HEALTH CARE FINANCING ADMINISTRATION

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REMARKS:

IDE memo

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

DEC 28 1994

FROM: Director
Bureau of Policy Development

SUBJECT: Medicare Coverage of Investigational Devices

TO: All Regional Administrators

Attached is a paper we have prepared describing existing Medicare policy on investigational devices. This paper represents a synthesis of Medicare's policy on noncoverage of investigational devices and policy of the Food and Drug Administration on investigational devices and device classification. The information presented is not new policy. It is a compilation and explanation of existing policies pertaining to the application of the "reasonable and necessary" requirement to the coverage of medical devices under Medicare.

We prepared this information as a resource for you to use in dealing with questions and claims processing issues. Therefore, it is appropriate for distribution to all Medicare contractors. If you have any questions on this paper, or want to share questions you get from your contractors, please contact Sharon Hippler, 410-966-4633.

Thomas A. Ault

Attachment

Medicare Policy with Respect to Investigational Devices

GENERAL MEDICARE POLICY

Section 1862(a)(1)(A) of the Social Security Act states, in part, that no payment may be made under Part A or B for any expenses for items or services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Medicare has historically interpreted the statutory terms "reasonable and necessary" to mean that a service must be safe and effective, and not experimental. For Medicare coverage purposes, the term experimental is used synonymously with the term investigational.

Instructions that Medicare contractors must follow in applying the "reasonable and necessary" provision to medical devices are set forth in section 3151.1 of the Intermediary Manual, section 2303.1 of the Medicare Carriers Manual, and section 260.1 of the Hospital Manual. Those sections, whose wording is identical, read as follows:

> Medical devices which have not been approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services using devices which have not been approved for marketing by the FDA.

This longstanding policy, which is binding on our contractors, explicitly excludes from coverage devices, and services using devices, that have not been approved for marketing by the FDA. This policy applies to any device that is subject to FDA review. The Medicare manuals do not allow any exceptions to this policy. 1/ Endnote

COVERAGE OF SERVICES RELATED TO INVESTIGATIONAL DEVICES

Other manual instructions at section 3101.14 of the Intermediary Manual, section 2300.1 of the Medicare Carriers Manual, and section 310.12 of the Hospital Manual, exclude coverage of services related to an investigational service/device. These manual sections state that:

> Services "related to" noncovered services (e.g., cosmetic surgery, noncovered organ transplants, noncovered artificial

organ implants, etc.), including services related to followup care and complications of noncovered services which require treatment during a hospital stay in which the noncovered service was performed, are not covered under Medicare.

Therefore, national policy not only precludes coverage of investigational devices, and services using such devices, but also services related to the use of investigational devices when they are provided as part of a covered hospital stay.

Payment outcomes that may occur when an investigational device is implanted during a hospital stay are as follows:

First, if the patient is admitted for a medically appropriate reason (e.g., "heart problems") and it is decided after the admission to implant an investigational device, Medicare would not pay for the surgical procedure. The hospital would be paid for a non-surgical admission under the appropriate Diagnosis Related Group (DRG). In effect, payment for items and services related to the implantation would be excluded, but payment may be made for care rendered during the hospital stay that is not related to the implantation.

Second, if the admission is for the purpose of implanting an investigational device, the entire hospital stay is denied and no payment is allowed.

Third, the physician's services related to the implantation of an investigational device are not covered irrespective of the circumstances.

It is important to note that, even in the case of FDA-approved devices that Medicare may ordinarily cover, such coverage is still predicated upon the device being medically necessary for the patient for whom it is prescribed. In the case of cardiac pacemakers, for example, our instructions are quite specific as to the proper determination of coverage, not only with respect to the patient's medical need for such a device, but also the type of device (single or dual-chamber pacemaker) that is medically necessary for that particular patient.

FDA Device Classification

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) is charged with the responsibility for ensuring that medical devices are safe and

effective before they are allowed to be marketed. FDA's authority to regulate medical devices arises in part from the Food, Drug, and Cosmetic Act (FDC Act) of 1938 as amended by the Medical Devices Act of 1976 (the 1976 amendments). Under the 1976 amendments, devices are divided into pre-amendment devices, i.e., those in commercial distribution prior to May 28, 1976, and post-amendment devices, i.e., those devices first in distribution on or after the enactment of the 1976 amendments. All devices are then further classified, usually by rulemaking, into one of three classes, depending on the degree of regulatory control necessary to assure safety and effectiveness. General statutory standards for determining the safety and effectiveness of devices are set forth in the FDC Act (21 U.S.C. sections 360c(a)(2) and (a)(3)). These standards are implemented by regulations set forth at 21 C.F.R. section 860.7.

Class I devices are the least regulated devices. These are devices that FDA has determined need be subject only to general controls, such as good manufacturing practice regulations. Class II devices are those which, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to assure safety and effectiveness. Class III devices are those which 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 (21 U.S.C. section 360c(a)(1)(C)).

FDA has a statutory obligation to evaluate and classify pre-amendment devices by regulation into the above three statutory categories (21 U.S.C. sections 360c, 360e(b) and (i)). A pre-amendment Class III device may be commercially distributed without a PMA from FDA until 90 days after FDA, by rulemaking, requires the filing of a PMA with respect to that particular device (21 U.S.C sections 351(f)(2) and 360c). Accordingly, pre-amendment Class III devices, such as breast implants and heart valves, may be legally marketed for years without pre-market approval until the date the FDA requires filing of PMAs for the particular pre-amendment Class III device.

The cornerstone of the regulatory system for post-amendment device classification is section 510(k) of the FDC Act (21 U.S.C. section 360(k)). This section requires first-time marketers of devices to report to the FDA 90 days before introducing or delivering for introduction into commerce a device intended for human use. Under this 510(k) regulatory scheme for post-amendment devices, a new device is regulated in the same manner as a Class I or II post-amendment device if the FDA finds that it is "substantially equivalent" to a pre-amendment device or a

Class I or II post-amendment device (21 U.S.C. section 360(k)). A post-amendment device that is not substantially equivalent to a legally marketed predicate device (i.e., a previously legally marketed device to which it is substantially equivalent) is placed in Class III, requiring pre-market approval, unless it is reclassified pursuant to petition (21 U.S.C. section 360c(f)).

Investigational Device Exemption (IDE) Devices

FDA's requirements for investigational use of devices vary depending on whether the devices are "significant risk" devices or "insignificant risk" devices (21 C.F.R. section 812.3(m)). Investigations of significant risk devices are subject to detailed regulatory control and require both hospital Institutional Review Board (IRB) and FDA approval. An unapproved Class III device may be investigated under an investigational device exemption (IDE) (21 U.S.C. section 360j(g)). A sponsor of such an investigation must submit a summary of the investigational plan to FDA, including the purpose of the investigation, intended use of the device, a protocol describing the methodology, risk analysis, monitoring procedures, labeling stating the product is investigational, informed consent materials, IRB information, and a reporting of prior investigations (21 C.F.R. section 812.20).

If approved, the IDE will permit the device to be available in a limited number of sites, for a limited number of patients, and under the supervision of identified researchers. FDA regulations prohibit manufacturers or investigators from charging for investigational devices a price higher than the costs of manufacture, research, development, and handling (21 C.F.R. section 812.7). An IDE will not be approved if: (1) there are reasons to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained; (2) informed consent is inadequate; (3) the investigation is scientifically unsound; or (4) there is reason to believe that the device is ineffective (21 C.F.R. section 812.30).

Premarket Approval Applications

FDA will issue an order approving a PMA if it finds that none of the grounds for disapproving an application exists (21 U.S.C. section 360e(d)(1)(A)). Accordingly, in order to approve a PMA, FDA must find that (1) there is a showing of reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling;

(2) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device conform to the requirements of 21 U.S.C. section 360j; (3) the proposed labeling is not false or misleading; and (4) adequate information exists to justify a deviation from a performance standard if the device does not conform to a performance standard in effect that is a condition to approval of the application (21 U.S.C. section 360e(d)(2)).

Labeling of Medical Devices

Approved devices (PMA devices), as well as some cleared devices (substantially equivalent devices that are referred to as 510(k) devices), have official labels listing the approved as well as contra-indicated uses (21 CFR 801, Subpart A--General Labeling Provisions). Devices that are being tested under an IDE must be labeled in accordance with 21 CFR 812.5. An IDE device that poses significant risk must have an FDA-approved protocol regarding the investigational use of the product. If the device is of nonsignificant risk, only IRB approval of the protocol is required. Examples of the type of information included in the protocol would be patient selection criteria, disease conditions and the conditions under which treatment is provided. Also, all devices under an IDE (unless already legally marketed for another intended use) must include a precautionary statement in a prominent position that states: "Caution - Investigational device. Limited by Federal (or United States) law to investigational use."

Patient Consent—Participation in an IDE

The FDA requires that the sponsor manufacturer ensure that all clinical investigators obtain a signed consent document for all patients participating in an IDE clinical trial.

Use of an FDA-Approved Device with an IDE Device

If a combination of devices has an FDA-approved component and a second component (which has not been approved for any use) which must be used in combination to achieve the intended effect, the combined use is subject to the requirement of the IDE approved protocol, i.e., the combined use is considered investigational. If a combination of devices has an approved component and an IDE component, but the components are not required to be used in combination, the use of the approved component is considered to fall within the scope of the practice of medicine.

Use of Two FDA-Approved (for other uses--mix and match) Devices Together

Whether the combination of two FDA-approved devices in one procedure is considered to have IDE status is dependent on the device's approval by FDA as well as how the particular device is defined by FDA regulations and labeling. For example, approved automatic implantable cardio-defibrillators (AICDs) and leads may be inter-changed, i.e., the labeling would not preclude this use. FDA ordinarily, and in this case, regards such unlabeled (or off-labeled) use to be the practice of medicine.

FURTHER DISCUSSION OF MEDICARE'S POLICY:

A medical device is considered investigational if it has not completed the applicable clearance (510(k)) or approval (PMA) process that a manufacturer, in accordance with FDA's requirements, must complete before it is allowed to fully market its product. Investigational devices, services using such devices, and services related to investigational devices are not covered by Medicare (IM 3151.1 and 3101.14, MCM 2303.1 and 2300.1. HM 260.1 and 210.12). (For exceptions see 1/ endnote.)

Unlabeled Use of Devices

An approved or cleared device may be covered by Medicare for a labeled indication and, based on contractor discretion, for an unlabeled use as long as this does not conflict with FDA requirements. For example, an approved cardiac catheter, whose label only includes a diagnostic indication, may be covered by a contractor for an unlabeled therapeutic indication, based on the contractor's determination that the unlabeled use is safe and effective.

Use of Approved Device With an IDE Device

If an approved cardiac defibrillator or pacemaker is used with investigational leads, the FDA considers the combined use to be investigational. Therefore, both devices would be excluded from coverage. (Leads are tiny coated wires that are implanted for use with pacemakers and defibrillators to both sense and respond to the patient's cardiac activity. They are an essential component of an implanted pacemaker or defibrillator system.) However, when both the AICD or pacemaker and the leads have been approved by FDA, even though not approved for use with each other, FDA ordinarily regards such use to be the practice of medicine, and has not sought regulatory control of such practices.

Relationship of IDE Devices to Current Medicare Policy

Medicare does not cover devices which are not yet approved or cleared by FDA. Although FDA law and regulations permit manufacturers to charge patients for some or all of the cost of devices used in clinical trials, such charges represent charges for noncovered items and services and are not payable by Medicare.

Relationship of Current Medicare Policy to Coverage of Complications Resulting from Investigational Service/Device

Medical and hospital services related to followup care and complications of noncovered services which require treatment during the same hospital stay in which the noncovered service was performed, (such as implantation of an investigational device) are not covered, even if they are the types of services that are ordinarily covered by the Medicare program (IM 3101.14, MCM 2300.1, and MM 210.12). Once the patient has left the hospital, however, medical and hospital services that may be required to treat a condition or complication which arises as a result of the non-covered hospital stay may be covered, provided that they are medically necessary for that patient.

CLAIMS OPERATION ISSUES

Contractor's Ability to Ascertain FDA-Approved Status from Claims Form

The current inpatient hospital claim form (HCFA 1450) does not call for the information necessary for identifying the type of medical device used or billed for. Focused medical review is needed to determine what type of device is used and whether it is FDA approved or investigational.

LIMITATION ON LIABILITY

Items and Services for Which Assignment is Taken

Items and services that are denied on the basis of section 1862(a)(1) of the Social Security Act as not "reasonable and necessary," and that are furnished by providers and by suppliers in which assignment is taken, are subject to the limitation on liability provision under section 1879 of the Social Security Act. Section 1879 permits Medicare payment to be made for such services that are denied as medically unnecessary when neither the beneficiary nor the provider or supplier knew, or coul reasonably have been expected to know, that payment for the

service would be denied. When the beneficiary did not have such knowledge, but the provider or supplier knew, or could reasonably have been expected to know, that Medicare payment would be denied, the liability for the charges for the denied service rests with the provider or supplier. When the beneficiary knew, or could reasonably have been expected to know, that Medicare payment would be denied, the liability rests with the beneficiary.

In every such case where limitation on liability may apply, a determination must be made as to whether the beneficiary and/or the provider or supplier knew, or should have known, that Medicare payment would be denied. Absent evidence to the contrary, the beneficiary is presumed not to have known that payment would be denied. Evidence to the contrary generally must establish that proper written notice was given to the beneficiary prior to receiving an item or service (see "Proper Notice" Requirements below).

Under the limitation on liability provisions, one of the following results will occur with respect to liability for the charges for the denied service:

- The provider or supplier does not give the beneficiary proper written advance notice, and it is determined that the provider or supplier knew, or could reasonably have been expected to know, that Medicare payment would be denied. This situation includes instances where no notice is given or the notice does not meet Medicare requirements for "proper notice." In this case, liability for the charges for the denied service rests with the provider or supplier.

- The provider or supplier gives the beneficiary proper written advance notice. In this case, since the beneficiary had knowledge, prior to receiving the service, that Medicare payment for the service would be denied, liability for the charges for the denied service rests with the beneficiary.

- The provider or supplier does not give the beneficiary proper written advance notice and it is determined that the provider or supplier did not know, and could not reasonably have been expect to know, that Medicare payment would be denied. In this case, Medicare payment is made for the service because neither the beneficiary nor the provider or supplier knew, or could reasonably have been expected to know, that payment for the services would be denied.

Items and Services for Which Assignment Is Not Taken

The section 1879 limitation on liability provisions do not apply to items and services for which assignment is not taken. However, under section 1842(l) of the Social Security Act, physician services for which assignment is not taken that are denied as "not reasonable and necessary" are subject to certain refund requirements. Under section 1842(l), a nonparticipating physician who does not accept assignment in a particular case must refund to the beneficiary any amount collected for a service which he furnished to the beneficiary if the service is denied as "not reasonable and necessary" under section 1862(a)(1). However, refund is not required if:

- The physician informed the beneficiary in advance that Medicare was likely to deny payment for the service and, after being so informed, the beneficiary agreed to pay (see "Proper Notice" Requirements below), or

- The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service.

Refund Requirements for Durable Medical Equipment (DME) Suppliers

The Social Security Act Amendments of 1994 (enacted October 31, 1994) imposed new liability requirements on suppliers of DME. Under this new legislation, a DME supplier must refund to a beneficiary any amount paid by the beneficiary for an item for which Medicare payment is denied because:

The DME supplier knowingly contacted the beneficiary in violation of telephone solicitation provisions in section 1834(a)(17)(A) of the Social Security Act (sections 1834(a)(18) and 1879(h));

The DME supplier did not meet supplier number requirements under section 1834(j)(1) of the Social Security Act (sections 1834(j)(4) and 1879(h)); or

- The DME carrier issued an advance denial under section 1834(a)(15) of the Social Security Act (sections 1834(j)(4) and 1879(h)).

These provisions apply to items furnished on both an assigned and unassigned basis.

In addition, items provided on an unassigned basis that are denied under section 1862(a)(1) as "not reasonable and necessary" are also subject to the refund requirements.

In all of the above cases, refunds are not required if:

- The DME supplier informed the beneficiary in advance that Medicare was likely to deny payment for the item and, after being so informed, the beneficiary agreed to pay (see "Proper Notice" Requirements below), or
- The DME supplier did not know, and could not reasonably have been expected to know, that Medicare would not pay for the item.

"Proper Notice" Requirements

"Proper notice" means that, in advance of the furnishing of an item or service, the beneficiary is provided with sufficient information, in writing, to enable him or her to understand (1) that Medicare payment for that particular item or service will likely be denied, and (2) the reasons why the provider or supplier believes that payment will be denied (i.e., why the service is not covered). Such a notice allows the beneficiary to make an informed consumer decision as to whether to obtain the item or service at his or her own expense.

The following statements would satisfy the requirement for proper advance notice:

Provider/Supplier Notice

> "Medicare will only pay for services that it determines to be 'reasonable and necessary' under section 1862(a)(1) of the Medicare law. If Medicare determines that a particular service, although it would otherwise be covered, is 'not reasonable and necessary' under Medicare program standards, Medicare will deny payment for that service. I believe that, in your case, Medicare is likely to deny payment for (specify particular service(s)) for the following reasons: (the provider/supplier gives the reason(s) for his or her belief)."

Beneficiary agreement:

"I have been notified by my provider/supplier that he or she believes that, in my case, Medicare is likely to deny payment for the services identified above, for the reasons stated. If Medicare denies payment, I agree to be personally and fully responsible for payment."

NOTE: While the beneficiary's agreement to pay is required under section 1842(l) of the Social Security Act and the new DME refund requirements, no such requirement exists under the section 1879 limitation on liability provisions. However, in our program instructions (Medicare Carriers Manual §7300.5(A)), we suggest that the beneficiary sign the agreement. If a beneficiary's signature is absent, in the case of a dispute about the beneficiary's agreement to pay, the beneficiary's allegations will be given credence.

Attachments

1/ Endnote

Intraocular Lenses (IOLs)

IOLs were initially covered under Medicare as the result of Congress stipulating that FDA ensure their availability even though still in IDE status. As numerous IOLs are now approved by FDA, HCFA is in the process of withdrawing coverage of investigational IOLs.

Breast Implants

Medicare continues to cover silicone gel-filled breast implants for reconstruction even though FDA has called for clinical data in support of the safety and effectiveness of currently marketed implants. All new applications for these implants must follow FDA IDE regulations. Based on advice and information from FDA we have determined that breast implants are not experimental within the meaning of section 1862(a)(1)(A) of the Social Security Act and consequently, can continue to be covered under Medicare.

- Puts HCFA in position of evaluating minor v. substantial change. / FDA policy needs to Δ
- Also, IG investigating hospital implanting invest. devices

- Shld Medicare benef. be involved in ~~invest~~. clinical trials

AAMC, AHA, Cath. Health, Gr. NY Health A., Am Card. Thoracic Surgeons, HIMA,

Christine Johnson - Medtronic

Policy memo reiterating Medicare policy.

- FDA -- if it's an IDE, won't be a minor change.

If refinements to something you know works

Wld classify devices as Class A and class B.

PAUL D. WELLSTONE
MINNESOTA

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COMMITTEES:
ENERGY AND NATURAL RESOURCES
LABOR AND HUMAN RESOURCES
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United States Senate

WASHINGTON, DC 20510-2303

To: Chris Jennings

Fr: Alex Clyde

Re: Medicare reimbursement for clinical trials involving IDE's

Da: April 21, 1995

As we discussed, Senator Wellstone has been contacted by a number of constituents, including Medtronic, Mayo Clinic, and St. Jude Medical, regarding HCFA's refusal to pay for any of the hospital or medical costs for patients in clinical trials involving an IDE.

I have attached a four page summary of the situation, as well as a two page summary of proposed legislation. Our hope is that this problem could be resolved administratively as a part of overall regulatory reform and that legislative action would not be necessary.

You mentioned on the phone that there might be some interest in talking this through. Representatives from Medtronic, Mayo Clinic and St. Jude Medical would be delighted to meet with you or whoever you think the appropriate person would be. They are getting ready to introduce legislation and have been working on developing bipartisan support. I know, however, that they would be grateful to see the problem solved without having to deal with a protracted political battle.

I will contact you next week to see if you think there is anything the Administration can do on this. Also, please feel free to contact me at 224-8455 if you have any questions. Thanks for your help.

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MEDICARE ACCESS TO NEW MEDICAL TECHNOLOGIES ACT OF 1995

- Fulfills the original intent of Medicare that beneficiaries get access to the latest technology.
- Promotes innovation and research in new medical technologies.
- Is budget neutral, and imposes no new costs for the Medicare program.
- Does not compromise safety.

HCFA'S CURRENT POLICY IS UNFAIR

Suppose you're on Medicare and your doctor recommends a cardiac pacemaker for your heart. You and your doctor face this dilemma. Your doctor could use a current pacemaker product which, while adequate and safe, does not represent the latest technology. Medicare would pay for all the costs.

What if your doctor feels you would do better with the latest model pacemaker, which is undergoing FDA-supervised clinical trials under an IDE (investigational device exemption)? It is smaller, lasts longer, is more reliable, has features allowing the doctor to monitor your heart condition with less frequent and shorter office visits, and is on the market already in Europe. Today, under HCFA policy, that device is not available to you.

Here's another example. You are diagnosed with heart disease and require a new heart valve. Your doctor recommends a tissue valve. The newest tissue valves on the market have the potential to last significantly longer than current models.

Longevity of a valve matters to you, since heart replacement surgery is lengthy, complicated and expensive. It involves cracking open your chest, stopping your heart and replacing a diseased valve with a prosthetic device. There is generally a one week hospital stay and a long recuperation period. Under current HCFA policy, your surgeon and the hospital probably will not offer you a choice of this innovative new product because FDA-supervised clinical trials will not be reimbursable under current HCFA policy.

HOW DOES HCFA JUSTIFY THIS POLICY?

The Medicare law requires coverage of all "reasonable and necessary" services. It does not exclude coverage for new technologies that are part of clinical trials. HCFA (Health Care Financing Administration) has decided to exclude coverage for medical devices made available under IDEs. While HCFA argues that the exclusion appears in various instructions and letters to Medicare contractors, the instructions are subject to unclear interpretations and have not been implemented consistently. HCFA justifies the exclusion on the grounds that it has no way to determine whether such IDE devices are safe and effective. But this ignores the fact that the FDA, in granting an IDE, has found the devices sufficiently safe and effective to proceed with the supervised clinical trials under the IDE, and the physician and patient have concluded that the IDE device is the best treatment alternative.

PROBLEM COMPOUNDED BY OFFICE OF INSPECTOR GENERAL (OIG).

Last summer the HHS Office of Inspector General subpoenaed information from about 135 hospitals that had sought reimbursement for procedures in which investigational devices were used. This approach has brought many clinical trials in academic research programs and major hospitals to a halt. This bill is intended to assure continued access by Medicare beneficiaries to these clinical trials.

WHAT DOES THIS BILL DO?

Fulfills Original Intention of Medicare

The Medicare Act intended to cover the reasonable costs of services including "new services and techniques as they are adopted in the future." This bill ensures that beneficiaries will have the opportunity to get state-of-the-art medicine. The current blanket exclusion of coverage for all costs associated with the use of investigational devices deprives seniors of the benefits of the newest technologies.

Promotes Medical Research in Academic Settings

HCFA's refusal to pay any of the hospital or medical costs under an IDE is seriously damaging the research function of academic medical centers and major hospitals. Clinical trials are the life-blood of information on the benefits of new technologies. Trials should include patients who are intended to benefit from them, including patients over 65 years of age.

Is Budget Neutral

This bill does not add to the costs of the Medicare program. If a procedure involving an investigational device is used, no payment will be made unless there would have been payment if an FDA-approved device had been used or an alternative procedure performed. In addition, any payment that is made will not exceed the amount that would have been paid using an FDA-approved device, an alternative procedure, or a lesser amount if the Secretary determines it is necessary to assure budget neutrality.

Does Not Compromise Safety

Devices used in IDEs are subject to extensive FDA control. Manufacturers must submit a detailed application which includes a comprehensive description of the device and the investigational study, a complete report of all prior investigations, a description of the methods, facilities and controls used for manufacturing, processing, and storage, and copies of all materials distributed to Institutional Review Boards (IRBs) that approve the trials and to patients to obtain informed consent.

FDA will not grant an IDE if it determines the risks to patients are outweighed by the anticipated benefits. It limits the use to specific sites and specific numbers of patients. Trials can be terminated at any time. During this investigational phase, the manufacturer is prohibited from promoting or commercializing the device or charging a price that exceeds the amount necessary to recover its costs.

THE NEED FOR IMMEDIATE ADMINISTRATIVE CLARIFICATION OF MEDICARE COVERAGE OF MEDICAL DEVICES

Present Law and Medicare Policy: Under Section 1862(a)(1)(A) of the Social Security Act, Medicare payment may be made only for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Medicare law is silent as to whether payment should be made for items or services involving medical devices in clinical trials under an FDA Investigational Device Exemption ("IDE"). The purpose of the IDE is to encourage to the extent consistent with the protection of public health and safety and with ethical standards the development of useful devices for patient care. Therefore, care using IDE devices is ensured a high degree of regulatory protection.

Questions have now been raised as to whether Medicare should reimburse procedures involving a device used under an IDE, even when the physician believes the use of the newer device would be most beneficial to the patient. In practice, hospitals and physicians have billed in good faith and been reimbursed for these procedures.

In June 1994, the Office of the Inspector General ("OIG") within the Department of Health and Human Services sent subpoenas to approximately 130 hospitals seeking information and records on billing for certain medical devices. One effect of these subpoenas has been to focus attention on Medicare reimbursement for devices furnished under an IDE, causing hospitals to question how they can afford to continue to make available to Medicare beneficiaries the latest advances in medical technology. These advances most often include "next generation" devices which usually represent only an incremental change and yet often may result in significant reductions in lengths of stay, patient mortality, and the need for repeat procedures.

Effect of Current Confusion in Medicare Policy on Beneficiaries and Clinical Research: This current confusion regarding Medicare payment for services involving investigational devices has resulted in some facilities excluding Medicare beneficiaries from clinical trials or, in other cases, discontinuing clinical trials entirely, thus causing dramatic and undesirable consequences for Medicare beneficiaries and clinical advancements in the United States.

In keeping with the United States' preeminence in clinical advancements, technological improvements are constantly being made to medical devices. Each of these incremental changes generally requires FDA approval, which can take 2-3 years and results in devices being marketed in the United States often several years after they have been introduced in Europe. As part of the FDA review process, FDA requires manufacturers to enroll patients in

approved clinical trials. With implantable devices this is required even if the change in the device is of a minor nature, such as a change in the size of the lead for a pacemaker, or if the new device has all of the same basic components and capabilities as the older device and the change solely involves providing an additional capability.

Many hospitals and physicians who are using new devices in clinical trials, and who are aware that these devices already are commercially available in other developed countries, wish to use them in treating Medicare beneficiaries because the newer devices often provide significantly better outcomes. 1/ However, the current confusion over Medicare reimbursement has made it extremely difficult to enroll elderly patients in clinical trials, which would allow the collection of important information concerning the performance of the technology in this distinct population group. This exclusion of Medicare beneficiaries would skew clinical trial data. Already some medical facilities have limited or discontinued clinical trials entirely and some manufacturers have moved clinical trials abroad where payment is not in question.

Because of the OIG investigation, hospitals and physicians are now under intense scrutiny for having furnished to Medicare beneficiaries, in good faith, the best available treatment in a manner consistent with carefully constructed investigative protocols overseen by both FDA and local Institutional Review Boards ("IRBs"). Moreover, peer review organizations ("PROs") and Medicare carriers and intermediaries have approved the medical necessity of the procedure for particular patients. In many instances, there would have been no issue as to Medicare coverage if the providers had used less advanced devices that had been approved by FDA for marketing instead of the IDE devices. Therefore, Medicare payment for services involving these devices has not required additional Medicare outlays from what otherwise would have been required had older devices been used.

1/ The advantages of an IDE device can be significant. For example, for certain new transvenous implantable cardioverter defibrillators, the transvenous leads allow the device to be implanted without opening the patient's chest. The result has been a reduction in both surgical mortality (from 3.5 - 5.5% to 0.5 - 1.0%) and length of stay from (10 days to 7 days) compared to the earlier generation device. Moreover, newer defibrillators, currently in clinical trials in the United States, are even smaller. The smaller size allows for implantation in the pectoral region, allowing yet more patients to receive the system without having their chest opened. Preliminary results indicate a further reduction in surgical mortality (<0.5%) and hospital stay (now 2-3 days). The manufacturer charges the hospital the same amount for the new device as it does for the approved older generation device.

Investigational Device Trials Subject to Strict Oversight. In seeking to clarify Medicare policy regarding payment for hospital and physician services related to clinical trials involving investigational devices, it should be noted that such clinical trials are subject to strict oversight regarding safety and effectiveness.

Hospitals are required by law to ensure that local IRBs approve and review all innovative therapies and procedures to safeguard patient rights and welfare. The size, composition, and functions of an IRB are defined by regulation, including the substantive criteria on which an IRB's review of research involving new technology is based. See 21 C.F.R. Part 56; 45 C.F.R. Part 46. Essentially, IRBs weigh the potential clinical benefits of a new device or procedure against any potential risks in determining that a clinical trial for a particular product or procedure is appropriate.

In addition, FDA exercises close supervision over the use of IDE devices. As part of the IDE application that is submitted to FDA, the sponsor must provide detailed information about the device and prior and ongoing clinical studies, including a description of the device and investigational study; sponsor information; a complete report of prior investigations of the devices; the investigational plan; and a description of the methods, facilities, and controls used for the manufacturing, processing, storage, and installation of the device. 21 C.F.R. § 812.20(b).

Moreover, the sponsor in the IDE application must request FDA approval for a specific number of clinical sites, the maximum number of patients to receive the device, and study length -- all supported by statistical analysis. FDA monitors compliance through the sponsor's progress reports and through the Bioresearch Monitoring Program, whereby FDA inspectors visit sites and companies and review study records. While an investigation may enroll fewer than the approved number of patients, it may not exceed the approved number; nor can the sponsor or investigator unduly prolong an investigation if the data indicate that the device will not receive approval. Once the investigation begins, both investigators and sponsors have a continuing obligation to submit a variety of reports.

Independent regional PROs and Medicare carriers and fiscal intermediaries also are charged with reviewing hospital and physician procedures and patient records to ensure that services that are furnished to individual patients are reasonable and necessary. See 42 C.F.R. Parts 421 and 456. The PROs, carriers, and intermediaries each have the authority to deny payment for any service and procedure that they determine is not medically necessary or appropriate for a particular patient.

Thus IRBs, FDA, PROs, and Medicare contractors all exercise very tight control over the use of new devices undergoing IDE clinical trials. A clarification of Medicare policy to clearly allow payment for hospital and physician services involving IDE medical devices will not reduce this close scrutiny. This oversight will ensure that Medicare payment is made only in those situations in which FDA and the IRB have explicitly approved the use of a device in a clinical trial, thus assuring that the safety of beneficiaries is protected. In addition, because the FDA prohibits the commercialization of a device furnished under an IDE and the amount that the manufacturer may charge for such a device is limited to its costs, Medicare payment cannot become a vehicle for obtaining widespread reimbursement for a device before FDA clearance for marketing is granted. Finally, the PRO and Medicare contractors will still be authorized to deny Medicare payment if the services furnished a patient, in light of his or her particular circumstances, are not reasonable and necessary.

Need for a Prompt Administrative Solution: Hospitals and physicians increasingly are facing an untenable choice when treating Medicare beneficiaries with serious medical conditions: should they use less advanced devices that may involve more invasive procedures but with certain reimbursement or use new technology that they believe may be significantly better for their patients but which may not be reimbursed? Medicare beneficiaries clearly should have access to the benefits of new technology. An administrative clarification of Medicare payment policy is urgently needed to allow Medicare patients continued access to quality care and to ensure that the United States will retain its preeminence in clinical research.