Title: Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices

Description: Section 404 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) is intended to ensure that FDA has effective processes to resolve the scientific disputes that occasionally arise between FDA and the regulated industry. Section 404 added new section 562 of the act which requires FDA to establish, by regulation, a procedure under which a person who is a sponsor, applicant, or manufacturer may request a review of a scientific controversy, when no other provision of the act or regulation provides such review.

In a final rule issued in the **Federal Register** on November 18, 1998 (63 FR 63978), FDA amended 21 CFR 10.75 to reflect the provisions of FDAMA. Each affected FDA center is responsible for developing and administering its own processes for handling requests for section 404 reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The draft guidance document outlines the requirements for persons who are sponsors, applicants, or manufacturers of medical devices and who wish to file a request for a review of a scientific dispute by the panel as set out in the guidance. Persons filing a request for review should provide a CDRH ombudsman with a concise summary of the scientific issue in dispute, including a summary of the particular FDA action or decision to which the requesting party objects, any prior advisory panel action and the results of all efforts that have been made to resolve the dispute, and a clear articulated summary of the arguments and relevant data and information. They may also provide material outside the official administrative record and not in the possession of FDA at the time the decision or action in dispute was made if it has a significant bearing on the issue or related public health considerations. The information that is collected will form the basis for resolving the dispute between the requester and FDA.

The likely respondents to this collection of information are medical device sponsors, applicants, or manufacturers who have a scientific dispute with FDA and who request a review of the matter by the Medical Devices Dispute Resolution Panel.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
6	1	6	20	120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Medical Devices Dispute Resolution Panel represents a new process for resolving scientific disputes. In arriving at the estimates in Table 1 of this document for the burden imposed in connection with a request for review by the Medical Devices Dispute Resolution Panel, FDA considered the number and substance of similar appeals of various types made to FDA in recent years, knowledge of similar submissions and discussions with manufacturers.

V. Comments

Interested persons may, on or before July 26, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments concerning the information collection requirements must be received by the Dockets Management Branch by June 28, 1999. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–10446 Filed 4–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3432–GN]

RIN 0938–AJ31

Medicare Program; Procedures for Making National Coverage Decisions

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

ACTION: General notice.

SUMMARY: This notice announces the process we will use to make a national coverage decision for a specific item or service under sections 1862 and 1871 of the Social Security Act. This notice will streamline our decisionmaking process and will increase the opportunities for public participation in making national coverage decisions.

EFFECTIVE DATES: This notice is effective June 28, 1999.

FOR FURTHER INFORMATION CONTACT: Ron Milhorn, (410) 786–5663; Maria Ellis, (410) 786–0309, for a graphical representation of the process.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/nara__docs/, by

using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call 202–512–1661; type swais, then log in as guest (no password required).

I. Background

We published a notice on April 29, 1987 (52 FR 15560), that described the process we used to make Medicare coverage decisions, including decisions regarding whether new technology and services can be covered. We invited the public to comment on the procedures, and specifically on procedures for allowing greater public input into the coverage decisionmaking process when appropriate.

In response to the comments we received on that notice, we developed a proposed rule. That proposed rule set forth our process and criteria for making coverage decisions under the Social Security Act (the Act). In addition, the proposed rule described the relationship between our coverage decisions and the roles played by the Food and Drug Administration (FDA) and other parties, including Medicare contractors. We published the proposed rule on January 30, 1989 (54 FR 4302).

We have made changes to our internal procedures in response to the comments we received following publication of the 1987 notice and the January 1989 proposed rule. In addition, over the past year, we have received numerous requests to revise our process to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage decision in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries.

II. Purpose of This Notice

We have decided not to adopt the January 29, 1989 proposed rule. This notice announces the process we will use to make a national coverage decision under the Medicare program. It sets forth the steps we are taking to make our national coverage decisionmaking process more open and understandable to the public. We intend to take the following steps:

- Explain why and how we make a national coverage decision and how we reconsider a previously-made decision. This notice outlines the review process and the steps involved. By offering this explanation, we hope to increase public awareness of the process we use, and to provide information about when and how the public may most effectively contact us to offer information on issues under consideration.
- Maintain a current list of issues we are considering for national coverage decisions. This list identifies our staff person responsible for reviewing each issue, the stage at which an issue is in the review process, and the materials we are reviewing to reach a decision on the issue.
- Make all of the above public and accessible using our Home Page (http://www.hcfa.gov) on the Internet as a primary tool for publicizing these matters. We believe use of our Home Page will offer quick and easy access that will enable the public to determine the status of any issue under review.
- Prepare and maintain a complete and indexed record for all issues that we review for national coverage decisions. This record, a summary of which will also be available on our Home Page as part of the record of the issue, will form the basis for any subsequent requests for reconsideration of the issue, as well as the formal record of review for any challenge to our coverage decision under section 1869(b)(3) of the Act.
- Continue to review new medical and scientific information in order to modify a national coverage decision when appropriate.

We are also announcing our intent to work with various sectors of the medical community to develop and publish guidance documents specific to their needs and interests. These ''sector-specific'' guidance documents will offer a more detailed explanation of how we would apply the general national coverage criteria to a new item or service proposed for coverage eligibility in the particular sector involved. Guidance documents will provide a vehicle for us to explain how the general criteria apply to the special circumstances unique to a particular sector of the health care industry. We will develop the guidance documents after we publish the proposed and final rules for the criteria we will use to make a national coverage decision.

This notice is intended to provide clearer information on our national coverage decisionmaking process, and to ensure that it is open and understandable to the public. We would welcome comments from the public on our process. Comments may be submitted to us in writing through the traditional mail service, or through our Home Page identified in section IV.K. of this notice.

III. Medicare Coverage—General Principles

A. Statutory Authority

Administration of the Medicare program is governed by title XVIII of the Act. Under the Medicare program, the benefits available to eligible beneficiaries are called ''covered'' services.

Medicare is a defined benefit program—the services covered are broadly defined in the Act, in what we call benefit categories. There are currently about 55 benefit categories in the Act, some broadly defined, others more narrowly defined. Specific health care services must fit into one of these benefit categories to be eligible for coverage under Medicare.

The Act does not list the specific items and services eligible for coverage under the Medicare program. Rather, it lists categories of items and services, and vests in the Secretary the authority to make decisions about which specific items and services within these categories can be covered by the Medicare program. That is, the Act allows Medicare to cover medical devices, surgical procedures, and diagnostic services, but generally does not specify which particular medical devices, surgical procedures, or diagnostic services can be covered, or, conversely, are excluded from coverage. The Congress vested in the Secretary the authority to make these more specific decisions regarding the items and services eligible for coverage under Medicare. Section 1862(a)(1)(A) of the Act states, in part, that no payment may be made for any expenses for services that are not ''reasonable'' and ''necessary'' for the diagnosis and treatment of illness or injury. For over 30 years, the Medicare program has exercised this authority to make coverage decisions regarding whether specific services that meet one of the broadly-defined benefit categories can be covered under the program.

We previously proposed that we would establish the procedures we would follow for making national coverage decisions by issuing regulations. The Administrative Procedure Act (APA), however, exempts ''rules of agency organization, procedure, or practice'' from the notice-and-comment rulemaking procedures (5 U.S.C. 553(b)(3)(A)). The primary purpose of the procedural rules exemption in the APA is to ensure that an agency retains latitude in organizing its internal operations. Additional flexibility is particularly important given the dynamic changes in the health care industry that may have a profound

effect on the health of Medicare beneficiaries.

The Congress has provided that national coverage decisions may be issued without requiring us to engage in notice-and-comment rulemaking procedures (sections 1871(a)(2) and 1869(b)(3)(B) of the Act). National coverage decisions are our national policy statements granting, limiting, or excluding Medicare coverage for a specific medical service, procedure, or device. A national coverage decision is binding on all Medicare carriers, fiscal intermediaries, peer review organizations (PROs), health maintenance organizations (HMOs), competitive medical plans (CMPs), health care prepayment plans (HCPPs) and, in the future, program safeguard contractors (PSCs) when published in HCFA program instructions or in the **Federal Register**. In addition, national coverage decisions made under section 1862(a)(1) of the Act may not be disregarded, set aside, or otherwise reviewed by an administrative law judge during the administrative appeals process (42 CFR 405.732 and 405.860).

By establishing the process we will use in making a national coverage decision by procedural rules rather than notice-and-comment rulemaking, we believe we will better be able to serve Medicare beneficiaries. Using a procedural rule does not mean that the process that we will use will be changed frequently or in an arbitrary manner. Before implementing any changes to the national coverage decision process, we will provide advance public notice about those changes. In addition, we will separately provide notice and an opportunity for public comment on the substantive criteria we would use in making a national coverage decision.

B. Medicare Contractors and Coverage Policies

We contract with private insurance companies, referred to as carriers and intermediaries to process Medicare claims (that is, claims-payment contractors). Local PROs (and, in the future, PSCs) are also involved in claims adjudication processes. We call all of these entities ''Medicare contractors.''

Medicare contractors review and adjudicate claims for services to assure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. In the absence of a specific national coverage decision, coverage decisions are made at the discretion of the local contractors.

Contractors may also publish local medical review policies (LMRPs) to provide guidance to the public and medical community within a specified geographic area. These LMRPs explain when an item or service will be considered ''reasonable and necessary'' and thus eligible for coverage under the Medicare statute. If a contractor develops an LMRP, its LMRP applies only within the area it serves. While another contractor may come to a similar decision, we do not require it to do so. An LMRP may not conflict with a national coverage decision once the national coverage decision is effective. If a national coverage decision conflicts with a previously made LMRP, the contractor must change its LMRP to conform it to the national coverage decision. A contractor may, however, make an LMRP that supplements a national coverage decision.

IV. HCFA's Process for Making National Coverage Decisions

A. Initiation of Coverage Review Process

We will initiate our review process for making a national coverage decision when we identify issues internally that we wish to consider for a national coverage decision or when we receive a formal request for us to review an issue and make a national coverage decision.

1. Initiation Based on Internal Decisions

We will initiate our review process if we determine that a service requires a national coverage decision. Examples of when we may do this include, but are not limited to, the following:

- There are conflicting carrier or intermediary policies.
- The service represents a significant medical advance, and no similar service is currently covered under Medicare.
- The service is the subject of substantial controversy among medical experts as to its medical effectiveness.
- The service is currently covered, but is widely considered ineffective or obsolete.
- There are program integrity issues surrounding significant underutilization or overutilization of the service.

2. Initiation Based on External Formal Request

We will also initiate our review process if we accept an external formal request for a national coverage decision. The rules for a formal request are outlined in section B.2.

B. Informal Contacts and Formal Requests for HCFA Review

We will treat any communication we may receive from an individual or organization inquiring about a national coverage decision as either an informal contact or a formal request.

1. Informal Contacts

We currently receive public contacts by telephone or in writing that raise general questions about the coverage of services. We consider these to be informal contacts. These include questions asking us to explain the current coverage of a particular service, or to assist and advise the requestor about how to formally request that we make a national coverage decision.

If the contact leads to questions about how to request a national coverage decision, we will advise the requestor of the information we need to have submitted with a formal request. We will offer assistance to the requestor to clarify the amount and kind of information necessary for us to evaluate whether an item or service meets the statutory requirement that the item or service is ''reasonable'' and ''necessary.''

In some cases, we will assume the task of gathering and preparing the information necessary to proceed to a formal request. This may occur when the request is made by a Medicare beneficiary or another member of the public who we could not reasonably expect to have access to scientific data that may be necessary to support a formal request. Because we expect a considerable amount of contact and discussion with the requestor and because some flexibility is needed, we do not believe that strict timeframes are warranted following this informal contact.

Although informal contacts are not confidential, we will not announce an informal contact that may lead to a request on our Home Page. We will not release, to the extent permitted by law, company proprietary material, trade secrets, or other information shared with us on a confidential basis before the contact makes a formal request.

2. Formal Requests

We will require a requestor to make a formal request for a national coverage decision in the following manner:

- The request must be in writing.
- The requestor must identify the request as a ''formal request for a national coverage decision.''
- The requestor must submit supporting documentation that we will specify. At a minimum, the requestor must submit the following information:

+ A full and complete description of the service in question, including the benefit category or categories of the Medicare program to which it applies.

+ A compilation of the medical and scientific information currently available.

+ A description of any clinical trials or studies currently underway, which

might be relevant to a decision regarding the coverage of the service. This description should be as complete as possible without disclosing confidential information.

+ In the case of a drug, device, or a service using a drug or device subject to regulation by the FDA, the status of current FDA administrative proceedings concerning the drug or device involved. In the case of any item regulated by the FDA, the FDA labeling for the item, together with an indication of whether the service for which a review is being requested is covered under the labeled indication(s). We recognize that FDA changes the labeling of drugs and 510(k) devices and devices with premarket approvals (PMAs). For the purposes of our review, we are interested in the labeled indications at the time of the submission of the formal request. If, during our review, the labeled indications change, we expect the requestor to notify us.

+ In the case of a request for reconsideration, new evidence supporting the request or an analysis of our earlier decision demonstrating that we materially misinterpreted the evidence submitted with the earlier request.

Upon receipt of a formal request, we will quickly review the request to determine if the requestor submitted adequate supporting documentation to enable us to review the service. If we determine that the request lacks adequate supporting documentation to enable us to review the service to make a national coverage decision, we will notify the requestor and identify the information that we require to enable us to review the service. We will not post the request on our list of pending coverage issues on our Home Page until we receive adequate supporting documentation.

C. Acceptance of Formal Request, Initiation of Timeframes

If we determine the request is adequately supported, we will accept the request and begin our review process. Acceptance of a formal request starts a series of internal timeframes that we are establishing for ourselves in this notice to ensure that requests are processed in a timely manner. The discussion, negotiations, and other work done before that point do not count toward meeting these timeframes. If we initiate review of a service for purposes of making a national coverage decision, we will follow this same review process, post these issues on our Home Page, and generally follow our timeframes and maintain the same openness we provide for issues that have been raised by formal requests.

We expect the timeframes we are establishing in this notice for ourselves generally will be the timeframes that we believe we will need to respond to a complex coverage issue. Generally, we would be likely respond in a shorter amount of time if the issue is not as complex, is not controversial, or is supported by clear medical and scientific evidence that establishes that the item or service is ''reasonable'' and ''necessary.'' Likewise, a significantly more complex and controversial coverage issue may result in longer processing timeframes. We understand the importance of making timely coverage decisions and the benefits that may be afforded Medicare beneficiaries. Therefore, we will expedite the processing of all formal requests for a coverage decision.

We will post the acceptance of a request by adding the item or service to the list of pending coverage issues on our Home Page. We will identify all subsequent actions, such as meetings and requests for assessments. This will permit interested individuals to track an issue through our entire review process. Interested individuals could contact us at optimal times to offer comments, furnish information (particularly scientific data), or meet to discuss the issue. This public tracking system will be a key element in making our national coverage decision process more efficient as well as more open and accessible to the public.

We will ordinarily respond in writing to the requestor within 90 calendar days of receiving the complete request. If the requestor submits additional medical and scientific information during this 90-day period, however, we will ordinarily respond to the requestor within 90 calendar days of receiving the additional information.

Because the FDA is charged with regulating whether devices or pharmaceuticals are safe and effective for use by consumers, we will generally accept a formal request for a device or a pharmaceutical only after it is officially approved or cleared for marketing by the FDA. One exception is if the FDA has granted a device a Category B investigational device exemption (IDE) or it has been approved as a nonsignificant risk IDE by an institutional review board. Our process for making a national coverage decision for Category B IDE devices is described in our regulations at 42 CFR 405.205. Parties interested in the coverage of a drug or device (other than a Category B IDE device), however, may contact us with an informal request while the drug or device is proceeding through the FDA approval process. We are willing to meet and discuss these situations. We will monitor the progress of the drug or device through the FDA process so that we may make a rapid coverage decision if FDA approval or clearance for marketing is obtained. The general timeframes we have set for formal requests will not begin, however, until we learn that the FDA has approved or cleared the device for marketing.

In general, within 90 days of receiving a formal request, we will respond in writing to the requestor and post this information on our Home Page. Our formal response to a formal request or an internally-initiated review will include, at a minimum, one of the following:

- A decision that the request duplicates another pending request and we will combine the requests and respond with a single decision.
- A decision that the request duplicates an earlier request for which we have already made a national coverage decision (and that there is insufficient new evidence to begin the process again).
- A referral for a technology assessment.
- A referral to the Medicare Coverage Advisory Committee (MCAC) for consideration.
- A national noncoverage decision (which precludes contractors from making Medicare payment).
- No national coverage decision (which allows for local contractor discretion).
- A national coverage decision with limitations on coverage.
- A national coverage decision without limitations on coverage.

If our decision is a national noncoverage decision or we decide not to make a national coverage decision, our response will also identify deficiencies in the evidence and the types of information that we will require to reach a national coverage decision or evidence we would need for us to withdraw a national noncoverage decision.

D. HCFA Processing of a Formal Request

We may process a formal request in one of the following ways:

1. Our review requires little or no outside input.

Issues that fall into this category are usually those for which the medical and scientific information submitted by the requestor (as well as any additional information available to us) is overwhelmingly in favor of, or against, coverage. We will usually complete our

review and issue our decision within 90 days of receiving the formal request.

2. Our review requires a referral to the MCAC or an outside assessment of the service.

Most national coverage issues fall into this category. These issues will generally be complex and controversial and often involve broad health policy concerns. Usually these issues also may require extensive consultation with specialty societies, medical researchers, and others familiar with the service and the evidence presented to support its coverage.

We will notify the requestor, usually well within 90 days from receiving the requestor's formal request, that the request will require a referral to the MCAC and the anticipated due date for our response. We will consider the need and amount of time for receiving a recommendation from the MCAC. If applicable, we will consider the need for, and amount of time that will be required to perform, a technology assessment and to review these findings. We will make every effort to assure that we obtain timely assessments.

We will inform the requestor that, although we will make every effort to meet the general timeframes, the use of assessments and/or a referral to the MCAC, together with the possibility of emerging new medical and scientific information, may sometimes result in revising our timeframe for responding to the request. We will post any changes for all timeframes on our Home Page to keep the public informed.

E. Additional Factors Affecting Our 90-Day Timeframe for Responding to Formal Requests

It is our intention to respond to a formal request for a national coverage decision within 90 days of receiving a request. In general, we expect to be able to meet our self-imposed timeframes. There may be circumstances, however, that would prevent us from meeting the timeframes. For instance, if the requestor subsequently submits additional information, or requests that our national coverage review be expanded or narrowed, we may decide that we are unable to respond until 90 days after receipt of the additional information or request. We would post the revised due date for our response on our Home Page. Also, if another interested individual submits additional information that materially affects our consideration of the issue, we may notify the requestor of the need to reset our due date for responding to the initial request.

In addition, if we discover additional information not submitted as part of the formal request (for example, reports of clinical trials, and assessments either completed or close to completion), we may notify the requestor and the public about the newly-discovered information and the need to reset our due date for responding to the initial national coverage decision request. For example, an assessment related to an issue we are considering may be scheduled to be issued shortly after our 90-day due date for responding to a formal request. We would normally wish to review the assessment because it may contain useful scientific and timely data before responding to the request. Also, changes or modifications in the FDA approval or clearance for marketing of a drug or device used in furnishing a service may affect the timing of our response to a formal request.

F. Medicare Coverage Advisory Committee

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) that announces the establishment of the MCAC. The MCAC will make recommendations to us about whether services can be considered ''reasonable'' and ''necessary'' under title XVIII of the Act. We expect the MCAC will meet approximately twice a year. The notice requested, by January 29, 1999, nominations for members for the Committee. (We have received more than 400 nominations.) The notice also announces the signing by the Secretary on November 24, 1998 of the charter establishing the Committee. This charter ends at close of business on November 23, 2000 unless renewed by the Secretary. The MCAC Charter is available on our Home Page.

In general, we may refer an issue to the MCAC if the service meets any of the following conditions:

- It is the subject of significant scientific or medical controversy—Is there a major split in opinion among researchers and clinicians regarding the medical effectiveness of the service, the appropriateness of staff or setting, or some other significant controversy that would affect whether the service is ''reasonable'' and ''necessary'' under the Act?
- It has the potential to have a major impact on the Medicare program.
- It is subject to broad public controversy.

If we refer a formal request to the MCAC, the discussion of the request at the MCAC meeting will be subject to the requirements of the Federal Advisory Committee Act. Therefore, we will publish a notice in the **Federal Register** generally 30 days before the meeting. It will announce the agenda and the time and place of the meeting so that all interested individuals will have the opportunity to attend the meeting and present their views. We will request that all evidentiary presentations be submitted to us in writing at least 20 days before the meeting. At the end of each meeting, there will be an additional period for the public to present comments. After considering all presentations and comments, the MCAC will create its recommendation to us concerning national coverage, which it must adopt by majority vote.

We expect the MCAC will make its recommendations to us as expeditiously as possible. We will provide an estimate of when we believe we will receive the MCAC referral; however, we cannot predict when the MCAC may decide, during its deliberations, that additional information is needed for it to make a recommendation to us.

Once the MCAC makes a formal recommendation to us, we will post it on our Home Page. Within 60 calendar days of receiving the recommendation, we will either adopt the MCAC recommendation (or adopt it with modifications) or notify the requestor and the public why we disagree with the MCAC recommendation. If we choose not to adopt the recommendation, our notification will explain the reasons why we have decided not to adopt the MCAC recommendation. We will also identify further evidence we will require be submitted to us. Again, we will post our decision on our Home Page.

G. Technology Assessments

During our review of a request, we may find that we will require a technology assessment to complete our review. Generally, a technology assessment provides a systematic analysis of the safety, efficacy, and effectiveness of a health care technology.

Two of the reasons we may request a technology assessment include the following:

- There is sufficient medical and scientific literature available to provide a basis for an assessment, but the complexity of the subject and/or complexity of the issue exceed our staff expertise or capability.
- The MCAC requests a technology assessment.

A key element of the assessment process is the need for the assessor to be impartial. If we require an assessment, we will obtain it from an impartial third party, such as the Agency for Health Care Policy and Research. Under agreement with us, the assessor will conduct or arrange for preparation or

purchase of the assessment, as appropriate.

If we receive a request for coverage on an item or service for which an assessment is already underway, we will immediately inform the requestor of the status and estimated timing of the assessment. If we initiate an assessment in response to a request, we will, within 45 days of requesting an assessment, inform the requestor of the estimated time for receiving the assessment.

We anticipate that a few technology assessments will be completed within 90 days of their initiation. Complex assessments will, of course, require additional time but will not normally take longer than 12 months from the time the assessment was begun. We will post completed technology assessments on our Home Page.

H. HCFA Announcement of National Coverage Decisions

Before we issue a national coverage decision as a ruling, program instruction to our contractors, or **Federal Register** document, we will announce our intention to make the national coverage decision in the form of a decision memorandum. The decision memorandum will merely announce our intention to make a national coverage decision. It will not be binding on our contractors until we publish the national coverage decision in the **Federal Register** or issue it as a program instruction or HCFA ruling.

If we do not refer an issue to the MCAC or for a technology assessment, we will forward the decision memorandum to the requestor and post it on our Home Page no later than 90 calendar days after we accept the formal request (or after we accept additional medical and scientific information supporting the request). In situations involving a referral to the MCAC or that require a technology assessment, we will forward the decision memorandum to the requestor and post it on our Home Page generally no later than 60 calendar days after receiving the MCAC recommendation or the technology assessment or the technical assessment followed by an MCAC recommendation.

The memorandum may contain remarks regarding the level and content of evidence presented and reviewed. Moreover, if significant, we will include the conclusions and recommendations of any assessments or the MCAC recommendations received. Finally, the memorandum may include any other factors that had a major influence on our decision, and will contain our rationale for the decision we made.

If we announce our intention to not cover or to reduce coverage of a service, the decision memorandum will include the reasons for noncoverage and identify the information we will require for a different coverage decision. The memorandum will not be effective immediately, but will become effective on the date specified in the national coverage decision.

I. Implementation of National Coverage Decisions

Within 60 calendar days of forwarding the decision memorandum to the requestor and posting the memorandum on our Home Page, we will issue a national coverage decision. As explained previously, we may publish a national coverage decision in a variety of forms such as program memorandum, manual instruction, HCFA ruling, or **Federal Register** notice. We will also publish a reference to each national coverage decision in the **Federal Register** as part of our quarterly listing of program issuances. We could also choose to publish a general notice in the **Federal Register**. If we withdraw or reduce coverage for a service, we will publish a general notice in the **Federal Register**.

The program instruction, **Federal Register** notice, or HCFA ruling will include the date on which our claims-payment contractors will implement any change in payment that may result from the national coverage decision. Generally, we expect to make a payment change effective within 180 calendar days of the first day of the next full calendar quarter that follows the date we issue the national coverage decision.

If we make a positive decision to cover an item or service, numerous complex and related steps remain before a payment change is made. We must determine which codes the providers, suppliers, and our contractors will use for submission and payment of claims consistent with our coverage decision and issue appropriate instructions. We must also determine the appropriate Medicare payment level. Finally, we must develop and issue claims processing instructions to our systems maintainers and claims-payment contractors to ensure accurate payment and to include the necessary program integrity safeguards and edits. Our contractors now implement systems changes at the start of a calendar quarter, and instructions are required well in advance in order to install and test the systems changes.

As stated previously, a national coverage decision is binding on all Medicare carriers, fiscal intermediaries, PSCs, PROs, HMOs, CMPs, and HCPPs when issued as a HCFA program instruction or HCFA ruling, or published in the **Federal Register**. Moreover, national coverage decisions made under section 1862(a)(1) of the Act are subject to limited administrative and judicial review (*See* 42 CFR 405.860.).

J. Revisiting National Coverage Decisions

After we implement a decision or if there is an existing national coverage decision, we will consider new requests to revise a national coverage decision concerning the service at any time. These requests should include additional medical and scientific information that we have not considered to make our original national coverage decision or an analysis of how we materially misinterpreted original information submitted by the requestor. We will not accept any new request that does not include this additional information.

If we receive the additional information as part of a request for reconsideration, we will consider this a new formal request and start our review process. The timeframes for our formal review process will apply to a new formal request. Our original national coverage decision will remain in effect until we withdraw that decision and make another national coverage decision.

K. How To Access HCFA's Home Page

Our Home Page can be accessed by entering ''http://www.hcfa.gov.'' To access information about our coverage process, select ''Development of coverage policies'' and then ''Medicare Coverage Process.''

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for section IV, HCFA's Process for Making National Coverage Decisions.

In accordance with that section, HCFA will accept an external formal request for a national coverage decision if the information collection requirements outlined above in section IV.B.2 are met. These requirements include:

- The request must be in writing.
- The requestor must identify the request as a ''formal request for a national coverage decision.''
- The requestor must submit supporting documentation that we will specify. At a minimum, the requestor must submit the following information:
- A full and complete description of the service in question, including the benefit category or categories of the Medicare program to which it applies.
- A compilation of the medical and scientific information currently available.
- A description of any clinical trials or studies currently underway, which might be relevant to a decision regarding the coverage of the service. This description should be as complete as possible without disclosing confidential information.
- In the case of a drug, device, or a service using a drug or device subject to regulation by the FDA, the status of current FDA administrative proceedings concerning the drug or device involved. In the case of any item regulated by the FDA, the FDA labeling for the item, together with an indication of whether the service for which a review is being requested is covered under the labeled indication(s). We recognize that FDA changes the labeling of drugs and 510(k) devices and devices with premarket approvals (PMAs). For the purposes of our review, we are interested in the labeled indications at the time of the submission of the formal request. If, during our review, the labeled indications change, we expect the requestor to notify us.
- In the case of a request for reconsideration, new evidence supporting the request or an analysis of our earlier decision demonstrating that we materially misinterpreted the evidence submitted with the earlier request.

The burden associated with this requirement is the time and effort necessary to disclose the materials referenced above to HCFA. We estimate that on average it will take each entity 40 hours to provide the materials and that there will be 200 requests on an annual basis. Therefore, the total annual burden associated with these requirements is 8,000 hours. While an estimate of 40 hours may appear low, given that entities will most likely have already compiled these data to meet the FDA approval process, we believe it to be accurate.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies directly to the following:

Health Care Financing Administration, Office of Information Services, Standards and Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke HCFA–3432–GN

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, HCFA Desk Officer.

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

Authority: Sections 1862, 1869(b)(3), and 1871 of the Social Security Act (42 U.S.C. 1395y, 1395ff(b)(3), and 1395hh).

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

Dated: April 21, 1999.

Nancy-Ann Min DeParle,

Administrator,

Health Care Financing Administration.

Dated: April 21, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–10460 Filed 4–22–99; 10:36 a.m.]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Sample Survey of Registered Nurses, 2000—New

The National Sample Survey of Registered Nurses (NSSRN) is carried out to assist in fulfilling three congressional mandates: (1) Section 951 of P.L. 94–63 requires gathering data on(a) the number and distribution of nurses by type of employment and location practice, (b) the number of nurses practicing full-time and part-time within the U.S. and within each State, (c) the average rate of compensation for nurses by type of practice and location of practice, (d) the activity status of the total number of nurses with advanced training or graduate degrees in nursing, by specialty, including nurse practitioners, nurse clinicians, nurse researchers, nurse educators, and nurse supervisors and administrators, and (f) the number of nurses entering the U.S. annually from other Nations; (2) Section 806(f) of P.L. 105–392 requires discipline workforce information and analytical activities for advanced nursing education, workforce diversity, and basic nursing education and practice; and (3) Section 792 of Title VII of the Public Health Service Act calls for the collection and analysis of data on health professions.

The information from this survey will serve policymakers, legislative bodies, health professionals, and Government agencies to inform workforce policies. Data collected in this survey will assist in determining the impact that changes in the health care system are having on employment status of registered nurses and their employment settings.

The proposed survey design for the 2000 NSSRN follows that of the previous six surveys and the projected sample size is approximately 49,200 registered nurses, with a response rate of 80%. Each respondent will be asked to complete a self-administered mail questionnaire containing items on educational background, duties, employment status and setting, geographic mobility, and income.

Respondent burden is estimated as follows: