a vent system, or vapor collection system, containing valves that could divert the emission stream away from the control device is used, each owner or operator of an affected source shall keep for at least 5 years up-to-date, readily accessible continuous records of:

(1) All periods when flow bypassing the control device is indicated if flow indicators are installed under § 63.563(a)(1) and § 63.564(b), and

(2) All times when maintenance is performed on car-sealed valves, when the car-seal is broken, and when the valve position is changed (i.e., from open to closed for valves in the vent piping to the control device and from closed to open for valves that vent the stream directly or indirectly to the atmosphere bypassing the control device) if valves are monitored under § 63.564(b).

(h) The owner or operator of an affected source shall keep the vapor-tightness documentation required under § 63.563(a)(4) on file at the source in a permanent form available for inspection.

(i) *Vapor tightness test documentation for marine tank vessels.* The owner or operator of an affected source shall maintain a documentation file for each marine tank vessel loaded at that source to reflect current test results as determined by the appropriate method in § 63.565(c)(1) and (2). Updates to this documentation file shall be made at least once per year. The owner or operator shall include, as a minimum, the following information in this documentation:

(1) Test title;  
 (2) Marine vessel owner and address;  
 (3) Marine vessel identification number;  
 (4) Loading time, according to § 63.563(a)(4)(ii) or (iii), if appropriate;  
 (5) Testing location;  
 (6) Date of test;  
 (7) Tester name and signature;  
 (8) Test results from § 63.565(c)(1) or (2), as appropriate;

(9) Documentation provided under § 63.563(a)(4)(ii) and (iii)(B) showing that the repair of leaking components attributed to a failure of a vapor-tightness test is technically infeasible without dry-docking the vessel; and  
 (10) Documentation that a marine tank vessel failing a pressure test or leak test has been repaired.

(j) *Emission estimation reporting and recordkeeping procedures.* The owner or operator of each source complying with the emission limits specified in § 63.562(b)(2), (3), and (4) shall comply with the following provisions:

(1) Maintain records of all measurements, calculations, and other documentation used to identify commodities exempted under § 63.560(d);

(2) Keep readily accessible records of the emission estimation calculations performed in § 63.565(l) for 5 years; and

(3) Submit an annual report of the source's HAP control efficiency calculated using the procedures specified in § 63.565(l), based on the source's actual throughput.

(4) Owners or operators of marine tank vessel loading operations specified in § 63.560(a)(3) shall retain records of the emissions estimates determined in § 63.565(l) and records of their actual throughputs by commodity, for 5 years.

(k) *Leak detection and repair of vapor collection systems and control devices.* When each leak of the vapor collection system, or vapor collection system, and control device is detected and repaired as specified in § 63.563(c) the following information required shall be maintained for 5 years:

(1) Date of inspection;  
 (2) Findings (location, nature, and severity of each leak);  
 (3) Leak determination method;  
 (4) Corrective action (date each leak repaired, reasons for repair interval); and  
 (5) Inspector name and signature.

[FR Doc. 95-22725 Filed 9-18-95; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Parts 405 and 411

[BPD-841-FC]

RIN 0938-AH21

#### Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services

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

ACTION: Final rule with comment period.

**SUMMARY:** This final rule establishes in regulations that certain devices with an investigational device exemption (IDE) approved by the Food and Drug Administration (FDA) and certain services related to those devices may be covered under Medicare. Specifically, it sets forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that are potentially covered under Medicare.

This rule responds to the mandate that Federal agencies streamline their regulatory processes to make them less burdensome and more customer-focused. It is intended to provide Medicare beneficiaries with greater access to advances in medical technology and encourage clinical researchers to conduct high quality studies of newer technologies.

**DATES: Effective Date:** This rule is effective November 1, 1995.

**Comment Date:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 20, 1995.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration,  
Department of Health and Human  
Services, Attention: BPD-841-FC,  
P.O. Box 26688, Baltimore, MD  
21207-0519.

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

Room 309-G, Hubert H. Humphrey  
Building, 200 Independence Avenue,  
SW., Washington, DC 20201, or  
Room C5-09-26, 7500 Security  
Boulevard, Baltimore, MD 21244-  
1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-841-FC. 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 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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many other public and academic libraries throughout the country that receive the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** Sharon Hippler, (410) 786-4633.

**SUPPLEMENTARY INFORMATION:**

I. Background

A. *Statutory Basis*

The Social Security Act (the Act) provides Medicare coverage for broad categories of benefits through the hospital insurance program, known as Part A, and the supplementary medical insurance program, known as Part B.

The Act does not, however, provide an all-inclusive list of covered items, services, treatments, procedures, or technologies. Except for certain items of durable medical equipment identified in section 1861(n) of the Act, some of the medical and other health services listed in section 1861(s) of the Act, and exclusions from coverage listed in section 1862 of the Act, the statute does not specify devices that are covered or excluded from coverage.

The Congress understood that questions about the coverage of specific services would invariably arise and would require a specific decision of coverage by the Secretary. Thus, it vested in the Secretary the authority to make those decisions. Among the provisions relevant to the determination of coverage is section 1862(a)(1)(A) of the Act, which states "Notwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services which \* \* \* are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." This is a key provision since the words "notwithstanding any other provision of this title \* \* \*" make this an overriding exclusion that may be applicable in a given situation despite the existence of provisions that would otherwise permit coverage. Thus, while the Congress provided for the coverage of certain services, with limited exceptions specified by HCFA, coverage for those services is prohibited unless they are "reasonable" and "necessary."

B. *Implementation of the Law*

Historically, HCFA has interpreted the statutory terms "reasonable" and "necessary" to mean that a device must be safe and effective, medically necessary, and not experimental. For most Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, a device

categorized by the FDA as being investigational served as an indication that it was not "reasonable" and "necessary" within the meaning of the Medicare program. As a general rule, these devices currently are not covered.

There is increasing recognition, however, that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers. The FDA places many of these devices within the investigational device exemption (IDE) category as a means of gathering the scientific information necessary to establish the safety and effectiveness of the particular device, even though there is scientific evidence that similar devices can be safe and effective. Arguably, these devices could be viewed as "reasonable" and "necessary" under Medicare and recognized for payment if it were possible to identify them in the FDA's process.

C. *January 1989 Proposed Rule on Coverage Decision Process*

On January 30, 1989, we published a proposed rule (54 FR 4302) that proposed to establish in regulations generally applicable criteria for determining whether a service is "reasonable" and "necessary" under the Medicare program, and the coverage decisionmaking process. In response to that rule, we received comments pertaining to the coverage of experimental procedures and services related to those procedures. In this rule, we are choosing to respond to comments on investigational devices and services related to those devices and to announce our final policy. We have not completed our deliberations on the other issues addressed in the January 1989 proposed rule. This rule does not respond to comments other than those pertaining to devices.

**Comment:** Twenty-two commenters suggested that we revise our proposed policy so that we do not automatically exclude from Medicare coverage all devices that the FDA considers investigational. Several of these commenters recommended that we allow coverage of investigational devices when they are used in FDA-approved clinical trials.

**Response:** We agree that there are some investigational devices that should be considered for coverage if they are used in accordance with an FDA-approved protocol. The devices that will be considered for possible coverage are those investigational devices for which the FDA has determined that the device type can be safe and effective. For example, we will consider for possible coverage those investigational devices

that are of the same type as a device for which a manufacturer has received FDA clearance or approval for marketing. We have entered into an interagency agreement with the FDA to identify those investigational devices that are of a device type for which the underlying questions of safety and effectiveness have been resolved. These devices may be covered if all other applicable Medicare coverage requirements are met.

*Comment:* One commenter recommended that we not change our previous policy that excluded coverage of investigational devices.

*Response:* We do not agree. We believe that there are certain investigational devices that should be covered if all other applicable coverage requirements are met. However, the investigational devices that we will consider for coverage will not include any device for which the FDA is unsure whether the device type in general can be safe and effective.

*Comment:* A number of commenters requested that we clarify the coverage rules concerning the furnishing of services related to experimental procedures (for example, a hospital stay).

*Response:* As stated earlier, we are limiting the focus of this rule to Medicare coverage of certain investigational devices and services related to those devices. Also, in the preamble to this rule and in new § 405.207, we explain our coverage policy concerning services related to a noncovered device.

## II. Provisions of This Final Rule

While the policies contained in this final rule will be effective November 1, 1995, we are providing a 60-day comment period for the receipt of public comments. We believe it is appropriate to provide an opportunity for comment on these policies because we are broadening the proposals concerning certain devices contained in the January 1989 proposed rule. Consequently, beneficiaries, providers, and suppliers that may have chosen not to comment because they may have believed they were not affected by the 1989 proposals may wish to comment on these broadened final policies. If our consideration of the comments we receive leads us to a change in these policies, we will publish another document.

### A. HCFA Coverage Decision Process

The Administration has set forth a mandate that all Federal agencies must streamline their regulatory processes to make them less burdensome and more

customer-focused. Agencies have been directed to review their policies and processes to determine which requirements can be reduced or eliminated without lowering health and safety standards. In accordance with this directive, the FDA reviewed its regulatory processes for devices and HCFA reviewed its Medicare coverage policies. This rule results in an improved process for covering certain investigational devices that is expected to benefit Medicare beneficiaries.

This new policy will lead to broader coverage of certain investigational devices and certain services related to those devices. A long-term benefit is to facilitate the collection of information about these devices through approved clinical trials, which will enable the marketing of these devices. Medicare beneficiaries will have earlier access to the latest advances in medical technology.

To assist HCFA in its coverage decision process, the FDA will follow a categorization process that differentiates between the clinical assessment of novel, first-of-a-kind devices and newer generations of legally marketed devices. The policy changes in this rule reflect the categorization of investigational devices that are the subject of FDA-approved IDEs.

The FDA uses the definition of a device that appears in 21 U.S.C. 321(h). A device, for purposes of the FDA process, refers to an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is—

- Recognized in the official National Formulary, or the U.S. Pharmacopeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,
- Intended for use in the diagnosis of conditions other than diseases such as pregnancy,
- Intended to affect the structure or any function of the body of man or other animals, or
- Considered an *in vitro* diagnostic product, including those previously regulated as drugs, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals

and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

When a sponsor (usually a manufacturer) submits a marketing

application for clearance or approval of a device to the FDA, the FDA evaluates the safety and effectiveness of the device. If sufficient information exists to determine its safety and effectiveness, the FDA may clear the device for marketing. In some instances, for certain devices, the FDA may require that clinical trials be conducted to obtain clinical information to determine the device's safety and effectiveness. Generally, in order for these devices to be shipped lawfully for purposes of conducting the clinical trial, the sponsor must obtain an approved investigational device exemption (IDE).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes:

*Class I*—Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

*Class II*—Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

*Class III*—Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Under the new categorization process to assist HCFA, the FDA assigns each device with an FDA-approved IDE to one of two categories: Experimental/Investigational (Category A) Devices, or Non-Experimental/Investigational (Category B) Devices. Under this categorization process, an experimental/investigational device (Category A) is an innovative device in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The criteria the FDA will use to categorize

an investigational device is described in the addendum to this rule.

Currently there are about 1,200 FDA-approved clinical trials of devices. The FDA is categorizing those devices as "experimental/investigational (Category A)" or "non-experimental/investigational (Category B)," a process that is expected to be completed by November 1, 1995. The great majority of these devices in clinical trials are likely to be categorized as "non-experimental/investigational (Category B)".

The FDA will notify HCFA, when it notifies the sponsor, either by electronic means or written communication, of its categorization decisions. Through these categorization decisions, the FDA will be advising HCFA as to the similarity of a device that has been approved for use in an FDA-approved clinical trial to a device that has been approved or cleared by the FDA for marketing.

HCFA excludes from Medicare coverage a device with an IDE that is categorized by the FDA as experimental/investigational (Category A). HCFA will continue to view these experimental/investigational (Category A) devices as not satisfying the statutory requirement that Medicare pay for only devices determined to be reasonable and necessary. HCFA is not changing its policy on this issue because essential considerations of health and safety are involved.

This rule does not affect HCFA's policy on services related to a noncovered device. That is, services related to the use of a noncovered device are not covered under Medicare. We are codifying in the regulations a provision explaining that services related to a noncovered device are not covered under Medicare. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

Services furnished to address medical complications arising from the use of the device (and that are not incident to normal recovery) may be covered. Services not related to the use of a noncovered device, which meet all other coverage requirements, can be covered under Medicare.

The following are some examples of services "related to" and "not related to" noncovered devices furnished while the beneficiary is an inpatient:

- A beneficiary is hospitalized to receive a noncovered device and breaks a leg while in the hospital. Services

related to care of the broken leg during this stay are "not related to" services and are covered under Medicare.

- A beneficiary is admitted to the hospital for a covered service and during the hospital stay received a noncovered investigational device. The services related to the admitting condition are covered because the reason for the admission was to receive covered services and not related to the diagnoses that led to the need for the noncovered device.

- A beneficiary is admitted to the hospital for covered services related to a condition that led to receiving a noncovered device during the same hospital stay. We would review all of the services and make a comparison of the date they are received to the date the beneficiary is identified as needing the noncovered device. If our review reveals that services were required because of receiving the noncovered device, the services "related to" the noncovered device will not be covered.

- After a beneficiary is discharged from a hospital stay during which he or she receives a noncovered investigational device, medical and hospital services to treat a condition or complication that arises as a result of the noncovered device or related noncovered services may be covered when they are reasonable and necessary in all other respects. Thus, coverage could be provided for subsequent inpatient hospital stays or outpatient treatment ordinarily covered by Medicare, even if the need for treatment arose because of a previous noncovered device or related noncovered services. Any subsequent services that could be expected to have been incorporated into a global fee, however, will not be covered.

The related services policy will also apply to experimental/investigational (Category A) and non-experimental/investigational (Category B) devices that are excluded from Medicare coverage. Therefore, Medicare policy will continue to preclude coverage of certain devices and services related to the use of those devices when they are furnished as part of a hospital stay.

It is our intention that a beneficiary not pay for a noncovered device or services related to a noncovered device when a beneficiary did not know that the device or related services are not covered. Existing regulations concerning limitations on liability in §§ 411.400 through 411.406 will apply to this broader coverage of certain investigational devices and services related to those devices. Medicare payment may be made for certain assigned claims for a service related to

a noncovered device if the service was excluded from coverage in accordance with § 411.15(k) as not medically necessary under section 1862(a)(1)(A) of the Act. A beneficiary who did not know and could not reasonably have been expected to know that payment would be denied under section 1862(a)(1)(A) of the Act receives protection from financial liability in accordance with §§ 411.400 through 411.406 under the limitation on liability provision of section 1879 of the Act. Similarly, when the beneficiary is protected and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier also receives protection from financial liability in accordance with the limitation on liability provision. Consequently, Medicare payment may be made to the provider or supplier.

For unassigned claims for related physician services excluded from coverage as not medically necessary under section 1862(a)(1)(A) of the Act, a beneficiary who did not know and could not reasonably have been expected to know that payment would be denied as not medically necessary may receive protection from financial liability in accordance with existing § 411.408 under the refund requirement provision of section 1842(l) of the Act. If the beneficiary is found not to have known, and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier will receive protection from financial liability under the refund requirement provision.

Under changes made by this final rule, HCFA will consider coverage of a device with an FDA-approved IDE, categorized by the FDA as non-experimental/investigational (Category B) for Medicare beneficiaries participating in FDA-approved clinical trials. As a general rule for all medical care, HCFA has authority to conduct a separate assessment of an item—s or service's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries. Medicare coverage of a non-experimental/investigational (Category B) device will be subject to the same process and criteria used by Medicare contractors when making coverage decisions for legally marketed devices. Coverage of the device is dependent on it meeting all other Medicare coverage requirements contained in the statute, regulations, and instructions issued by HCFA.

The FDA-approved IDE study protocols restrict investigational device shipment to a limited number of investigational sites for testing on a specific number of patients. To the extent Medicare covers a non-experimental/investigational (Category B) device, coverage is limited to beneficiaries meeting the protocol requirements. For example, coverage of an investigational device may be limited to Medicare beneficiaries participating in trials conducted by certain health care practitioners in an approved clinical trial.

Medicare coverage of a non-experimental/investigational (Category B) device is predicated, in part, upon the device continuing to meet criteria that led to this designation by the FDA. In the event a device fails to meet the criteria for Category B designation or its use violates relevant IDE requirements necessitating the withdrawal of the IDE approval, the FDA will immediately notify the sponsor and HCFA. HCFA will re-evaluate the device's continued eligibility for Medicare payment.

Payment under Medicare for a non-experimental/investigational (Category B) device will be 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. In cases involving a hospital stay, the diagnosis related group (DRG) payment under the prospective payment system ordinarily will not be affected.

#### *B. Re-evaluation of Categorization Decision*

We anticipate that instances will arise under which a device sponsor believes that a device, categorized by the FDA as experimental/investigational (Category A), should be categorized as non-experimental/investigational (Category B). In these instances, the sponsor may request that the FDA re-evaluate its categorization decision. Only after the FDA has completed its re-evaluation, and concluded that the device still is an experimental/investigational (Category A) device, may a sponsor request review by HCFA. A sponsor may request review by HCFA even if no Medicare claims are involved.

##### 1. FDA Action

Under this process, the sponsor may submit a written request for re-evaluation to the FDA (at the same address it submitted its original application), together with information and rationale that it believes support recategorization. Only the sponsor of a

device may seek a re-evaluation of the FDA IDE categorization decision.

Time limits on seeking a re-evaluation will not be imposed. The FDA will review the request and inform the sponsor, and HCFA, of its decision. If the FDA does not agree to recategorize the device, the sponsor may seek further review by HCFA.

##### 2. HCFA Action

Upon written request to the HCFA Administrator from the sponsor of a device with an FDA-approved IDE, HCFA will review the categorization of the device. As part of this process, HCFA will review all information submitted by the sponsor and the FDA's recommendation. HCFA will review only information in the FDA record to determine whether to change the categorization. HCFA will not accept or review any information from the sponsor that was not previously reviewed by the FDA. While HCFA, during the re-evaluation process, will be the final decisionmaker concerning categorization of a device for Medicare coverage purposes, HCFA relies heavily on the FDA review of the scientific information related to the device and consequently the FDA recommendation. HCFA will issue a written decision and notify the sponsor and the FDA. No further reviews will be available to the sponsor.

##### 3. Update of Categorization Decision

If the circumstances that led to the initial categorization decision change (for example, a premarket approval application is approved for a device similar to one under investigation), the FDA will re-evaluate the categorization designation and notify the sponsor and HCFA of any change. Neither the FDA categorization and re-evaluation nor HCFA's review constitute an initial determination for purposes of the Medicare appeals processes under 42 CFR part 405, subparts G or H, or parts 417, 473, or 498.

#### *C. Quarterly Announcement of Categorization Decisions*

HCFA publishes quarterly in the Federal Register a notice that lists HCFA manual instructions, substantive and interpretive regulations and other Federal Register notices, and statements of policy that relate to the Medicare and Medicaid programs. HCFA will announce in the quarterly notice all IDE categorizations, using IDE numbers the FDA assigns. The initial notice will include all FDA-approved IDE numbers organized by the categories to which the device numbers are assigned (that is, Category A or Category B, and identified

by the IDE number). Subsequent notices will include the additions and deletions to the initial list of all devices with an FDA-approved IDE.

#### *D. Confidentiality of Investigational Device Exemption Information*

Data and information otherwise exempt from public disclosure may be revealed in judicial proceedings if the data or information are relevant. HCFA will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances. Because HCFA relies on information submitted to the FDA under 21 U.S.C. 360j(g), HCFA will consult with the FDA to ensure that the confidentiality of the information is protected to the extent possible.

#### *E. Contractor Coverage Decisions of Devices With an FDA-approved IDE*

##### 1. Current Contractor Functions

Sections 1816 and 1842 of the Act provide for most claims processing and administrative functions for Medicare to be handled by public or private insurance organizations (commercial insurers or Blue Cross/Blue Shield Associations) acting as fiscal agents or contractors for the Medicare program.

The contractors responsible for the administration of Part A benefits are called fiscal intermediaries. The major role of the intermediaries is to review and pay claims submitted by providers (such as hospitals, skilled nursing facilities, and home health agencies) for covered services furnished to Medicare beneficiaries. The intermediary makes payments for hospital inpatient services generally under the prospective payment system. It makes payments for hospital and other provider outpatient services by reviewing submitted cost reports and making reasonable cost determinations or payment determinations under a fee schedule following policies set by HCFA.

Under Part B, the contractors are called carriers. Part B services are paid on a fee schedule, reasonable charge, or reasonable cost basis. One of the major functions of the carriers is to determine the appropriate amount of payment for each medical care service paid for under the program. Carriers also are responsible for reviewing and paying claims to or on behalf of beneficiaries for the services furnished.

The functions performed by Medicare contractors include utilization review, beneficiary hearings and appeals, professional relations, and statistical activities, in addition to claims review and processing. Currently, there are 29

carriers, 46 intermediaries, and some other entities under contract with HCFA that perform reviews and process claims for Medicare beneficiaries.

## 2. Current Criteria and Procedures for Contractor Coverage Decisions

Contractors make Medicare coverage decisions within the parameters set by statutory authority and regulations and program instructions issued by HCFA. If HCFA has issued a national coverage decision, contractors are bound by that decision. If no national coverage decision has been issued, a contractor must decide whether the service in question is reasonable and necessary and therefore covered by Medicare.

Medicare contractors may specifically consider, among other factors, whether the service is—

- Medically necessary in the particular case and whether the amount, duration, and frequency of use or application of the service are medically appropriate;
- Furnished in accordance with accepted standards of medical practice; and
- Furnished in a setting appropriate to the patient's medical needs and condition (such as inpatient care at a hospital or skilled nursing facility, outpatient care at a hospital or physician's office, or home care).

## 3. Changes to Contractor Process

Under this rule, contractors will review the instructions HCFA issues to determine if a non-experimental/investigational (Category B) device is potentially covered under Medicare. After determining that a device is potentially covered, the contractor will apply HCFA's long-standing criteria and procedures for making coverage decisions. When considering whether a non-experimental/investigational (Category B) device is furnished in accordance with accepted standards of medical practice, it will consider those standards that relate to an FDA-approved clinical trial.

In accordance with HCFA coverage policy, Medicare contractors are precluded from covering any device that is an experimental/investigational (Category A) device.

### F. Appeals Under Part A and Part B

While the categorization decision is not itself an initial determination, if HCFA denies a Medicare claim on the basis that the device is an experimental/investigational (Category A) device, the initial determination denying the claim encompasses the categorization decision. A proper party to the denied Medicare claim has a right to appeal the

experimental/investigational (Category A) categorization as an initial determination under 42 CFR part 405, subparts G or H.

A decision that a device is experimental/investigational (Category A) means that the device is experimental and, therefore, excluded from coverage as not reasonable and necessary under section 1862(a)(1)(A) of the Act. HCFA's acceptance of the FDA categorization of an experimental/investigational (Category A) device constitutes a national coverage decision and is binding on HCFA's contractors. In accordance with section 1869(b)(3)(A) of the Act, national coverage decisions made by HCFA under section 1862(a)(1) of the Act may not be reviewed by administrative law judges.

## III. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all device manufacturers and providers 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 if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This regulation removes certain investigational devices from being presumed excluded by Medicare and places them in a category under which they may be covered. On a claim-by-claim basis, Medicare contractors verify or determine that devices are covered under the circumstances presented by the claim or bill. This regulation does not change that process, except the contractors must ascertain whether these devices were furnished to beneficiaries participating in, and in accordance with the requirements of, approved clinical trials. Once coverage is verified, payment is made at the level established for a similar device that has been approved as covered by Medicare.

We anticipate that this regulation will lead to a beneficial but not a major expansion of coverage of devices. Each year the FDA receives approximately

200 IDE applications for review. The majority of these IDEs are approved for study. At the present time, there are approximately 1,200 clinical trials underway involving devices, which are being conducted under FDA-approved IDEs.

We expect that this regulation will have a number of beneficial effects. It will provide Medicare beneficiaries with greater access to advances in medical technology. It will allow Medicare beneficiaries faced with a decision of choosing between a fully covered device and one undergoing clinical trials to choose the investigational device without losing Medicare coverage. Because Medicare payment is based on the payment for a fully covered device, that choice would not result in increased costs to Medicare for those devices.

At the present time, device manufacturers and the providers that furnish services involving non-experimental/investigational devices (Category B) are not eligible for Medicare payments. We estimate that this regulation will result in negligible costs to the Medicare program. We expect affected entities would receive less than \$10 million per year over the next 5 years.

Virtually all of these devices replace devices for which Medicare coverage is currently available and which would have been furnished to beneficiaries if we had not changed the policy. The services are primarily furnished on an inpatient basis in hospitals. Hospitals are paid on a prospective basis so that prices are not adjusted based on changes in the price-components (that is, device costs) of individual DRGs. Instead, the payment base under the prospective payment system is annually updated based on a host of considerations, including the increased cost of inputs. As a result, this change in coverage will not significantly affect Medicare's current payments and will only affect its future payments in concert with the other factors affecting the DRG update decisions.

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.

#### 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 1980 (44 U.S.C. 3501 et seq.).

#### V. 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, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

#### List of Subjects

##### 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

##### 42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

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

A. 42 CFR part 405 is amended to read as follows:

#### **PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

1. A new subpart B, consisting of §§ 405.201–405.215, is added to read as follows:

##### **Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology**

- Sec.
- 405.201 Scope of subpart and definitions.
- 405.203 FDA categorization of investigational devices.
- 405.205 Coverage of a non-experimental/investigational (Category B) device.
- 405.207 Services related to a noncovered device.
- 405.209 Payment for a non-experimental/investigational (Category B) device.
- 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.
- 405.213 Re-evaluation of a device categorization.
- 405.215 Confidential commercial and trade secret information.

##### **Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology**

Authority: Secs. 1102, 1862, and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395y, and 1395hh).

##### **§ 405.201 Scope of subpart and definitions.**

(a) *Scope.* This subpart establishes that—

(1) HCFA uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) HCFA may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

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

*Class I* refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

*Class II* refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

*Class III* refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

*Contractors* refers to carriers, fiscal intermediaries, and other entities that contract with HCFA to review and adjudicate claims for Medicare services.

*Experimental/investigational (Category A) device* refers to an innovative device believed to be in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

*IDE* stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

*Non-experimental/investigational (Category B) device* refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for

which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

*PMA* stands for "premarket approval" and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

*Sponsor* refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

##### **§ 405.203 FDA categorization of investigational devices.**

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

##### **§ 405.205 Coverage of a non-experimental/investigational (Category B) device.**

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and HCFA and the procedures described in paragraph (a)(2) of this section apply.

##### **§ 405.207 Services related to a noncovered device.**

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because HCFA determines the device is not "reasonable" and

“necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises because of the use of a noncovered device or from the furnishing of related noncovered services.

**§ 405.209 Payment for a non-experimental/investigational (Category B) device.**

Payment under Medicare for a non-experimental/investigational (Category B) 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.

**§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.**

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all HCFA administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

**§ 405.213 Re-evaluation of a device categorization.**

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by HCFA only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor HCFA's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both HCFA and the sponsor of its decision.

(c) *Request to HCFA.* If the FDA does not agree to recategorize the device, the sponsor may seek review from HCFA. A device sponsor must submit its request in writing to HCFA. HCFA obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. HCFA reviews all material submitted by the sponsor and the FDA's recommendation. HCFA reviews only information in the FDA record to determine whether to change the categorization of the device. HCFA issues a written decision and notifies the sponsor of the IDE and the FDA.

**§ 405.215 Confidential commercial and trade secret information.**

To the extent that HCFA relies on confidential commercial or trade secret information in any judicial proceeding, HCFA will maintain confidentiality of the information in accordance with Federal law.

**Subpart G—[Amended]**

2. The authority citation for subpart G continues to read as follows:

Authority: Secs. 1102, 1151, 1154, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c-3, 1320c-4, 1395ff(b), 1395hh, 1395ii and 1395pp).

3. In subpart G, a new § 405.753 is added to read as follows:

**§ 405.753 Appeal of a categorization of a device.**

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect

of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

**Subpart H—[Amended]**

4. The authority citation for subpart H continues to read as follows:

Authority: Secs. 1102, 1842(b)(3)(C), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b)).

5. In subpart H, a new § 405.877 is added to read as follows:

**§ 405.877 Appeal of a categorization of a device.**

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

B. 42 CFR part 411 is amended as set forth below:

**PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT**

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).

2. In § 411.15, the introductory text is republished and new paragraph (o) is added to read as follows:

**§ 411.15 Particular services excluded from coverage.**

The following services are excluded from coverage.

\* \* \* \* \*

(o) *Experimental or investigational devices, except for certain devices—*

(1) Categorized by the FDA as a non-experimental/investigational (Category B) device defined in § 405.201(b) of this chapter; and

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

3. In § 411.406, paragraph (e) is revised to read as follows:

**§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.**

\* \* \* \* \*

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a PRO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

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

Dated: September 11, 1995.

Bruce C. Vladeck,  
*Administrator, Health Care Financing Administration.*

Dated: September 12, 1995.

Donna E. Shalala,  
*Secretary.*

Note: This addendum will not appear in the Code of Federal Regulations.

Addendum—Criteria for Categorization of Investigational Devices

*Category A: Experimental/ Investigational*

Category A devices include the following:

(1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments<sup>1</sup> Class III devices, refer to the criteria under Category B).

<sup>1</sup> Pre-amendments devices are devices that were marketed before the enactment of the 1976 Medical

(2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

*Category B: Non-experimental/ Investigational*

Category B devices include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required.

(5) Pre-amendments Class III devices that become the subject of an IDE after the FDA requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the FDA required the submission of an IDE.

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the FDA will agree on the additional criteria to be used. The FDA will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 95-23132 Filed 9-13-95; 4:00 pm]

BILLING CODE 4120-01-P

Device Amendments to the Food, Drug, and Cosmetic Act; that is, in commercial distribution before May 28, 1976.

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Pat 73**

[MM Docket No. 90-189; RM-6904, RM-7114, RM-7186, 7415, RM-7298]

**Radio Broadcasting Services; Farmington, Grass Valley, Jackson, CA**

AGENCY: Federal Communications Commission.

ACTION: Final rule.

**SUMMARY:** This document allots Channel 232A to Farmington, California, and substitutes Channel 232B1 for Channel 232A at Grass Valley, California, and modifies the license of Station KNCO, Grass Valley to specify operation on Channel 232B1. to accommodate these actions, this document substitutes Channel 259A for Channel 232A at Jackson, California, and modifies the license of Station KNGT, Jackson, California, to specify operation on Channel 259A. The reference coordinates for the Channel 232A allotment at Farmington, California, are 37-57-00 and 121-00-00. The reference coordinates for Channel 232B1 at Grass Valley, California, are 39-14-44 and 120-57-52. The reference coordinates for Channel 259A at Jackson, California, are 38-20-24 and 120-43-13. See 55 FR 13810 (April 12, 1990).

**EFFECTIVE DATE:** October 27, 1995.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Mass Media Bureau, (202) 776-1654.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the *First Report and Order* in MM Docket No. 90-189, adopted September 1, 1995, and released September 12, 1995. The full text of this decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: Secs.303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.