

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 HCCPs. 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.