

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