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SEP 15 1995

Interagency Agreement

Between the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) regarding Medicare coverage of certain investigational medical devices.

I. Purpose

To establish a process by which FDA will assist HCFA to place IDE devices into categories based on the level of risk the device presents to patients. This categorization will be used by HCFA as part of its determination of which devices meet the requirements for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act (the "reasonable and necessary" clause). To be covered under Medicare, the device must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

II. Authority

The legal authority to enter into this Agreement is provided in sections 1874 and 1862(a)(1)(A) of the Social Security Act and sections 520(g) and 701(a) of the Federal Food, Drug and Cosmetic Act.

III. Background

In his National Performance Review, Vice President Gore directed the health agencies of the Department of Health and Human Services (HHS) to review their policies and processes to determine which requirements could be reduced or eliminated without lowering health and safety standards. In accordance with this directive, FDA reviewed its current

regulatory approval processes and HCFA reviewed its Medicare coverage policies for medical devices that have not received full FDA approval.

The Medicare program has historically interpreted the statutory terms "reasonable and necessary" to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. For Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, an approved Investigational Device Exemption (IDE) application served as an indication that the device was not "reasonable and necessary" within the meaning of the Medicare program. Under this policy, Medicare coverage was denied for devices that require, but have yet to receive, 510(k) clearance and those that have received an IDE but have not received PreMarket Approval (PMA).

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

Accordingly, FDA and HCFA are developing a revised policy to meet the needs of Medicare beneficiaries. The purpose of this effort is to determine if it is feasible to expand Medicare coverage to include certain medical devices that have not yet received FDA marketing approval/clearance without compromising the safety of medical care provided to Medicare beneficiaries. The intent is to devise ways to:

- o assure Medicare beneficiaries greater access to advances in proven medical technology;

- o encourage clinical researchers to conduct high quality studies; and,
- o clarify Medicare coverage of reasonable and necessary medical services during clinical trials for investigational devices.

IV. Scope of Work and Responsibilities

The Health Care Financing Administration, in conjunction with the Food and Drug Administration, will develop a process to differentiate between novel, first-of-a-kind medical devices and newer generations of proven technologies. New Medicare policies will be established in accordance with the requirements for Federal rule-making under section 553 of the Administrative Procedure Act.

This Interagency Agreement (IA) supports this process under which HCFA will establish a stratified policy for Medicare coverage of certain IDE devices under FDA review. For purposes of assisting HCFA in determining Medicare coverage, the FDA will place all IDEs it approves in one of two categories:

- o Category A - Experimental - innovative devices believed to be in class III for which "absolute risk" of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved). That is, FDA is unsure whether the device type can be safe and effective.
- o Category B - Non-experimental/Investigational - device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., 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. ¹

In order to properly categorize device investigations, HCFA and FDA have agreed to employ criteria outlined in the Attachment. As experience is gained in making categorizations, the criteria may be updated.

For purposes of determining Medicare coverage, medical devices classified under this system as "Category B: Non-experimental/Investigational," could be viewed as "reasonable and necessary" if they also meet all other Medicare coverage requirements. In some cases, HCFA may also wish to conduct a separate assessment of the device to determine medical necessity and appropriateness specifically with respect to Medicare beneficiaries.

In support of this basic agreement HCFA and FDA agree to the following:

- o FDA will assign each FDA-approved IDE to one of the two categories listed in attachment and notify HCFA of its categorization no less than each calendar quarter, either by electronic means or written communication.
- o Medicare coverage of devices under "investigation" is predicated, in part, upon their status with FDA. In

Note: Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes. Class I devices are the least regulated devices. These are devices that FDA has determined need to 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 post-market 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. Class III devices require Pre-Market Approval (PMA).

- the event a sponsor loses its category B categorization or violates relevant IDE requirements necessitating FDA's withdrawal of approval of the IDE, FDA will immediately notify HCFA in order that HCFA may reevaluate the coverage status of the device under Medicare. HCFA will establish specific procedures for the withdrawal of Medicare coverage. These procedures will be described in Medicare regulations.
- o FDA-approved IDE study protocols for each clinical study will require that devices be available in a circumscribed number of sites for an approved number of patients. HCFA will provide Medicare coverage and payments in accordance with these limitations and other protocol requirements (i.e., services provided by certain health care practitioners).
 - o FDA will assign each IDE an identification code or number which will enable HCFA to establish special claims processing procedures for Medicare claims associated with the clinical trial. FDA will complete this process for existing IDEs by November 1, 1995.
 - o FDA will require that the sponsor/manufacture and clinical investigators adhere to pertinent regulations, including obtaining informed consent for all patients participating in the clinical trial.
 - o FDA will establish a process for the reconsideration of the categorization of IDE devices. As part of this process, FDA will analyze all information submitted by a party in support of a request for reconsideration. HCFA will establish a process to review requests for reconsideration that are denied by FDA. FDA will provide necessary technical and expert support relating to FDA's categorization of devices to HCFA during the review process. FDA will provide information to HCFA to substantiate its decision on the categorization of each medical device under review.
 - o Reimbursement under the Medicare program for a device under an approved IDE will be limited to what Medicare would have paid for a comparable approved device.

V. Period of Agreement

This agreement takes effect upon the signatures of the two parties. The policy will be effective when final regulations are published in the Federal Register, expected to be on or about November 1, 1995. The agreement will continue in effect for an indefinite period.

VI. Modification/Cancellation Provisions

This Interagency Agreement (IA) may be modified at any time by mutual agreement of the parties. It may be canceled if both parties so agree in connection with a review, or if a Federal statute is enacted that materially affects the IA. In the event there is a cancellation of the IA, that cancellation will not be effective for at least 6 months.

VII. Confidentiality of IDE Information

FDA will provide HCFA access to all information in the IDE application for making Medicare coverage and payment determinations, insuring protection against program fraud and abuse, and claims processing. All IDE applications will remain on FDA premises. However, relevant portions of these applications may be duplicated by HCFA, as necessary, for purposes of Medicare coverage determinations.

To the extent that such information is in the possession and control of HCFA, it is subject to the disclosure and withholding rules established by Federal statutes and regulations. Applicable Federal statutes include, but are not limited to, the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), the Social Security Act (42 U.S.C. 1306a), and the Trade Secrets Act (18 U.S.C. 1905). Under this agreement, FDA will have a role in ensuring that its data release standards are met, either by reviewing any materials and paperwork to be released by HCFA, or through some other forms of oversight. Moreover, HCFA has no present intention of disclosing, or authorizing

the disclosure of, individual/patient or proprietary information.


VIII. Points of Contact

HCFA: Thomas Ault, Director
Bureau of Policy Development

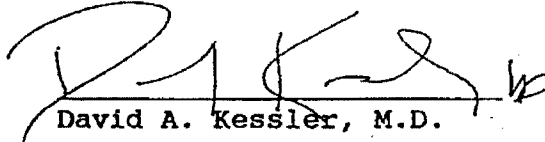
FDA: D. Bruce Burlington, M.D.
Director, Center for Devices
and Radiological Health

IX. Signatures of Acceptance

8/29/95
Date


Bruce C. Vladeck, Administrator
Health Care Financing Administration

9/8/95
Date


David A. Kessler, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Attachment

CRITERIA FOR CATEGORIZATION OF
INVESTIGATIONAL DEVICES

Category A: Experimental

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 Class III devices, refer to the criteria under Category B); or
2. Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication or use.

Category B: Non-experimental/Investigational

1. Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, i.e., to establish substantial equivalence to a previously/currently legally marketed device; or
2. Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device; or
3. Class III devices with technological advances compared to a PMA approved device, i.e., a device with technological changes that represent advances to a device that has already received pre-market approval (generational changes); or
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; or
5. Pre-amendments Class III devices that become the subject of an IDE after FDA requires premarket approval, i.e., no PMA was submitted or the PMA was denied; or

6. Non-significant risk device investigations for which 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 FDA will agree on the additional criteria to be used. FDA will then use this criteria to assign the device(s) to a category. As experience is gained in the categorization process, this attachment may be modified.