OMB control Nos.	Approved CFR sections in title 42, title 45, and title 20 (note: sections in title 45 are preceded by ''45 CFR,'' and sections in title 20 are preceded by ''20 CFR'')
0938–0897	412.22, 412.533.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3062–N]

RIN 0938–AK61

Medicare Program; Revised Process for Making Medicare National Coverage Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice revises the process we will use to make a national coverage determination for a specific item or service under sections 1812, 1832, 1861, 1862, 1869, and 1871 of the Social Security Act, as revised by sections of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. This notice further clarifies our decision-making process and increases the opportunities for public participation.

EFFECTIVE DATE: This notice is effective on October 27, 2003.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, (410) 786–0840.

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I. Background

In the April 27, 1999 **Federal Register** (64 FR 22619), we published a notice that announced changes to our internal procedures for developing a national coverage determination (NCD) and making the NCD process more open and understandable to the public. As we strive for continuous improvement of our processes, and in recognition of the changes that section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) requires, we are revising our process for developing an NCD in order to make the process more efficient and ensure that we have access to all relevant information to make fully informed decisions. (BIPA, Pub. L. 106–554, was enacted on December 21, 2000.) The processes described in this notice apply to both scope of benefit and section 1862(a)(1) determinations as defined in the Social Security Act (the Act). This notice replaces the April 27, 1999 notice and will be effective on October 27, 2003. Improvements include the following:

- Updating and organizing the reconsideration process into one section, and distinguishing it from an initial request to make an NCD.
- Defining, streamlining, and organizing the contact/inquiry information into one section.
- Revising, formalizing, and updating the elements that constitute a complete, formal request to reflect best practices.
- Adding a section on information that does *not* constitute a complete, formal request.
- Updating and clarifying the conditions for acceptance of a complete, formal request.
- Making it clear that all evidence currently available must be adequate for us to conclude that the item or service is reasonable and necessary.
- Establishing two main tracks for the initial NCD request. One track is a highly time-structured track only available to aggrieved parties (section IV.E track #2), as defined in section 522 of BIPA. The other track is open to anyone, including aggrieved parties, beneficiaries, and manufacturers, and offers a more collaborative and less time-stringent process (section IV.E track #1).

Historically, we have based our coverage determinations on descriptive information, and scientific and clinical evidence. Under the revised BIPA coverage process, we will continue to use descriptive information, and scientific and clinical evidence as a basis for our coverage determinations.

II. Purpose of This Notice

This notice outlines the process we will use to make an NCD under the Medicare program. It sets forth the steps we are taking to make the NCD process more efficient, while maintaining as open and transparent a process as appropriate. It describes the following:

- A tracking system that provides public notice of our acceptance of a complete, formal request and subsequent actions in a web-based format.
- The process we will institute to afford notice and opportunity to comment before implementation of an NCD.
- Information that does and does *not* constitute a complete, formal request.
- The process for asking us to reconsider an existing NCD based on new information, including new medical or scientific evidence.
- The basis and purpose of a decision memorandum and where it can be accessed on our Web site.
- The revisions made to the NCD process under BIPA, including a response to public comments, and how these revisions affect the current NCD process and any subsequent challenges to an NCD.

In addition, we will continue to pursue an ongoing effort to work with various sectors of the scientific and medical community to develop and publish on the CMS Web site documents that describe our approach when analyzing scientific and clinical evidence to develop an NCD. Interested parties will be able to offer comments. Accordingly, these documents will make our coverage process more open and offer the public a better understanding into our NCD process.

In our April 1999 notice, we announced that we anticipated publishing a final coverage criteria rule that would be followed by sector-specific guidance documents (64 FR 22620). Since then, we published a notice of intent to engage in rulemaking for coverage criteria (May 16, 2000, 65 FR 31124) and had a subsequent town

hall meeting. Given that there are substantial competing interests about the coverage criteria, we believe it best not to pursue rulemaking. In the meantime, as we have done in the past 35 years, we would continue to need to make coverage decisions and interpret what is ''reasonable and necessary.'' We believe that in the interest of expediting NCDs and making the process as predictable as possible that, in the interim, nonbinding sector-specific guidance documents would be helpful. Sector-specific guidance documents refer to how our expectations and evaluation of evidence may differ in some respects depending on the nature of the topic under review. Evidence can vary greatly, for example, between a diagnostic and an item of DME or between a near-term fatal condition and a life-long chronic condition.

Thus, we are notifying the public that we may choose to publish sector-specific guidance documents even in the absence of a final rule. We will consider doing so as the need arises. This is also notice that we currently do not plan to develop a proposed rule based on the May 2000 Notice of Intent.

Section 522(b) of BIPA amends section 1862(a) of the Act to require the Secretary ''to make available to the public the data (other than proprietary data) considered in making the determination.'' In a notice of proposed rulemaking published on August 22, 2002 (67 FR 54534), we described the process for handling proprietary information related to NCDs. After considering public comments, we will establish and announce a policy that addresses that issue and defines ''proprietary'' data in the final rule.

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 scope of benefits available to eligible beneficiaries is prescribed by law and divided into several main parts. Part A is the hospital insurance program, and Part B is the voluntary supplementary medical insurance program.

The scope of benefits under Part A and Part B is defined in the Act. See sections 1812 (scope of Part A), 1832 (scope of Part B); and 1861(s) (definition of medical and other health services). Part C, known as the Medicare+Choice program, includes at a minimum, all of the items and services (other than hospice care) available under Part A and Part B to individuals residing in the area served by the plan. Some benefit categories are defined more broadly than others. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded, to be eligible for coverage under the Medicare program.

The Act does not contain a comprehensive list of specific items or services eligible for Medicare coverage. Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program. That is, the Act allows Medicare to cover medical devices, surgical procedures, and diagnostic services, but generally does not identify specific covered or excluded items or services.

Medicare payment is contingent upon a determination that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is ''reasonable and necessary.'' Section 1862(a)(1)(A) of the Act states that, subject to certain limited exceptions, no payment may be made for any expenses incurred for items or services that are not ''reasonable and necessary'' for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. For over 30 years, we have exercised these authorities to make a coverage determination regarding whether a specific item or service meets one of the broadly defined benefit categories and can be covered under the Medicare program.

As revised by section 522 of BIPA, an NCD is now defined to be a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Act, but does not include a determination about which code, if any, is assigned to a particular item or service covered under title XVIII, or a determination with respect to the amount of payment for a particular covered item or service.

In general, an NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service. Often, an NCD is written in terms of a particular patient population that may receive (or not receive) Medicare reimbursement for a particular item or service. An NCD is binding on all Medicare carriers, fiscal intermediaries (FIs), quality improvement organizations (QIOs), health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs). Before October 1, 2001, NCDs made under section 1862(a)(1) of the Act could not be reviewed by administrative law judges (ALJs). Effective October 1, 2001, BIPA expanded the definition of NCDs, and provides that all NCDs shall not be reviewed by ALJs under section 1869(f)(1) of the Act.

It is important to distinguish between a decision memorandum and an NCD. The decision memorandum is the public document that lays out and describes the analytic framework for our decision on a topic under NCD review. Its purpose is to inform the reader of the decision, the reasons for the decision and process followed, and provide a summary of the evidence considered. The decision memorandum alerts the public of our intent to implement the decision at some point in the future. The NCD itself follows the decision memorandum, sometimes by a number of months. It is the formal instruction to our claims processing contractors regarding how to process claims (when to pay, when not to pay, pay only when certain clinical conditions are met). Those instructions have a specific effective date dictating when claims will be processed according to the new criteria.

Generally, once we receive a complete formal request, it takes 90 days to develop a decision memorandum. As noted above, the decision memorandum is not the NCD, but rather is one step towards making an NCD for an item or service. After the decision memorandum is prepared, we must prepare the actual NCD. The NCD may be issued as a manual instruction or other document such as a program memorandum, ruling, or **Federal Register** notice. The NCD may be accompanied by additional information for our contractors that is necessary to ensure that Medicare claims will be properly processed when the NCD is effective. As noted above, except in very limited circumstances, preparing the NCD will occur after this 90-day review process.

We expect to make any payment changes or other systems changes dictated by the NCD instructions effective within 180 calendar days of the first day of the next full calendar quarter that follows the date we issue the decision memorandum. Thus, the decision memorandum and payment change can take up to 270 days from the date a formal request for an NCD is accepted for review by CMS. The date when a Medicare beneficiary may obtain the item or service and receive Medicare payment for that item or service under an NCD that expands coverage will not be known until the NCD is completed and has been assigned an effective date. The NCD will be implemented by all of

our contractors on the effective date. Additional details concerning this process, as well as certain limited exceptions, are described later in this notice.

B. Medicare Contractors and Coverage Policies

We contract with private insurance companies, referred to as carriers and FIs, to process Medicare claims; that is, claims-payment contractors. Local QIOs are also involved in the claims adjudication process. We refer to all of these entities as ''Medicare contractors.''

Medicare contractors review and adjudicate claims to ensure that Medicare payments are made only for those items or services covered under Medicare Part A or Part B. In the absence of a specific NCD, coverage determinations are made locally by the Medicare contractors within the boundaries established by the law. Sometimes these determinations are made on a claim-by-claim basis.

Medicare contractors will also publish local coverage determinations (LCDs) that will provide guidance to the public and medical community within a specified geographic area. An LCD is defined in section 522 of BIPA as a determination made by an FI or a carrier under Medicare Part A or Part B, as applicable, for whether or not a particular item or service is covered on an intermediary-wide or carrier-wide basis under those parts, in accordance with section 1862(a)(1)(A) of the Act. An LCD may not conflict with an NCD, but the LCD may supplement an NCD.

C. Procedural

We continue to expect that all evidence currently available must be adequate for us to conclude that the item or service is reasonable and necessary. In the absence of adequate evidence, we may conclude that the item or service is not reasonable and necessary.

D. Differences Between Food and Drug Administration (FDA) and CMS Review

Parties interested in the coverage of a drug or device (other than a Category B investigational device exemption (IDE) device, which is addressed through a separate process as described in 42 CFR 405.201 through 405.215) may contact us with an inquiry on Medicare coverage while the particular drug or device is proceeding through the Food and Drug Administration (FDA) premarket review process. We are willing to meet and discuss issues within this context. Because the FDA is charged with regulating whether devices or pharmaceuticals are safe and effective for use by consumers, generally we will not accept a request for a device or pharmaceutical that has not been approved or cleared for marketing by the FDA for at least one indication; one exception is Category B IDE devices. An IDE Category B device is a non-experimental/investigational device for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval or clearance for that device type.

Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions, respectively. However, CMS and its contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority (67 FR 66755, November 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for Medicare coverage, except for Category B devices under an IDE clinical trial (*see* 60 FR 48417, September 19, 1995), FDA approval/clearance alone does not generally entitle that device to coverage.

IV. CMS's Process for Making National Coverage Determinations

There are several ways an individual or entity can contact us about NCDs. One approach involves informal contacts, discussed in section IV.A of this notice. The other approach involves ''formal requests.''

If we have not issued an NCD for a particular item or service, an external requestor may use one of two formal tracks to submit a request to make an initial NCD. One track, established by section 522 of BIPA, is available only to aggrieved parties, as defined by statute to be ''individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the items or services that are the subject of the coverage determination'' and is highly time-structured. The other track is open to anyone, including aggrieved parties, other beneficiaries, and manufacturers, and offers a more collaborative and less time-stringent process. The NCD development process under BIPA-legislated time frames will only be initiated when we receive a complete, formal request from an aggrieved party.

A. Informal Contacts and Inquiries

The public frequently raises general questions about the coverage of items and services to us by telephone, the postal mail system, electronic means, or in person. These questions may include, but are not limited to, asking us to explain the current coverage of a particular item or service, or requesting assistance with, or advice about, a possible submission of a formal request for an NCD. We consider all of these contacts to be informal. Although informal contacts are not confidential, we will not announce the substance of these contacts on our Web site.

If the requestor asks for specific information about how to request an NCD, we will advise them on implications of such a request and explain what is required for us to accept a submission as a complete, formal request. We will offer suggestions to the requestor to clarify the amount and kind of information necessary for us to evaluate whether an item or service is ''reasonable and necessary'' under the Act, and in limited instances, we may offer to assist the requestor in meeting these requirements.

B. What Constitutes a Complete, Formal Initial Request for a National Coverage Determination or Formal Request for Reconsideration

We consider a request to be a complete, formal request, only if *all* of the following conditions are met:

- The formal request letter must be in writing.
- The formal request letter and supporting documentation must be submitted electronically (unless there is good cause for only a hardcopy submission).
- The requestor must identify the request as a ''formal request for an NCD'' or a ''formal request for reconsideration'' and identify the NCD development track chosen (described in detail in section IV.E of this notice).
- The requestor must state the benefit category or categories of the Medicare program to which the requestor believes the item or service applies. Examples of benefit categories may include durable medical equipment, physician services, inpatient hospital services, and diagnostic tests. The requestor may

recommend one or more benefit categories for the item or service and must submit supporting documentation justifying the recommendation. We must have all information, both from the requestor and internally, to make a benefit category determination, before the request can be considered complete. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate benefit category.

- The requestor must submit adequate supporting documentation along with the formal letter, including the following:

—A full and complete description of the item or service in question.

—A specific, detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used.

—A compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. This may include portions of primary study data that have been separately submitted to the FDA as part of its submission package and are deemed most relevant for our review.

—If the requestor has submitted an application to the FDA for market approval of the product for which coverage is sought, then a copy of the ''integrated summary of safety data'' and ''integrated summary of effectiveness data,'' or the combined ''summary of safety and effectiveness data,'' portions of the FDA application should be included in the request for an NCD. These documents will ensure that our review is comprehensive.

—An explanation of the design, purpose, and method of using the item or equipment, including whether the item or equipment is for use by health care practitioners or patients.

—A statement from the requestor (in cases in which there is an aggrieved party, the statement must be from that party) containing the following:

++An explanation of the relevance of the evidence selected.

++Rationale for how the evidence selected demonstrates the medical benefits for the target Medicare population.

++Information that examines the magnitude of the medical benefit.

++Reasoning for how coverage of the item or service will help improve the medical benefit to the target population.

++In the case of an aggrieved party, how that party is ''in need'' of the item or service.

—A description of any clinical trials or studies currently underway that might be relevant to a decision regarding coverage of the item or service.

—Information involving the use of a drug or device subject to FDA regulation as well as the status of current FDA regulatory review of the drug or device involved. An FDA regulated article would include the labeling submitted to the FDA or approved by the FDA for that article, together with an indication of whether the article for which a review is being requested is covered under the labeled indication(s). (We recognize that the labeling on FDA-approved products sometimes changes. For purposes of our review, we are interested in the labeled indications at the time a requestor submits a formal request. If, during our review, the labeled indication or status of a pending FDA approval or clearance changes, we expect the requestor to notify us.)

—In the case of items that are eligible for a 510(k) clearance by the FDA, identification of the predicate device to which the item is claimed to be substantially equivalent.

C. When a National Coverage Determination Request or Reconsideration Request Is Not Considered Complete and Formal

When a requestor submits a request for an NCD or reconsideration, we will review the materials to determine if it meets the definition of a complete, formal request as defined in section IV.B of this notice. If the request lacks adequate supporting documentation to enable us to conduct our review, we will notify the requestor and explain our rationale. If we accept the request, we will notify the requestor of the acceptance. We will also post our acceptance on our Web site under our list of pending coverage issues.

As we previously stated, we will not consider a request to be a complete, formal request if any of the following occur:

- Request is not in writing.
- Request is not accompanied by sufficient, supporting documentation.
- Information provided does not address relevance, usefulness, or the medical benefits of the item or service to the Medicare population.
- Information does not fully explain the design, purpose, and method of using the equipment for which the request is made.
- Information provided is not supported by scientific or clinically relevant data.
- Information provided is not relevant to the item or service for which the request is made.
- Request does not clearly identify the statutorily defined benefit category to which the requestor believes the item or service applies and does not contain enough information for us to make a benefit category determination.
- Request is considered an informal contact described in section IV.A.

D. Acceptance of a Complete, Formal National Coverage Determination or Reconsideration Request

In the rare event that we have a large volume of NCD requests to review at once, we retain the flexibility to prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries. This flexibility will enable us to ensure that we can pay priority attention to those requests that have potential for significant impact on our beneficiaries—a life-saving cancer treatment, a breakthrough in cardiac pacing, etc. In order to do so, we may have to temporarily suspend or diminish our review of other issues that, while important, do not have the same profound potential. We expect to use any such authority infrequently.

For these cases, two lists, an accepted list and lower priority list (based on impact) will be maintained and available on our Web site; the lower priority list will be processed based on the order of acceptance as resources become available. Requestors can use this public priority list to verify whether the request has been accepted, the status of the request, and where the requestor is in the order of priorities.

Upon acceptance of a request, we will notify the requestor and post a tracking sheet announcing our review of this issue on the list of pending coverage issues on the coverage Web site. Posting of the tracking sheets permits interested individuals to participate and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be an opportunity for public participation and submission of additional evidence. (If after accepting the request, we decide that the request does not fall under a benefit category, we will issue a noncoverage NCD.)

E. Review of a Complete, Formal Request for a National Coverage Determination

Development of a complete, formal request for an NCD can be initiated in one of three ways:

Track #1: Request for New National Coverage Determinations Initiated by Any Party, Including Beneficiaries, Manufacturers, Providers, or Suppliers.

A request to make an NCD can be received from an individual or entity who identifies an item or service as a potential benefit (or to prevent potential harm) to the Medicare population; this requestor can be either an aggrieved party as defined by section 522 of BIPA, or a nonaggrieved party. This may include a manufacturer, provider, supplier, or party who requests our consideration of a particular issue for an NCD. All requests must meet the requirements in this notice. An initial request can only be made if we have not previously issued an NCD for a particular item or service.

If an individual or other entity initiates a request, we expect to generally issue a decision memorandum within a 90-day period. More complex issues, or issues that require referral to the Medicare Coverage Advisory Committee or for a Technology Assessment, would generally take longer than 90 days. Generally, we expect to make a payment change effective within 180 calendar days of the next full calendar quarter that follows the date we issue the decision memorandum.

Though the 90-day clock in this option is not as strict as the process used only for aggrieved parties, this track offers a more collaborative process than track two. The opportunities for greater collaboration will flow from the more flexible approach to the 90-day clock. Requestors and other interested parties will be able to provide additional information, clarify issues, and engage in dialogue as questions arise. The ability to follow this path is necessarily constrained when we are under a strict, narrowly-framed 90-day response timeline.

Track #2: Request by an Aggrieved Party for New National Coverage Determinations Where There Were No National Coverage or Noncoverage Determinations.

Aggrieved parties are defined in section 1869(f)(5) of the Act as ''individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the items or services that are the subject of the coverage determination.'' Section 1869(f)(4) of the Act permits these individuals to make a request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary had not previously made a coverage or noncoverage determination. Thus, this track can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD.

As noted in section E, track 1, 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 a decision memorandum. This time is necessary to identify and make any necessary coding, payment, and systems changes. However, if an aggrieved party initiates a request under track 2, we expect to issue a decision memorandum and an NCD (that is, the manual instruction or other appropriate document) to our contractors by no later than the end of the 90-day period, in accordance with the statutory timeframe. The NCD will include the effective date of the policy. In cases where we are not able to complete our review within this 90-day timeframe, the law requires that we issue a notice that includes an identification of the remaining steps in the review process and a deadline by which we will complete that review.

A decision memorandum will include a clear statement of the basis for the determination including our responses to comments we receive from the public. The actual effective date of the NCDs will depend on whether we must make changes to our claims processing systems to allow Medicare payment; this step is not included in the 90-day clock. However, whether systems changes are needed and how long they may take to implement will be reflected in the effective date contained in the NCD.

Track #3: Internally Generated Request.

We may generate a request to make an NCD in the interest of the general health and safety of Medicare beneficiaries. Generally, this process is similar to the externally generated request process.

F. NCD Reconsideration Process

When an NCD currently exists, any individual or entity may request that we reconsider any provision of that NCD by filing an acceptable request for an NCD reconsideration. We will consider a request to revise an existing NCD at any time, but only if the requestor presents documentation that meets either of the following criteria:

- Additional material medical and/or scientific information that was not considered during the initial review, that is, results from new clinical trials, new scientific or medical publications, or studies supporting the request.
- Arguments that our conclusion materially misinterpreted the existing evidence at the time the NCD was made.
- If the request is for reconsideration of the benefit category determination, the requestor must recommend a benefit category and, in support of the recommendation, submit either (1) new information that was not considered during the initial benefit category determination, or (2) arguments that our determination decision materially misinterpreted the applicable statutory provisions, the applicable regulatory provisions, or the existing evidence at the time the benefit category determination was made.

We will not accept a request for reconsideration that is not submitted in writing, identified as ''A Formal Request for Reconsideration,'' and accompanied by the required, additional, supporting information as described more fully in sections IV.B and IV.C. Upon receipt of the additional information as outlined above, we will consider this a formal request for an NCD reconsideration and initiate the reconsideration process. We generally expect to complete the reconsideration process and issue a decision memorandum within 90 calendar days. Our current NCD will remain in effect during the reconsideration process until we issue a revised NCD, if applicable.

A reconsideration of an NCD must be distinguished from a challenge to an existing NCD. Under section 522 of BIPA and section 1869(f)(1) of the Act, aggrieved parties may elect to challenge an existing NCD. On August 22, 2002, we published a proposed rule (67 FR 54534) that addresses procedures for the Departmental Appeals Board (Board) review process under section 522 of BIPA.

A request for review of new clinical and scientific evidence that was published or available only after the date the initial NCD was issued may be submitted as a request for reconsideration. The reconsideration of an existing NCD is part of our coverage determination process so that our medical and scientific experts have an opportunity to examine this new evidence. Thus, a reconsideration of an NCD is separate and distinct from an initial NCD request and separate from the Board review process under section 522 of BIPA.

As noted above, because reconsiderations are outside of the strict BIPA timeline, they offer several alternative opportunities for individuals

and entities that may make the process more advantageous:

- The reconsideration process does not involve a formal adjudicatory hearing.
- The process may be more collaborative with the original clinical reviewers at CMS, with greater opportunity for clarification and dialogue.

G. Improvements in the National Coverage Determination Process

Our 90-day clock for considering or reconsidering coverage requests will begin once we have accepted the complete, formal request. Acceptance of a complete formal request begins a series of internal timeframes over the course of 90 days.

We will post the acceptance of a complete, formal request on our Web site. This initiates a 30-day comment (public input) period, during which submission of evidence or other comments relevant to the request will be accepted in accordance with section 522(b) of BIPA. During this time, the public, including the requestor of the NCD or reconsideration, may submit comments and additional information or evidence of studies regarding the NCD issue under review. We will provide a response to these comments in our decision memoranda.

There may be times, such as a public health emergency, when there is good cause for developing an NCD more rapidly, and we may need to reduce the time period for public comment. For instance, in the case of a national disaster, it may be necessary to quickly modify an NCD to facilitate access to covered services in a particular service area. In these emergency situations, we may expedite the development of an NCD and reduce the notice and comment period, during which evidence can be submitted. For instance, following the flooding in Texas in the summer of 2001, we issued an NCD shortly after a request was made in order to permit payments for transplant recipients.

After the close of the 30-day comment (public input) period, we will only accept additional information or evidence from the public if we request information or during subsequent Medicare Coverage Advisory Committee (MCAC) proceedings, if applicable. We must strictly enforce the 30-day comment (public input) period, in which evidence can be submitted, to ensure that we make timely decisions. We will consider and incorporate the relevant public input, and any subsequent information received during MCAC meetings, in the decision memorandum and before implementing the NCD for the particular item or service.

We will use the remainder of the 90-day timeframe to research and evaluate the NCD request. This process entails, but is not limited to, the following activities:

- Review pertinent data and scientific literature a requestor submits.
- Research relevant sources of evidence in addition to evidence a requestor submits. These may include, but are not limited to, other peer-reviewed medical, technical, and scientific literature, recommendations of expert panels, unpublished data used to secure FDA approval, and clinical experience.
- Formulate inclusion and exclusion parameters for literature searches.
- Develop analytic questions needed for subsequent policy formulation.
- Determine whether the issue warrants further review either by the MCAC or through a health technology assessment (HTA) from an agency such as the Agency for Healthcare Research and Quality (AHRQ).
- Evaluate all pertinent evidence.

In general, by the end of the 90-day period following formal acceptance of an NCD or reconsideration request, we will issue a decision memorandum on that request. We will outline, in a decision memorandum, one of the following three actions:

(1) Our intention to issue an NCD, with or without limitations.

(2) Our intention to issue a national noncoverage determination.

(3) A determination that an NCD or a noncoverage determination is not appropriate at the present time.

We will provide notice if we determine that additional time will be necessary to complete an NCD review. We will identify the remaining steps in the review process and the deadline by which we will complete the review and take an action described in (1), (2), or (3) above. This option may include such actions as referring the request to the MCAC or to a third party for an HTA as described in section IV.H of this notice.

A decision memorandum is not an NCD, but rather a statement announcing our intent to issue policy. The decision memorandum details the analysis of the scientific and clinical literature, and provides the rationale for the coverage determination. The decision memorandum will include the rationale we used in reaching our determination. If we make a coverage determination to modify an existing NCD that results in a reduction of coverage, in whole or in part, we will also publish a notice in the **Federal Register** and announce our coverage determination on our Web site. The decision memorandum is not binding on our contractors, and no change in existing policy is effective until we publish the revised NCD in the relevant coverage manual or other issuance with a specific effective date. Generally, by the end of the 270-day period following formal acceptance of an NCD or reconsideration request, we will make effective the payment changes for an NCD on that request.

We will create and maintain a complete and adequate record of all NCDs that are developed. The record will provide an explanation of our rationale for an NCD and include the evidence we considered. This record will form the basis for any subsequent requests for reconsideration of the NCD, and will also serve as the formal record of review for any subsequent challenges to the NCD under section 1869(f)(1) of the Act. Information contained in the record will conform to the proprietary data policy in the 522 BIPA final rule.

H. Health Technology Assessments (HTAs)

During our review of an NCD request, we may require an HTA to complete our review. Generally, an HTA provides an independent analysis of all scientific and clinical evidence available on a particular health care technology. We may request an HTA when there is conflicting or complex medical and scientific literature available, or when we believe an independent analysis of all relevant literature will assist us in determining whether an item or service is reasonable and necessary. We may also request an HTA in preparation for an upcoming MCAC meeting.

We will obtain services from the Agency for Healthcare Research and Quality, or a third party with the requisite experience in HTA and evidence-based medicine to ensure the technical competence and fairness of the HTA.

If we receive a formal request for coverage on an item or service for which an HTA is already underway, we will inform the subsequent requestor of the status of the pending HTA, as well as an estimated time for completion. Any request for an HTA will be reflected on our Web site tracking sheet, followed by either the executive summary or the full and complete HTA.

I. Medicare Coverage Advisory Committee (MCAC)

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the MCAC, and requesting nominations for membership. The MCAC has met

periodically since September 1999, to discuss coverage issues, make judgments about the adequacy and conclusions of existing scientific evidence, make recommendations to us about whether particular items or services can be considered ''reasonable and necessary'' under title XVIII of the Act, and to advise the Secretary on matters relating to the interpretation, application, or implementation of section 1862(a)(1) of the Act. The MCAC operates under a 2-year charter. The MCAC charter is available on our Web site.

The primary role of the MCAC is to provide independent, expert advice and assistance to us in making sound coverage decisions based upon the reasoned application of scientific evidence. Voting members must possess the scientific and technical competence commensurate with this purpose. In addition, a consumer and industry representative serve as nonvoting members on each panel. To ensure their full participation, nonvoting members have access to all information and data (other than information exempt from disclosure relating to trade secrets or where the disclosure would present a conflict of interest) made available to voting members. The MCAC meetings are open to the public, and time is allotted for public comment on the particular coverage issue under consideration.

In general, we may refer a coverage issue to the MCAC if it meets any of the following conditions:

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

If we refer a coverage issue to the MCAC, we will schedule a public meeting to discuss the coverage issue under consideration. All MCAC meetings are subject to the requirements of the Federal Advisory Committee Act. We will publish a notice in the **Federal Register** generally 30 days before holding an MCAC meeting. We will announce in our notice the draft agenda, time, and place of the meeting so that all interested persons will have ample notification. During the course of each meeting, there will be time allotted for public comment. We ask that all requests for presentation and consideration of evidence to the MCAC, submit a request to us in writing at least 20 days before the meeting. The MCAC considers all available evidence, presentations, and comments. The MCAC makes recommendations to us. Those recommendations are advisory.

We expect the MCAC to make recommendations as expeditiously as possible. We will provide an estimate of when we believe we will receive the MCAC recommendation. Once the MCAC makes a formal recommendation, we will post it on our Web site. Generally, within 60 calendar days of receiving the formal MCAC recommendation, we will issue a decision memorandum. In the decision memorandum, we will explain the MCAC recommendation, and how it was considered in our final determination.

J. Implementation of National Coverage Determinations

The general 90-day clock for NCD and reconsideration requests described for individuals who are not aggrieved parties or aggrieved parties who elect the collaborative approach includes time for the analysis, processing, and development of a decision memorandum. Upon making a decision, numerous internal, related steps remain before a payment change can take place. We must determine which codes the providers, suppliers, and Medicare contractors will use for submission and payment of claims consistent with the decision and issue corresponding instructions. We must also determine the appropriate Medicare payment level. As previously mentioned, coding and payment decisions are not included within the definition of an NCD for purposes of a Board review. Finally, NCDs often require us to develop and issue claims processing instructions to our systems maintainers and Medicare contractors to ensure accurate payment. Medicare contractors generally implement systems changes at the start of a calendar quarter, and instructions are required well in advance of the beginning of each quarter in order to install and test the systems changes.

The NCD (issued as a program memorandum, manual instruction, **Federal Register** notice, or CMS ruling) will include the effective date when our Medicare contractors will implement any change in payment that may result from the NCD. 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 decision memorandum. As stated previously, an NCD is binding on all Medicare contractors; that is, carriers, FIs, QIOs, HMOs, CMPs, and HCPPs. NCDs that expand coverage are binding on Medicare+Choice plans. We will also publish a reference to each national coverage decision in the **Federal Register** as part of our quarterly listing of program issuances.

K. Essential Differences in This Notice

In summary, this notice distinguishes between the two tracks available for an external party to request a new NCD when no NCD currently exists. For an initial request, the highly time-structured track is only available to aggrieved parties, as defined in section 522 of BIPA. The other track is open to anyone, including aggrieved parties, beneficiaries, and manufacturers, and offers a more collaborative and less time-stringent process. We also explain the steps that anyone can take to request a reconsideration of an existing NCD.

L. How To Access CMS's Home Page

Our home page can be accessed by entering ''*http://www.cms.hhs.gov*.'' To access information about our coverage process, select ''Development of Coverage Policies'' and then ''Medicare Coverage Process,'' or *http://www.cms.hhs.gov/coverage.*

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60 days 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 PRA requires that we solicit comment on the following issues:

- Need for the information collection and its usefulness in carrying out the proper functions of our agency.
- Accuracy of our estimate of the information collection burden.
- 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.

However, the collection requirements referenced in section IV.B ''What Constitutes a Complete, Formal Initial Request for a National Coverage Determination or Formal Request for Reconsideration'' of this notice, are currently approved under OMB approval number 0938–0776.

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Since this notice revises the process we will use to make an NCD for a specific item or service and has no economic impact on the Medicare program, we have determined this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. We believe that few small entities will submit requests. We estimate that approximately five beneficiaries or small entities may submit a request in a year.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of State, local, or tribal governments.

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

Authority: Sections 1862, 1869(f), 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; and Program No. 93774, Medicare-Supplementary Medical Insurance Program).

Dated: September 15, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 15, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–24361 Filed 9–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Counter Terrorism Products Regulated by the Center for Biologics Evaluation and Research: Effective Strategies to Assist in Product Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Counter Terrorism Products Regulated by the Center for Biologics Evaluation and Research: Effective Strategies to Assist in Product Development.'' The purpose of the public workshop is to provide a forum for discussing strategies to assist in the effective development of products regulated by the Center for Biologics Evaluation and Research (CBER) that may be used in counter terrorism efforts (e.g., vaccines, blood and blood products including immunoglobulins, gene therapies, and human cellular and tissue-based products).

Date and Time: The workshop will be held on October 23, 2003, from 8:30 a.m. to 5 p.m., and on October 24, 2003, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Gloria Blankenship, CBER (HFM–49), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, e-mail: *Blankenship@cber.fda.gov*.

Registration: Mail, e-mail, or fax your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Gloria Blankenship, (see *Contact Person*) by October 10, 2003. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Gloria Blankenship (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide a forum for sharing information and strategies to assist in the efficient and successful development of products regulated by CBER and used for counter terrorism efforts. CBER is interested in promoting a discussion of issues related to the development of counter terrorism products, including manufacturing and clinical issues, and other relevant issues. The workshop is intended to help sponsors address commonly asked questions and avoid common misunderstandings and to provide practical information on successful product development strategies.

FDA invites participants to submit issues for discussion prior to the workshop. There will be an opportunity to raise additional questions and issues for discussion at the meeting. Mail or fax your issues and questions to Gloria Blankenship (see *Contact Person*) by October 10, 2003.

FDA will post on CBER's Web site (*http://www.fda.gov/cber/*) the agenda for this meeting, when finalized.

Transcripts: Please note that transcripts of the meeting will not be prepared.

Dated: September 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–24303 Filed 9–25–03; 8:45 am]

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