CMS Manual System

Pub. 100-08 Medicare Program Integrity

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 63 **Date: JANUARY 23, 2004**

CHANGE REQUEST 3010

I. SUMMARY OF CHANGES: This manual change will provide detail on the conversion from LMRP to LCD and explain what steps contractors must take when one of their policies is challenged under BIPA 522.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 7, 2003
***IMPLEMENTATION DATE: February 23, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	13/Table of Contents
R	13/1/Medicare Policy
R	13/1.1/National Coverage Decisions (NCDs)
R	13/1.2/Coverage Provisions in Interpretive Manuals
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R	13/3/Individual Claim Determinations
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R	13/5/Content of an LCD
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R	13/8.1/The Carrier advisory Committee
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R	13/8.1.2/Membership on the CAC
R	13/8.1.3/Role of CAC Members
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R	13/8.2/Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP)
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R	13/11/Local Coverage Determination (LCD) Reconsideration Process
R	13/12/Retired LCDs
N	13/13/Challenge of an LCD
N	13/13.1/The Challenge
N	13/13.2/The LCD Record
N	13/13.3/Ex Parte Contacts
N	13/13.4/Discovery
N	13/13.5/Subpoenas
N	13/13.6/Evidence
N	13/13.7/Dismissals for Cause
N	13/13.8/New Evidence
N	13/13.9/Contractor Options
N	13/13.10/The ALJ Decision
N	13/13.11/Effectuating the Decision
N	13/13.12/Appeals
N	13/13.13/Board Review of an ALJ Decision
N	13/13.14/Effect of a Board Decision
N	13/13.15/Future New or Revised LCDs

***III. FUNDING:**
These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-08	Transmittal: 63	Date: January 23, 2004	Change Request 3010

SUBJECT: Benefit Improvement Protection Act (BIPA)

I. GENERAL INFORMATION

A. Background: The Benefit Improvement Protection Act (BIPA) §522 regulation was published on November 7, 2003 with an effective date of December 7, 2003. In order to effectuate this regulation, LMRPs are being converted into Local Coverage Determinations (LCDs)—a term established by the regulation. This manual change will provide detail on the conversion and explain what steps contractors must take when one of their policies is challenged under BIPA 522.

B. Policy: CMS-3063-F, published November 7, 2003.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3010.1	When clarifying a national "reasonable and necessary" policy, contractors shall reference that national policy in the "CMS National Coverage Policy" section of the LCD.	Contractor
3010.2	Contractors shall convert LMRPs into LCDs.	Contractor
3010.2.1	Effective December 7, 2003, contractors shall issue LCDs instead of LMRPs.	Contractor
3010.2.2	Contractors shall convert all existing LMRPs into LCDs before December 2005.	Contractor
3010.2.3	When making the conversion from LMRP to LCD, contractors shall also research and revise their manual references in order to ensure their accuracy.	Contractor
3010.3	Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD.	Contractor
3010.4	Contractors shall consider all reconsideration requests from any interested party doing business in the Contractor's jurisdiction.	Contractor
3010.5	Contractors shall maintain an "LCD record" for each active LCD.	Contractor

3010.6	Contractors shall, upon notice from an administrative law judge (ALJ), send the LCD record to appropriate parties.	Contractor
3010.7	Contractors shall, upon receipt of a challenge from the ALJ, initiate reconsideration of the policy to determine whether to revise or defend the policy.	Contractor
3010.8	Contractors should review any new evidence that is submitted and submit a statement regarding whether the new evidence is significant.	Contractor
3010.9	If defending the policy the contractor shall, within 30 days of receipt of the aggrieved party's statement, submit a statement defending the policy.	Contractor
3010.10	Contractors shall review new evidence deemed "significant" by the ALJ and decide whether to initiate a reconsideration.	Contractor
3010.11	Contractors have the discretion to retire an LCD under review any time before the date the ALJ issues a decision regarding that LCD.	Contractor
3010.11.1	Contractors shall notify the ALJ within 48 hours of retiring an LCD that is under review.	Contractor
3010.12	Contractors have the discretion to revise an LCD under review to remove or amend the LCD provision listed in the complaint at any time before the date the ALJ issues a decision regarding that LCD through the reconsideration process.	Contractor
3010.12.1	Contractors shall notify the ALJ within 48 hours of issuing a revised version of the LCD that is under review.	Contractor
3010.13	If the contractor feels that discovery sought is irrelevant or unduly repetitive, unduly costly or burdensome, or will unduly delay the proceeding, he or she should file a motion for a protective order before the date of production of the discovery.	Contractor
3010.14	Contractors may seek a subpoena by filing a written motion with the ALJ not less than 30 days before the date fixed for the hearing.	Contractor
3010.15	If the ALJ grants the contractor's motion for subpoena, the contractor shall serve the subpoena by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or	Contractor

	her last dwelling place or principal place of business.	
3010.16	If the LCD is found to be invalid, the contractor shall effectuate the ALJ's decision within 30 days.	Contractor
3010.16.1	The contractor shall provide individual claim relief.	Contractor
3010.16.2	The contractor shall remove the offending provision or retire the entire policy.	Contractor
3010.17	Contractors have the discretion to appeal any part of an ALJ's decision that states that a provision of an LCD is unreasonable to the Departmental Appeals Board by sending the following to the Board: (i) The full names and addresses of the parties, including the name of the LCD. (ii) The date of issuance of the ALJ's decision. (iii) The docket number that appears on the ALJ's decision. (iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.	Contractor
3010.18	If contractors incorrectly receive a "Challenge" they shall forward the challenge to the appropriate office designated at http://www.medicare.gov/coverage/static/appeals.asp, notify the aggrieved party that the complaint has been forwarded, and initiate a reconsideration of the policy.	Contractor
3010.19	Contractors shall comply with any lawful orders of the ALJ or Departmental Appeals Board (the Board).	Contractor

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: December 7, 2003 **Implementation Date: February 23, 2004** **Pre-Implementation Contact(s):** **Misty Whitaker 410-786-3087** **Post-Implementation Contact(s):** **Misty Whitaker 410-786-3087**	These instructions should be implemented within your current operating budget.

Medicare Program Integrity Manual
Chapter 13 – *Local Coverage Determinations*

Table of Contents
(Rev. 63, 01-23-04)

1 - Medicare Policies
(Rev. 63, 01-23-04)

The primary authority for all coverage provisions and subsequent policies is the *Social Security Act* (the Act). Contractors use Medicare policies in the form of regulations, NCDs, coverage provisions in interpretive manuals, and LCDs to apply the provisions of the Act.

1.1 - National Coverage Determinations (NCDs)
(Rev. 63, 01-23-04)

NCDs are developed by CMS to describe the circumstances for Medicare coverage *nationwide* for a specific medical service procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) under §1862(a)(1) of the Act or other applicable provisions of the Act. NCDs are usually issued as a program instruction. Once published in a CMS program instruction, an NCD is binding on all Medicare carriers/*DMERCS*, FIs, Quality Improvement Organizations (QIOs, formerly known as Peer Review Organizations or PROs), Program Safeguard Contractors (PSCs) and beginning 10/1/01 are binding for Medicare+Choice organizations. NCDs made under §1862(a)(1) of the Act are binding on Administrative Law Judges (ALJ) during the claim appeal process. (See 42 CFR 405.732 and 42 CFR 405.860). An example of a NCD can be found at http://cms.hhs.gov/pubforms/06_cim/ci50.htm#_1_56.

When a new NCD is published, the contractor shall notify the provider community as soon as possible of the change and corresponding effective date. This is a *Provider Communications (PCOM)* activity. Within 30 calendar days after an NCD is issued by CMS, contractors shall either publish the NCD on the contractor Web site or link to the MCD from the contractor *W*eb site. The contractor shall not solicit comments on national coverage decisions. Contractors *shall* amend affected *LCD*s in accordance with §4C *of this chapter*. *Since ALJs are bound by NCDs but not LCDs, simply repeating an NCD as an LCD will cause confusion as to the standing of the policy. If a contractor is clarifying a national "reasonable and necessary" policy, the contractor shall reference that national policy in the "CMS National Coverage Policy" section of the LCD.*

The contractor shall apply NCDs *when reviewing claims for services addressed by NCDs*. When making individual claim determinations, contractors have no authority to deviate from NCD if absolute words such as "never" or "only if" are used in the policy.

National Coverage *Determinations* should not be confused with "National Coverage Requests" or "Coverage Decision Memoranda".

- **National Coverage Request** -- A national coverage request is a request from any party, including contractors and CMS staff, for CMS to consider an issue for a national coverage decision. The information CMS requires prior to accepting a national coverage request is described in the *"Federal Register"* (FR) Notice entitled "*Revised Process* for Making *Medicare National* Coverage *Determinations*" and is located

http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-24361.pdf. If CMS decides to accept the request, information is posted on the coverage Web site at http://cms.hhs.gov/coverage. National Coverage Requests may contain Technology Assessments. Contractors should submit national coverage requests to Coverage and Analysis Group, Office of Clinical Standards and Quality, S3-02-01, 7500 Security Boulevard, Baltimore, Maryland 21244 and provide a copy to MROperations@cms.hhs.gov and the appropriate RO. State "National Coverage Request" in the subject line.

- **Coverage Decision Memorandum** - CMS prepares a decision memorandum before preparing the national coverage decision. The decision memorandum is posted on the CMS Web site, that tells interested parties that CMS has concluded its analysis, describes the clinical position, which CMS intends to implement, and provides background on how CMS reached that stance. Coverage Decision Memos are not binding on contractors or ALJs. However, in order to expend MR funds wisely, contractors should consider Coverage Decision Memo posted on the CMS Web site. The decision outlined in the Coverage Decision Memo will be implemented in a CMS-issued program instruction within 180 days of the end of the calendar quarter in which the memo was posted on the Web site. (An example of a Coverage Decision Memo can be found at http://cms.hhs.gov/coverage/8b3-a1.htm.

National Coverage Decisions should not be confused with coverage provisions in interpretive manuals.

1.2 - Coverage Provisions in Interpretive Manuals

(Rev. 63, 01-23-04)

Coverage provisions in interpretive manuals are instructions *that* are used to further define when and under what circumstances services may be covered (or not covered). The contractor shall not solicit comments on coverage provisions in interpretive manuals. Contractors *shall* amend affected *LCD*s in accordance with §4C *of this chapter*.

The contractor shall apply coverage provisions in interpretive manuals to claims that are selected for review. When making claim determinations, contractors *shall not deviate* from these coverage provisions if absolute words such as "never" or "only if" are used. Requirements for prerequisite therapies listed in coverage provisions in interpretive manuals (e.g., "conservative treatment has been tried, but failed") *shall* be followed when deciding whether to cover a service.

1.3 - Local Coverage Determinations (LCDs)

(Rev. 63, 01-23-04)

Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term "local coverage determination" (LCD). An LCD is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to

whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist of only "reasonable and necessary" information, while LMRPs may also contain benefit category and statutory exclusion provisions.

The final rule establishing LCDs was published November 11, 2003. Beginning December 7, 2003 local policies will be referred to as LCDs with the understanding of the relative standing of both LCDs and LMRPs. Effective December 7, 2003, contractors will issue LCDs instead of LMRPs. Additionally, over the next 2 years contractors will convert all existing LMRPs into LCDs. Until that conversion is complete, the term LCD, for the purpose of section 522 challenges, will refer to both:

1.) Reasonable and necessary provisions of an LMRP and,
2.) An LCD that contains only reasonable and necessary language.

CMS has developed an application within the Medicare coverage database back-end that will facilitate this conversion. This application is scheduled to be available to contractors on or about December 3, 2003. The contractor will covert the pertinent LMRP information into an LCD and place the remaining information (benefit category, statutory exclusion, and coding provisions) in an article or delete it. Statutory exclusion and benefit category provisions in LMRPs existing before December 7, 2003 will remain in effect until that policy is converted into an LCD.

Effective 12/07/2003, contractors should no longer create new LMRPs and shall instead create LCDs. All LMRP shall be converted to LCDs no later than December 2005. Any non-reasonable and necessary language a contractor wishes to communicate to providers shall be done through an article. Any draft LMRPS that are in the notice period before December 7,2003 should be entered into the MCD as a draft LCD. The draft LCD will then be released as a final LCD on the scheduled effective date. Additionally, when making the conversion from LMRP to LCD, contractors shall also research and revise their manual references in order to ensure their accuracy. Until all CMS manuals are revised, LMRPs will have the same effect as LCDs.

Codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCs codes that spell out which services the LCD applies to, lists of ICD-9-CM codes for which the service is covered, lists of ICD-9 codes for which the service is not considered reasonable and necessary, etc. These coding descriptions should only be included if they are integral to the discussion of medical necessity.

Coding guidelines are not elements of LCDs and should be published in articles or deleted. Inclusion in LCDs may mislead the public that they can be challenged under the 522 provision. The following are examples of coding guidelines:

- A provision stating that a 4-inch thick mattress should be billed using code XXYYZ.

- A statement that in order to be correctly coded a level X visit shall include complex medical decision making and a review of systems.

LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. (See Section 7.1 of this chapter).

The contractor should adopt LCDs that have been developed individually or collaboratively with other contractors. The contractor shall ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

Any policy developed between February 1, 2001 and December 7, 2003 that has not been converted to an LCD shall be in the format described in PIM Exhibit 6. A separate Exhibit describing the format of an LCD will be forthcoming. Additional information on the LCD format is available on the Fu & Associates Web page.

Contractors shall ensure that LCDs present an objective and positive statement and do not malign any segment of the medical community. LCDs do not address fraud and contractors should not use terms such as "fraud" and "fraudulent" in their LCDs. For example, the following sentence would be inappropriate in an LCD. "If, on postpay review this carrier finds that XYZ procedure was billed to Medicare after the effective date of this LCD, it will consider that billing fraudulent." This sentence would be more accurate and less inflammatory if the word "fraudulent" were replaced with the phrase "not reasonable and necessary."

3 - Individual Claim Determinations

(Rev. 63, 01-23-04)

Contractors may review claims on either a prepayment or postpayment basis regardless of whether a NCD, coverage provision in an interpretive manual, or *LCD* exists for that service. However, automated denials can be made only when clear policy or certain other conditions (see chapter 3, §5.1) exist. When making individual claim determinations, the contractor shall determine whether the service in question is covered *based on an LCD or the clinical judgment of the medical reviewer.* A service may be covered by a contractor if it meets all of the conditions listed in §5.1, *Reasonable and Necessary* Provisions in *LCD*s below.

4 - When To Develop New/Revised *LCDs*

(Rev. 63, 01-23-04)

The use of a *LCD* helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment and denial.

A -- Contractors *Shall* Develop New/Revised *LCDs*

Contractors *shall* develop *LCDs* when they have identified a service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review.

Contractors shall implement new Least Costly Alternative (LCA) determinations through an LCD. "Least Costly Alternative" is a national policy provision that shall be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principle to payment for non-DME services as well.

When revising an existing policy to include an LCA determination the entire LCD should be posted, but only the new LCA determination will be subject to comment. You should highlight the new LCA determination that is subject to comment.

The requirement to go through the LCD process does not apply to LCA determinations for individual claims, existing LCA determinations, or to the current moratorium on issuing LCA policy on Vitamin D analogues.

B -- Contractors *MAY* Develop New/Revised *LCD*

Contractors *have the option to* develop *LCDs* when any of the following occur:

- A validated **widespread problem** demonstrates a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume services); See Chapter 3,§ 2A, Error Validation Review, for an explanation of the problem validation process. Multi-state contractors may develop uniform *LCDs* across all its jurisdictions even if data analysis indicates that the problem exists only in one state.

- A *LCD* is needed to assure **beneficiary access** to care.

- A contractor has assumed the *LCD* development **workload of another contractor** and is undertaking an initiative to create uniform *LCDs* across its multiple jurisdictions; or is a **multi-state contractor** undertaking an initiative to create uniform *LCDs* across its jurisdiction; or

- **Frequent denials** are issued (following routine or complex review) or frequent denials are anticipated.

C -- Contractors *SHALL* REVIEW *LCD*

Contractors *shall* ensure that the *LCDs* appearing on the contractor's *LCD W*eb site and the *LCDs* appearing in the Medicare Coverage Database are identical. Contractors are encouraged to make use of the Medicare Coverage Database "*Save as* HTML" feature to assist in *keeping the LCDs on their contractor Web sites current.*

Within 90 Days

Contractors *shall* review and appropriately revise affected *LCD* within 90 days of the publication of program instruction (e.g., Program Memorandum, manual change, etc.) containing:

- A new or revised NCD;
- A new or revised coverage provision in an interpretive manual; or
- A change to national payment policy.

Within 120 Days

The Medicare Coverage Database will notify contractors of each *LCD* that is affected by an update to a HCPCS code or ICD-9-CM code.

The database automatically incorporates code deletions into revised LCDs (and LMRPs and articles) that are placed in "to be reviewed" status. In all cases (code deletions, code insertions, and code description changes) a new version of the LCD (and LMRP and article) is automatically made to incorporate the change, and the new version is placed in the "to be reviewed" status.

Contractors *shall* review and approve and/or appropriately revise affected *LCD* within 120 days of the date of this notification. Contractors *shall* revise the effective date, revision number, and the revision history on all revisions due to major HCPCS and ICD-9-CM changes. Contractors need not revise the effective date, revision number and revision history on revisions due to minor HCPCS changes. Contractors *shall* ensure that corresponding changes are made to the *LCD* appearing on the contractor's *LCD W*eb sites.

NOTE: The Medicare Coverage Database will only alert contractors to the existence of new codes if the new code falls within a code range listed in the *LCD*.

Annually

To ensure that all *LCDs* remain accurate and up-to-date at all times, at least annually, contractors *shall* review and appropriately revise *LCD*s based upon CMS NCD, coverage provisions in interpretive manuals, national payment policies and national coding policies. If an *LCD* has been rendered useless by a new/revised national policy, the *LCD shall* be retired. This process *shall* include a review of the *LCD*s in the Medicare Coverage Database and on the contractor's *W*eb site.

Contractors should consider retiring *LCDs* that are no longer being used for prepay review, post pay review or educational purposes. For example, contractors should consider retiring *LCDs* for outdated technology with no claims volume.

5 - Content of an *LCD*

(Rev. 63, 01-23-04)

Contractors shall ensure that *LCDs* are developed for services only within their jurisdiction.

The *LCD shall* be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals. If an NCD or coverage provision in an interpretive manual states that a given item is "covered for diagnoses/conditions A, B and C," contractors *should* not use that as a basis to develop *LCD* to cover **only** "diagnoses/conditions A, B and C." When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors *shall* allow for individual consideration **unless** the *LCD* supports automatic denial for some or all of those other diagnoses/conditions.

5.1 – *Reasonable and Necessary* Provisions in *LCDs*

(Rev. 63, 01-23-04)

A service may be covered by a contractor if:

- It is reasonable and necessary under 1862(a)(1)*(A)* of The Act.

Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

In order to be covered under Medicare, a service *shall* be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed *LCD* for the service is considered reasonable and necessary under 1862(a)(1)*(A)*. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and

- At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of §1862(a)(1)*(A) and* include but are not limited to:

- Pneumococcal, influenza and hepatitis B vaccines are covered if they are reasonable and necessary for the prevention of illness;
- Hospice care is covered if it is reasonable and necessary for the palliation or management of terminal illness;
- Screening mammography is covered if it is within frequency limits and meets quality standards;
- Screening pap smears and screening pelvic exam are covered if they are within frequency limits;
- Prostate cancer screening tests are covered if within frequency limits;
- Colorectal cancer screening tests are covered if within frequency limits; and
- One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an interlobular lens.

5.2. - Coding Provisions in *LCD*s

(Rev. 63, 01-23-04)

Only codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCs codes that spell out which services the LCD applies to, lists of ICD-9 codes for which the service is covered, lists of ICD-9 codes for which the service is not considered reasonable and necessary, etc.

5.3 - Use of Absolute Words in *LCD*s

(Rev. 63, 01-23-04)

Contractors *should* use phrases such as "rarely medically necessary" or "not usually medically necessary" in proposed *LCD*s to describe situations where a service is considered to be, in almost all instances, not reasonable and necessary. In order to limit unsolicited documentation, clearly state what specific clinical situation would have to exist to be considered reasonable and necessary. If a contractor chooses to apply these kinds of policy provisions (whether in NCD, national coverage provisions in interpretive manuals, or *LCD*s) during prepay review, they *should* not do so via automated review if documentation is *to be* submitted with the claim *for* manual review *of* such claims.

When strong clinical justification exists, contractors may also develop *LCDs* that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in *LCDs*, contractors are not required to make any exceptions or give individual consideration based on evidence. Contractors should create edits/parameters that are as specific and narrow as possible to separate cases that can be automatically denied from those requiring individual review.

5.4 - *LCD* Requirements That Alternative Service Be Tried First

(Rev. 63, 01-23-04)

Contractors *should* incorporate into *LCDs* the concept that use of an alternative item or service precedes the use of another item/service. This approach is termed a "prerequisite." Contractors *shall* base any requirement on evidence that a particular alternative is safe, *as* effective, or appropriate for a given condition without exceeding the patients' medical needs. Prerequisites *shall* be based on medical appropriateness, not on cost effectiveness. Non-covered items (e.g., pillows to elevate feet) may be listed. Any prerequisite for drug therapy *shall* be consistent with the national coverage decision for labeled uses. Whenever national policy bases coverage on an assessment of need by the beneficiary's provider, prerequisites should not be included in *LCDs*. As an alternative, contractors may use phrases in proposed *LCDs* like "the provider should consider..."

6 - *LCD* Format

(Rev. 63, 01-23-04)

All contractor *LCDs shall* be listed in the Medicare Coverage Database.

All *LCDs shall* be posted on the contractor's Web site in HyperText Markup Language (HTML). The Medicare Coverage Database *has* a feature that will allow a contractor to "*save as* HTML" a file of a recently entered *LCD*. Contractors *should* alter the appearance of the HTML file to meet their own Web site needs, e.g., change the background color.

6.1 - AMA Current Procedural Terminology (CPT) Copyright Agreement

(Rev. 63, 01-23-04)

Any time a CPT code is used in publications on the contractor Web site or in other electronic media such as tapes, disks or CD-ROM, contractors *shall* display the AMA copyright notice in the body of each *LCD*. Contractors *shall* use a point and click license on a computer screen or Web page any time CPT codes are used on the Internet.

7 - *LCD* Development Process

(Rev. 63, 01-23-04)

When a new or revised *LCD* is needed, contractors do the following:

- Contact the CMD facilitation contractor, other contractors, the local carrier or intermediary, the DMERC (if applicable), the Medicare Coverage Database or QIOs (formerly PROs) to inquire if a policy which addresses the issue in question already exists;

- Adopt or adapt an existing *LCD*, if possible; or

- Develop a policy if no policy exists or an existing policy cannot be adapted to the specific situation.

The process for developing the *LCD* includes developing a draft *LCD* based on review of medical literature and the contractor's understanding of local practice.

A -- Multi-State Contractors

A contractor with *LCD* jurisdiction for *two* or more States is strongly encouraged to develop uniform *LCDs* across all its jurisdictions. However, carriers *shall* continue to maintain and utilize CACs in accordance with §8 below.

7.1 - Evidence Supporting *LCDs*
(Rev. 63, 01-23-04)

Contractor *LCDs shall* be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to *LCDs*. The initial action in gathering evidence to support *LCDs shall* always be a search of published scientific literature for any available evidence pertaining to the item/service in question. In order of preference, *LCDs* should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

    - Scientific data or research studies published in peer-reviewed medical journals;

    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or

    - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality *shall* be evaluated before a conclusion is reached.

LCDs, which challenge the standard of practice in a community and specify that an item is never reasonable and necessary, *shall* be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

Less stringent evidence is needed when allowing for individual consideration or when reducing to the least costly alternative.

7.2 – *LCDs* That Require A Comment and Notice Period
(Rev. 63, 01-23-04)

Contractors *shall* provide for both a comment period and a notice period in the following situations:

- All **New *LCDs***
- Revised *LCDs* that **Restrict** Existing *LCDs* - Examples: adding non-covered indications to an existing *LCD*; deleting previously covered ICD-9 codes.
- Revised *LCDs* that make a Substantive Correction - If the contractor identifies an error published in an *LCD* that substantively changes the reasonable and necessary intent of the *LCD*, then the contractor *shall* extend the comment and/or notice period by an additional 45 calendar days.

7.3 - *LCDs* That Do Not Require a Comment and Notice Period
(Rev. 63, 01-23-04)

When a comment and notice period is unnecessary, contractors may immediately publish a revised *LCD* electronically (e.g., *Medicare Coverage Database, Contractor* Web site, email). In the following situations, the comment and notice processes are unnecessary:

- **Revised *LCD* that Liberalizes *an* Existing *LCD*** - For example, a revised *LCD* expands the list of covered indications/diagnoses. The revision effective date may be retroactive.
- **Revised *LCD* Being Issued for Compelling Reasons** - *SHALL* OBTAIN RO APPROVAL - For example, a highly unsafe procedure/device.
- ***Revised LCD that Makes a* Non-Substantive Correction** - For example, typographical or grammatical errors that do not substantially change the *LCD*. The revision effective date may be retroactive.
- **Revised *LCD* that makes a Clarification** - For example, adding information that clarifies the *LCD* but does not restrict the *LCD*. The revision effective date may be retroactive.
- ***Revised LCD that Makes a* Non-discretionary Coverage/Payment/Coding Update**s - Contractors *shall* update *LCDs* to reflect changes in NCDs, coverage provisions in

interpretive manuals, payment systems, HCPCS, ICD-9 or other standard coding systems within the timeframes listed in §4C. The revision effective date may be retroactive depending on the effective date of the NCD, etc.

- ***Revised LCD to Make*** **Discretionary Coding Updates That Do Not Restrict** -adding revisions that explain a coding issue so long as the revision does not restrict the *LCD*. The revision effective date may be retroactive.

- ***Revised LCD to Effectuate an Administrative Law Judge's Decision on a BIPA 522 challenge.***

7.4 - *LCD* Comment *and* Notice Process

(Rev. 63, 01-23-04)

When a new or revised *LCD* requires comment and notice (See §7.2) contractors *shall* provide a minimum comment period of 45 calendar days on the draft *LCD*. After the contractor considers all comments and revises the *LCD* as needed, the contractor *shall* provide a minimum notice period of 45 calendar days on the final *LCD*.

Contractors *shall* solicit comments from the medical community. Carriers solicit comments from the Carrier Advisory Committee (CAC.) DMERCs solicit comments through the DMERC Advisory Process (DAP.) Contractors respond to comments either individually or via a comment/response document (see §7.4.2). Where appropriate, the contractor shall incorporate the comments into the final *LCD*. Contractors notify providers of the *LCD* effective date. New *LCDs* may not be implemented retroactively.

7.4.1 - The Comment Period

(Rev. 63, 01-23-04)

A -- When The Comment Period Begins

For *LCDs* that affect services submitted to carriers, the comment period begins at the time the policy is distributed to the CAC either at the regularly scheduled meeting or in writing to all members of the CAC. Contractors shall distribute these draft *LCDs* to the CAC members via hardcopy or via email.

For *LCDs* that affect services submitted to intermediaries, the comment period begins when the policy is distributed to medical providers or organizations. Contractors may distribute these draft *LCDs* to medical providers and organizations via:

- Hardcopy mailing of the entire draft *LCD*,

- Hardcopy mailing of the title and Web address of the draft *LCD*, or

- E-mail containing the title and Web address of the draft *LCD*.

B-- When The Comment Period Ends

Contractors *shall* provide a minimum comment period of 45 calendar days. Contractors have the discretion but are not required to accept comments submitted after the end of the comment period.

C-- Draft *LCD* Distribution

When a new or revised *LCD* requires comment and notice (See §7.2), all contractors *shall* solicit comments and recommendations on the draft *LCD* and get input from, at least:

- Groups of health professionals and provider organizations that may be affected by the *LCD*;
- Representatives of *relevant* specialty societies;
- Other intermediaries/carriers;
- Quality Improvement Organizations (formerly known as PROs) within the region;
- Other CMDs within the region;
- General public (see §7.4.4, Draft *LCD* Web site Requirements);
- The *Regional Office*, associate regional administrator, for distribution to the appropriate regional staff (e.g., coverage experts, reimbursement experts). The RO staff will review the *LCD*s for any operational concerns; and
- The appropriate Advisory process:
    - The CAC, for carriers (See §8.1)
    - The DAP, for DMERCs (See §8.2)

Contractors *shall* indicate in each distribution the date the comment period ends.

D -- Draft *LCD* Open Meetings

Contractors *shall* provide open meetings for the purpose of discussing draft *LCD*s. Carriers *shall* hold these open meetings prior to presenting the policy to the CAC. To accommodate those who can not be physically present at the meetings, contractors *shall* provide other means for attendance (e.g., telephone conference) and accept written or e-mail comments. Written and e-mail comments *shall* be given full and equal consideration as if presented in the meeting. Members of the CAC may also attend these open meetings.

Interested parties (generally those that would be affected by the *LCD*, including providers, physicians, vendors, manufacturers, beneficiaries, and caregivers) can make presentations of information related to draft policies. Contractors *shall* remain sensitive to organizations or groups which may have an interest in an issue (e.g., laboratories, providers who provide services in nursing facilities, home care, or hospice and the associations which represent the facilities/agencies) and invite them to participate in meetings at which a related *LCD* is to be specifically discussed.

7.4.2 - Draft *LCD* Web site Requirements

(Rev. 63, 01-23-04)

Draft *LCD* on the Contractor Web site

Contractors *shall* post draft *LCDs* on *their* Web sites. *The* Web site *shall* clearly indicate the start and stop date of the comment period and list an e-mail and postal address to which comments can be submitted.

LCD Status Page

Contractors *shall* post to their Web sites an *LCD* status page that includes the draft *LCD* title, date of release of draft *LCD* for comment, e-mail and postal address for comments to be sent, end date for comment period, current status (see the following status indicators), *Date of Release for Notice,* and Web site link to *the active LCD (i.e., the notice period is complete and the policy is in effect.)*

LCD Status Indicators
D = draft under development; not yet released for comments C = draft *LCD* released for comment E = formal comment period has ended; comments now being considered F = final new/revised *LCD* has been issued *for notice*. *A= active policy; notice period complete and the policy is in effect*

Comment/Response Document

Contractors *shall* post to their Web sites a summary of comments received concerning the draft LMRP/*LCD* with the contractor's response. *This comment/response document shall be posted prior to or on the start date of the notice period*. The comment/response document *shall* be posted *(remain visible)* on the Web *for at least a* 6 month *period*.

The MCD allows users to attach comment/response documents to their draft document which will be visible when the LCD is reviewed.

7.4.3 - The Notice Period
(Rev. 63, 01-23-04)

When a new or revised *LCD is issued following a comment period* (see §7.2), contractors *shall* ensure that the effective date follows a minimum notice period of 45 calendar days.

A -- When The Notice Period Begins

Contractors *shall* make final *LCDs* public via *publication on their Web site. A summary of the LCD shall be published in a news bulletin.*

B -- When The Notice Period Ends

The notice period ends 45 calendar days after the notice period begins unless extended by the contractor. If the notice period is not extended by the contractor, the effective date of the *LCD* is the 46th calendar date after the notice period began.

7.4.4 - Final *LCD* Web Site Requirements
(Rev. 63, 01-23-04)

A -- Final *LCD* on the Contractor Web Site

Contractors *shall* post all final *LCDs* on their Web Site. Every *c*ontractor *W*eb site *shall* contain all final *LCDs* for that *c*ontractor. The number of active *LCDs* in the Medicare Coverage Database should equal the number of final *LCDs* on the contractor Web Site.

Contractors who are an intermediary and a carrier within the same corporation *shall* have separate Web pages for the*ir LCDs*. Contractors *shall* notify all providers of the contractor LCD Web address. If a contractor becomes aware of a provider without web access, the contractor *shall* advise providers *that they may request hard copy LCDs.*

B -- Final *LCD* in the Medicare Coverage Database *(MCD)*

The public can access the *MCD* at **www.cms.hhs.gov/*mcd***.
Contractors *shall* update the *MCD* when they issue a new or revised *LCD* or retire an existing *LCD*.

Contractors *shall* develop a mechanism for ensuring the accuracy of the information entered into the *MCD*. This mechanism *shall* include, at a minimum, a process by which data that is entered into the database is reviewed and verified for accuracy within *four* days of appearing to the public on the web.

8 - The *LCD* Advisory Process
(Rev. 63, 01-23-04)

8.1 - The Carrier Advisory Committee
(Rev. 63, 01-23-04)

Carriers *shall* establish one CAC per State. Where there is more than one carrier in a State, the carriers *shall* jointly establish a CAC. If there is one carrier for many States, each State shall have a full committee and the opportunity to discuss draft *LCD*s and issues presented in their State. Carriers maintain a current directory of CAC members which is available to CO, RO staff, and the provider community on request. Carriers that develop identical policies *for their entire jurisdiction* may establish a single CAC with permission from the RO. In order to obtain a waiver from the RO, contractors *shall* obtain agreement from CAC members within the *jurisdiction*.

8.1.1 - Purpose of the CAC
(Rev. 63, 01-23-04)

The purpose of the CAC is to provide:

- A formal mechanism for physicians in the State to be informed of and participate in the development of an *LCD* in an advisory capacity;
- A mechanism to discuss and improve administrative policies that are within carrier discretion; and
- A forum for information exchange between carriers and physicians.

Carriers *shall* clearly communicate to CAC members that the focus of the CAC is *LCD*s and administrative policies and not issues and policies related to private insurance business. The CAC is not a forum for peer review, discussion of individual cases or individual providers. While the CAC *shall* review all draft *LCD*s, the final implementation decision about *LCD*s rests with the CMD.

The CMD jointly develops the agenda with the co-chair representing the CAC to include concerns about *LCD*s and local administrative issues.

8.1.2 - Membership on the CAC
(Rev. 63, 01-23-04)

The CAC is to be composed of physicians, a beneficiary representative, and *representatives o*f other medical organizations. Each is individually described in Exhibit 3.

8.1.3 - Role of CAC Members

(Rev. 63, 01-23-04)

CAC members serve to improve the relations and communication between Medicare and the physician community. Specifically, they:

- Disseminate proposed *LCD*s to colleagues in their respective State and specialty societies to solicit comments;
- Disseminate information about the Medicare program obtained at CAC meetings to their respective State and specialty societies; and
- Discuss inconsistent or conflicting MR policies.

8.1.4 - CAC Structure and Process

(Rev. 63, 01-23-04)

A - Number of Representatives

Each specialty shall have only one member and a designated alternate with approval of committee co-chairs. Additional members may attend when policies that require their expertise are under discussion. Carriers maintain a current local directory of CAC members that is available to CO, RO, or the provider community on request.

B - Tenure

Carriers have discretion to establish the duration of membership on the committee. The term should balance the duration of time needed to learn about the process to enhance the level of participation and functioning with the desire to allow a variety of physicians to participate. Consider a 2-3 year term.

C - Co-Chairs

The CAC shall be co-chaired by the contractor medical director and one physician selected by the committee. The co-chairs:

- Run the meetings and determine the agendas;
- Provide the full agenda and background material to each committee member at least 14 days in advance; and
- Encourage committee members to discuss the material and disseminate it to interested colleagues within their specialty and to clinic or hospital colleagues for whom the item may be pertinent. The members may bring comments back to the meeting or request that their colleagues send written comments to the CMD separately.

Attendance at the meeting is at the discretion of the committee members. If the item is of importance to their specialty, encourage members to attend or send an alternate. This is the primary forum for discussion of proposed *LCD*s developed by the CMD. The 45-calendar-day comment process required for all *LCD*s starts when the proposed *LCD* is distributed to the committee members. (See PIM Chapter 13 §7.4.1*)*.

Co-chairs present all proposed *LCD*s to the CAC for discussion. If the need arises to develop and implement *LCD*s before the next scheduled meeting, they solicit comments from committee members by mail or e-mail.

D - Staff Participation

The Director of Medicare Operations *shall* assure that appropriate contractor staff attend to address administrative issues on the agenda. Other staff may also be required to attend include:

- Professional relations representative;
- MR manager and
- MFIS/*PSC Network*.

E - Location

Carriers work with the State medical society and committee members to select a meeting location that will optimize participation of physician committee members.

F - Frequency of Meetings

Hold a minimum of 3 meetings a year, with no more than 4 months between meetings. In the circumstance where a contractor is switching from 4 CAC meetings per year to 3 meetings, it is acceptable to have more than 4 months between the meetings. However, the contractor *shall* notify the RO that this one time occurrence is taking place.

G - Data

Each meeting should include a discussion and presentation of comparative utilization data that has undergone preliminary analysis by the carrier and relates to discussion of proposed *LCD*. Carriers solicit input from CAC members to help explain or interpret the data and give advice on how overutilization should be addressed. The use of data to illustrate the extent of problem billing (e.g., average number of services per 100 patients) *might* help justify the need for a particular policy. The comparative data should be presented using graphs, charts, and other visual methods of presenting data. Carriers may present egregious individual provider's data as long as the provider's identification is not disclosed or cannot be deduced.

H - Payment for Participation

Participation in the CAC is considered a service to physician colleagues. Carriers do not provide an honorarium or other forms of compensation to members. Expenses are the responsibility of the individuals or the associations they represent.

I - Recordkeeping

Carriers keep minutes of the meeting and distribute them to members. Carriers submit the following items from CAC meetings to the RO MR staff within 10 days following the meetings:

- A copy of the meeting agenda (include the date of the meeting);
- A prompt copy of meeting minutes (not approved);
- A copy of the approved minutes from the prior meeting, including a summary of this discussion and the number of attendees, broken down into committee members, alternates or observers and RO staff; and
- Tentative date of the next meeting.

Contractors *should* (but are not required to) prepare a version of the CAC minutes to be placed on their Web site. This version could differ from a more detailed internal version. Contractors *shall* assure that the Web site version of the minutes does not include any information that would be protected by FOIA's exemption (b)(6) -- information that would be an invasion of personal privacy (such as a CAC member's home phone number) or any other kind of sensitive information. When contractors receive a request for a hard copy of CAC minutes, the request should go to the contractor's FOIA coordinator for processing through the freedom of information request process.

J - Communicating With CO on National Issues

While the CMD should encourage CAC members to work through their respective organizations and Practicing Physicians Advisory Council (PPAC) to effect national policy, the CAC is not precluded from commenting on these issues. When appropriate, the CMD may choose to forward a formal letter to *CMS* CO from the CAC. Send these letters through the RO, where they will be answered or forwarded to the appropriate component in CO for response.

K - Support for Beneficiary Member

Provide individual support to the beneficiary representative in understanding the CAC role and process. This includes assisting the beneficiary representative in understanding the *LCD*s so they are better able to determine the effect of the policy on the beneficiary community. Carriers are encouraged to find ways to involve the beneficiary community in efforts to stem abuse through *LCD* development.

8.2 - Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP)

(Rev. 63, 01-23-04)

The DMERC *shall* establish a forum of DME advisory workgroups in each region to discuss DME issues and concerns with physicians, clinicians, beneficiaries, suppliers, and manufacturers. Options for this forum *should* include ad hoc workgroups that are time-limited and/or topic specific. Advisory participants do not advise the Federal Government. Therefore, the rules governing open meetings of Federal Government committees do not apply to the DAP process. Encourage individuals who are concerned with the issues or processes pertaining to DME to attend.

The purpose of the DAP is to provide:

- A formal mechanism to obtain input regarding Regional *LCDs (RLCDs*) development and revision;
- A mechanism to discuss and improve administrative policies that are within the DMERCs' discretion; and
- A forum for information exchange between the DMERCs, physicians, clinicians, beneficiaries, suppliers, and manufacturers.

9 - Provider Education Regarding *LCD*s

(Rev. 63, 01-23-04)

Contractors *shall* educate the provider community on new or significantly revised *LCD*s (e.g., training sessions, speaking at society meetings or writing articles in the society's newsletter).

Carriers are required to publish DMERC summary policies, and other pertinent information supplied by DMERCs, as requested, as part of regular bulletin distributions.

10 - Application of *LCD*

(Rev. 63, 01-23-04)

Contractors *should* apply *LCD*s to claims on either a prepayment or postpayment basis. If a contractor decides to enforce an *LCD* on a prepayment basis, the contractor *shall* design an MR edit. (See PIM Chapter 3, §5) Contractors have flexibility to add, alter, or eliminate MR edits at any time. Contractors should not apply a *LCD* retroactively to claims processed prior to the effective date of the policy.

11 -*LCD Reconsideration Process*
(Rev. 63, 01-23-04)

Contractors who have the task of developing *LCD*s *shall* have an *LCD* Reconsideration Process in accordance with the following instructions.

A - Purpose

The *LCD* Reconsideration Process is a mechanism by which interested parties can request a revision to an *LCD*.

B - Scope

The *LCD* Reconsideration Process is available only for final *LCD*s. The whole *LCD* or any *provision* of the *LCD* may be reconsidered.

C - General

Contractors *shall* respond timely to requests for *LCD* reconsideration. In addition, contractors *have the discretion to* revise or retire their *LCD*s at any time on their own initiatives.

D – Web site Requirements for the *LCD* Reconsideration Process

Contractors *shall* add to their current *W*eb sites information on the *LCD* Reconsideration Process. This information *should* be on the home page or linked to another location. It *shall* be labeled "*LCD* Reconsideration Process" and *shall* include:

- A description of the *LCD* Reconsideration Process; and
- Instructions for submitting *LCD* reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.

E - Valid *LCD* Reconsideration Request Requirements
(Rev. 63, 01-23-04)

1. Contractors:

   SHALL consider all *LCD* reconsideration requests from:

   - Beneficiaries residing or receiving care in a contractor's jurisdiction; and
   - Providers doing business in a contractor's jurisdiction.
   - Any interested party doing business in a contractor's jurisdiction.

2. Contractors *should* only accept reconsideration requests for *LCD*s published in final form. Requests *shall* not be accepted for other documents including:

- National Coverage Decisions (NCD);
- Coverage provisions in interpretive manuals;
- Draft *LCD*s;
- Template *LCD*s, unless or until they are adopted by the contractor;
- Retired *LCD*s;
- Individual claim determinations;
- Bulletins, articles, training materials; and
- Any instance in which no *LCD* exists, i.e., requests for development of an *LCD*.

If modification of the *LCD* would conflict with an NCD, the request would not be valid. The contractor should refer the requestor to the NCD reconsideration process. Requestors can be referred to www.cms.hhs.gov/coverage/8a1.asp or www.access.gpo.gov/nara/index.html .

3. Requests *shall* be submitted in writing, and *shall* identify the language that the requestor wants added to or deleted from an *LCD*. Requests *shall* include a justification supported by new evidence, which may materially affect the *LCD*'s content or basis. Copies of published evidence *shall* be included.

   The level of evidence required for *LCD* reconsideration is the same as that required for new/revised *LCD* development. (PIM Chapter 13, Section 7.1)

4. Any request for *LCD* reconsideration that, in the judgment of the contractor, does not meet these criteria is invalid.
5. Contractors *have the discretion* to consolidate valid requests if similar requests are received.

F - Process

1. The requestor should submit a valid *LCD* reconsideration request to the appropriate contractor, following instructions on the contractor's *W*eb site.
2. Within 30 days of the day the request is received, the contractor *shall* determine whether the request is valid or invalid. If the request is invalid, the contractor *shall* respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the contractor should follow the requirements below.
3. Within 90 days of the day the request was received, the contractor *shall* make a final *LCD* reconsideration decision on the valid request and notify the requestor of the decision with its rationale. Decision options include retiring the policy, no revision, revision to a more restrictive policy, or revision to a less restrictive policy.
4. If the decision is either to retire the *LCD* or to make no revision to the *LCD*, then within 90 days of the day the request was received, the contractor *shall* inform the requestor of that decision with its rationale.
5. If the decision is to revise the *LCD*, follow the normal process for *LCD* development.
6. Contractors *shall* keep an internal list of the *LCD* Reconsideration Requests received and the relevant dates, subject, and disposition of each one.

12 - Retired *LCD*s
(Rev. 63, 01-23-04)

Contractors *shall* list the retired date on all retired *LCD*s. Contractors *shall* have a mechanism for archiving retired *LCD*s. This mechanism *should* be hard copy, electronic or Web-based. This mechanism *shall* also allow the contractor to respond to requests and retrieve the *LCD* that was in effect on any given day. Contractors *shall* post on their Web site information regarding how to obtain retired *LCD*.

13 - Challenge of an LCD
(Rev. 63, 01-23-04)

In addition to creating the term "Local Coverage Determination" (LCD), BIPA 522 creates an appeals process for an "aggrieved party" to challenge LCDs/LCD provisions that are in effect at the time of the challenge. "Aggrieved party" is defined as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan (MAC), or in another Medicare managed care plan), and is in need of coverage for a service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received.

The term LCD refers to both 1.) A reasonable and necessary provision of an LMRP and 2.) A separate, stand alone LCD that contains only reasonable and necessary language.

If appropriate, CMS may choose to participate as a party in the process. (See §426.415 of the regulation).

13.1- The Challenge
(Rev. 63, 01-23-04)

An aggrieved party who chooses to file an LCD challenge before receiving the service shall file a complaint within 6 months of the issuance of a written statement from his or her treating practitioner. An aggrieved party who chooses to file an LCD challenge after receiving the service shall file the complaint within 120 days of the initial denial notice.

The aggrieved party bears the burden of proof and burden of persuasion (which will be judged by a preponderance of the evidence) in an LCD challenge. In other words, the aggrieved party shall come forward with evidence to support his/her claim and prove that it is more likely than not that the provision(s) in question should be found invalid. (See section 426.30 of the regulation).

Upon acceptance of a complaint from an aggrieved party, the Administrative Law Judge (ALJ) will forward a copy of the complaint to the contractor. The contractor will then be required to send a copy of the LCD record to the ALJ and all other parties involved in the LCD review (i.e., the aggrieved party/parties) within 30 days (subject to extension for good cause shown). Addresses of these parties will be provided in the letter from the ALJ. The contractor shall also

send a copy of the LCD record and a copy of all materials sent by the ALJ to CMS at 7500 Security Blvd, Baltimore, MD 21230, Mail Stop C3-02-16, Attn: LCD Challenge Staff.

Within 10 days of receiving a valid challenge from the ALJ, the contractor shall initiate a reconsideration of the challenged policy. In instances where the contractor feels the policy is reasonable despite the new evidence presented, the contractor shall simply continue with the review process in order to defend the policy. In cases where the contractor feels that the policy is unreasonable in light of the new evidence, the contractor shall revise the policy through the reconsideration process and notify the ALJ within 48 hours of issuing a revised policy. The contractor shall then forward a copy of the revised LCD to the ALJ. If the provision in question is not entirely removed, the review will continue on the revised LCD. (See §426.420 of the regulation.)

13.2- The LCD Record

(Rev. 63, 01-23-04)

The contractor shall, by June 2004, maintain an LCD record for each active LCD (both stand alone LCDs and LCDs within LMRPs). In order to fulfill this requirement, contractors shall develop and maintain an LCD record when any new LCD is developed. Additionally, the contractor will have 30 days to provide an LCD record to the ALJ when an LCD is challenged. Finally, contractors shall develop and maintain an LCD record for all other LCDs by June 1, 2004.

The LCD record sent to the aggrieved party consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD.
(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:
(i) Scientific articles.
(ii) Technology assessments.
(iii) Clinical guidelines.
(iv) Documentation from the FDA regarding safety and efficacy of a drug or device with the exception of proprietary data and privileged information.
(v) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.
(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).
(4) An index of documents considered that are excluded from the record provided to the aggrieved part but provided to the ALJ because of their proprietary nature. (See §426.418 of the final regulation)

*The LCD record furnished to the aggrieved party **does not** include the following:*
(1) Proprietary data or privileged information.
(2) Any new evidence.

The LCD record furnished to the ALJ will include the following

(1) All documents furnished to the aggrieved party.

(2) Privileged information and proprietary data considered that shall be filed with the ALJ under seal. This information shall be clearly marked as "proprietary" so the ALJ will know to keep it confidential. (See *§426.419 of the final regulation).*

Within 30 days of receiving the record, the aggrieved party shall file a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD.

Upon the receipt of the aggrieved party's statement, the contractor will have 30 days to submit a written response to the ALJ in order to defend the LCD. Generally, the response should explain why the aggrieved party's statement is incorrect. These statements will become part of the record.

If the ALJ finds the record complete and adequate to support the validity of the LCD, the review process ends.

If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ will permit discovery and the taking of evidence (see §§426.432 and 426.440 of the regulation) and evaluate the LCD (see §426.431 of the regulation) This process shall apply when an LCD record has been supplemented.

Upon agreement of the parties, any conferences, arguments or hearings may be held in person, via telephone, or via any other means (See §426.405 of the regulation.)

13.3- Ex Parte Contacts

(Rev. 63, 01-23-04)

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any substantive matter at issue in a case, unless all parties are given notice and an opportunity to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures. (See Section §426.406 of the regulation)

13.4- Discovery

(Rev. 63, 01-23-04)

If the ALJ orders discovery, then he or she will establish a reasonable timeframe for completion of discovery. If the Contractor (or any party) feels that the discovery sought is irrelevant or unduly repetitive, unduly costly or burdensome, or will unduly delay the proceeding, he or she should file a motion for a protective order before the date of production of the discovery.

A party may obtain discovery via a request for the production of documents and/or via the submission of 10 written interrogatory questions relating to a specific LCD. The term "documents" includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing in the discovery section of the Regulation will be

interpreted to require the creation of a document. Requests for admissions, depositions, or any other forms of discovery will not be used in the 522 appeals process. The ALJ will notify all parties in writing when the discovery period will be closed. (See § 426.432 of the regulation)

13.5- Subpoenas

(Rev. 63, 01-23-04)

A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence at or before the hearing. A party seeking a subpoena shall file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion shall designate the witnesses, specify any evidence to be produced, describe the address and location with sufficient particularity to permit the witnesses to be found, and state the pertinent facts that the party expects to establish by the witnesses or documents and whether the facts could be established by other evidence without the use of a subpoena. (See § 426.435 of the regulation)

Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

If the ALJ grants a motion requesting issuance of a subpoena, the subpoena shall do the following:

(1) Be issued in the name of the ALJ.
(2) Include the docket number and title of the LCD under review.
(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.
(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

The party seeking the subpoena will serve it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business. The individual to whom the subpoena is directed may file motion to quash the subpoena with the ALJ within 10 days after service.

The exclusive remedy for or refusal to obey a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)). That section provides the appropriate district court of the United States, upon application of the Commissioner of the Social Security Administration/Secretary of the Department of Health and Human services, can issue an order and charge a person who doesn't comply with that order with contempt of court.

13.6 - Evidence

(Rev. 63, 01-23-04)

The ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence. The ALJ shall exclude evidence that he/she determines is clearly irrelevant, immaterial, or unduly repetitive. The ALJ may accept privileged information or proprietary data, but shall maintain it under seal.

The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report. Experts submitting reports shall be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record. Unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record will be open to examination by all parties. (See Section 426.440).

13.7 - Dismissals for cause
(Rev. 63, 01-23-04)

The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to attend or participate in a prehearing conference or hearing without good cause shown or comply with a lawful order of the ALJ without good cause shown.

The ALJ shall dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision
(2) The complaint is not timely.
(3) The complaint is not filed by an aggrieved party.
(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating practitioner.
(5) The complaint challenges a provision or provisions of an NCD
(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.
(7) The aggrieved party withdraws the complaint

13.8- New Evidence
(Rev. 63, 01-23-04)

An aggrieved party may submit new evidence pertaining to the LCD provision(s) in question. New evidence is defined as clinical or scientific evidence that was not considered by the contractor before the LCD was issued. The ALJ will review the new evidence and decide whether this evidence has the potential to significantly affect the evaluation of the LCD provision(s) in question under the reasonableness standard provided for in BIPA 522. (See §426.340 of the regulation.)

The reasonableness standard is defined in the regulation as the standard that an ALJ or the Board shall apply when conducting an LCD review. In determining whether LCDs are valid, the adjudicator shall uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ/Board.

If the ALJ determines that the new evidence does not have the potential to significantly affect the ALJ's evaluation of the LCD provision(s), this evidence will be included in the record of the hearing to prevent it from being resubmitted as new evidence at a later date, and the review will continue.

If the ALJ determines that the new evidence has the potential to significantly affect the ALJ's evaluation of the LCD provision(s), then the ALJ will suspend the proceedings and send the new evidence to the contractor for review. The contractor will have 10 days, generally, to review the new evidence and decide whether the contractor will initiate a reconsideration.

If the contractor informs the ALJ that a reconsideration will be initiated, then the ALJ will set a reasonable timeframe, generally, but not more than, 90 days, by which the contractor will complete the reconsideration as described in Section (11) of this chapter.

The ALJ will lift the stay in proceedings and continue the review on the challenged provision(s) of the original LCD, including the new evidence in the record of the hearing, if the contractor:

(1) Informs the ALJ that a reconsideration will not be initiated; or

(2) The 90-day reconsideration timeframe is not met.

(a) If an LCD is reconsidered and revised within the 90-day timeframe allotted by the ALJ/Board, then the revised LCD and any supplement to the LCD record will be forwarded to the ALJ and all parties and the review will proceed on the LCD.

The contractor should review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;
(2) New evidence submitted with an amended complaint;
(3) New evidence produced during discovery; and
(4) New evidence produced when the ALJ consults with scientific and clinical experts.
(5) New evidence presented during any hearing.

The contractor should submit a statement regarding whether the new evidence is significant within such deadline as the ALJ may set. (See §426.417 of the regulation.)

13.9 - Contractor Options
(Rev. 63, 01-23-04)

A--Retiring the LCD

A contractor has the discretion to retire an LCD under review any time before the date the ALJ issues a decision regarding that LCD. Retiring an LCD under review has the same effect as a decision under §426.460(b) of the final regulation, which is described below.

B--Revising the LCD

A contractor has the discretion to revise an LCD under review to remove or amend the LCD provision listed in the complaint at any time before the date the ALJ issues a decision regarding that LCD through the reconsideration process. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under §426.460(b) of the final regulation, which is described below.

A contractor shall notify the ALJ within 48 hours of—

(1) Retiring an LCD that is under review, or

(2) Issuing a revised version of the LCD that is under review.

If the contractor issues a revised LCD, they shall forward a copy of the revised LCD to the ALJ. If the provision in question is not entirely removed, the review will continue on the revised LCD. (See §426.420 of the regulation.)

13.10 - The ALJ Decision

(Rev. 63, 01-23-04)

Within 90 days from closing the review record to the taking of evidence, the ALJ is required either to issue a decision, including a description of appeal rights, or to provide notice that the decision is pending, and an approximate date a decision will be issued. (See § 426.447 of the regulation).

After the ALJ has made a decision regarding an LCD complaint, the ALJ will send a written notice of the decision to each party.

If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board. (See §426.465 of the final regulation.)

ALJ decisions may be written narrowly to hold specific provision(s) invalid as applied to specific clinical indications and for similar conditions.

13.11 - Effectuating the Decision

(Rev. 63, 01-23-04)

If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor, the contractor will provide the following according to §426.460(b) of the final regulation:

*(1) **Individual claims:** If the contractor does not appeal the ALJ decision and if an aggrieved party's claim/appeal(s) had previously been denied, the contractor shall reopen the aggrieved party's claim and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid. If a revised LCD is issued, the contractor will use the revised LCD in*

reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD. If an aggrieved party has not yet submitted a claim, the contractor will adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid. In either case, the claim will be adjudicated without using the LCD provision(s) found invalid.

*(2) **Coverage determination relief**. If the contractor does not appeal the ALJ decision, the contractor will implement the ALJ decision within 30 days by doing one of the following:*

(i) Revise the LCD to remove the provision(s) of the LCD that the ALJ decision stated was/were not valid under the reasonableness standard. The revised LCD is effective for dates of service on or after the 30th day following the ALJ's decision.

(ii) Retire the LCD in its entirety and not use the LCD in adjudicating claims with dates of service on or after the 30th day following the ALJ decision. (See §426.460 of the final regulation.)

13.12 - Appeals
(Rev. 63, 01-23-04)

A contractor has the discretion to appeal any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable to the Departmental Appeals Board (the Board). The appeal shall be received by the Board within 30 days of the date the ALJ's decision was issued, or it shall include a rationale stating why the late appeal should be accepted by the Board. An appeal to the Board stays implementation of the Contractor's decision until the Board issues a final decision.

To file an appeal described in paragraph (a) of this section, a contractor shall send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.
(ii) The date of issuance of the ALJ's decision.
(iii) The docket number that appears on the ALJ's decision.
(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.
(See §426.465 of the regulation.)

13.13 - Board Review of an ALJ Decision.
(Rev. 63, 01-23-04)

*If the Board determines that an appeal is acceptable, the Board **will** do the following:*

- *Permit the party that did not file the appeal an opportunity to respond to the appeal.*
- *Hold an oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision.*
- *Review the LCD review record and the parties' arguments.*

- *Issue a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.*

- *Dismiss an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question. (See §426.476 of the final regulation.)*

A contractor has the discretion to retire or revise an LCD during the Board's review of an ALJ's decision. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party is entitled to individual claim relief provided under §426.488(b) of the regulation. (See §426.478 of the regulation).

A party (contractor or aggrieved party) who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision by sending the Board and any other party written notice announcing the intent to withdraw the appeal. (See §426.480 of the regulation).

The Board shall issue a written decision to all parties to the review of the ALJ decision. The decision shall include the following:

- *The Board's Findings (i.e., A statement upholding the part(s) of the ALJ decision named in the appeal, a statement reversing the part(s) of the ALJ decision named in the appeal, a statement modifying the part(s) of the ALJ decision named in the appeal, or a statement dismissing the appeal of an ALJ decision and a rationale for the dismissal);*

- *The date of issuance;*
- *The docket number of the review of the ALJ decision;*
- *A summary of the ALJ's decision; and*
- *A rationale for the basis of the Board's decision.*

*The Board **may not** do the following**:***

- *Order CMS or its contractors to add any language to a provision or provisions of an LCD;*
- *Order CMS or its contractors to pay a specific claim;*
- *Order CMS or its contractors to pay a specific claim;*
- *Set a time limit to establish a new or revised LCD;*
- *Review or evaluate an LCD other than the LCD named in the ALJ's decision;*
- *Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes; or*
- *Order CMS or its contractors to implement an LCD in a particular manner.*

13.14 - Effect of a Board Decision

(Rev. 63, 01-23-04)

If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that than LCD is invalid, the contractor or CMS is not required to take any action.

If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor will provide individual claim relief and coverage determination relief as described above and at §426.460(b) of the regulation.

If the Board reverses an ALJ's decision dismissing a complaint, the Board remands to the ALJ and the LCD review continues. (See §426.488 of the regulation.)

If the Board remands a case to the ALJ, the Board will notify each aggrieved party at his or her last known address, the contractor and CMS of the Board's remand decision and explain why the case is being remanded and the specific actions ordered by the Board. (See §426.489 of the regulation.)

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision. (See §426.490 of the regulation.)

13.15 - Future New or Revised LCDs

(Rev. 63, 01-23-04)

The contractor shall not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated. (See §426.463 of the regulation)

If Contractors incorrectly receive a "Challenge" they shall forward the challenge to the appropriate office designated at http://www.medicare.gov/coverage/static/appeals.asp, notify the aggrieved party that the complaint has been forwarded, and initiate a reconsideration of the policy.