

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