

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