Medicare Program Integrity Manual

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

Transmittal 24 **Date: APRIL 5, 2002**

CHANGE REQUEST 2061

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
1			2.1 through 2.7.7
13		1-12	

NEW/REVISED MATERIAL--EFFECTIVE DATE: October 1, 2002
IMPLEMENTATION DATE: October 1, 2002

CLARIFICATION/MANUALIZATION--EFFECTIVE/IMPLEMENTATION DATE: October 1, 2002

Chapter 1 -- removes the local medical review policy (LMRP) and related sections from Chapter 1 and moves them into a new chapter -- Chapter 13.

Chapter 13, Section 1, Medicare Policy -- moves existing language from Chapter 1.

Chapter 13, Section 1.1, National Coverage Determinations (NCDs) -- moves existing language from Chapter 1.

Chapter 13, Section 1.2, Coverage Provisions in Interpretive Manuals -- moves existing language from Chapter 1.

Chapter 13, Section 1.3, Local Medical Review Policy -- moves existing language from Chapter 1.

Chapter 13, Section 2, Articles -- moves existing language from Chapter 1.

Chapter 13, Section 3, Individual Claim Determinations -- moves existing language from Chapter 1.

Chapter 13, Section 4, When To Develop New/Revised LMRP -- moves existing language from Chapter 1; adds sub headings.

Chapter 13, Section 5, Content of an LMRP -- moves existing language from Chapter 1.

Chapter 13, Section 5.1, Coverage Provisions in LMRPs -- moves existing language from Chapter 1.

Chapter 13, Section 5.2, Coding Provisions in LMRPs -- moves existing language from Chapter 1.

Chapter 13, Section 5.3, Documentation Provisions in LMRPs -- is reserved for future use.

Chapter 13, Section 5.4, Least Costly Alternative -- moves existing language from Chapter 1.

Chapter 13, Section 5.5, Use of Absolute Words in LMRPs -- moves existing language from Chapter 1. In order to eliminate a perceived conflict with the Paperwork Reduction Act, deletes the words 'documentation or' from the phrase "state what specific documentation or clinical situation would have to exist to be considered reasonable and necessary."

Chapter 13, Section 5.6, LMRP Requirements That Alternative Service Be Tried First -- moves existing language from Chapter 1.

Chapter 13, Section 6, LMRP Format -- moves existing language from Chapter 1.

Chapter 13, Section 6.1, AMA Current Procedural Terminology (CPT) Copyright Agreement -- moves existing language from Chapter 1.

Chapter 13, Section 7, LMRP Development Process -- moves existing language from Chapter 1.

Chapter 13, Section 7.1, Evidence Supporting LMRPs -- moves existing language from Chapter 1.

Chapter 13, Section 7.2, LMRPs That Require A Comment and Notice Period -- moves existing language from Chapter 1; clarifies the situations where the LMRP Comment and Notice process must be followed.

Chapter 13, Section 7.3, LMRPs That Do Not Require A Comment and Notice Process -- moves existing language from Chapter 1; clarifies the situations where the LMRP comment process is not required.

Chapter 13, Section 7.4, LMRP Comment and Notice Process -- moves existing language from Chapter 1; restructures existing language.

Chapter 13, Section 7.4.1, The Comment Period -- moves existing language from Chapter 1; adds a heading.

Chapter 13, Section 7.4.2, Draft LMRP Web site Requirements -- moves existing language from Chapter 1; adds a cross-reference to §7.2;

Chapter 13, Section 7.4.3, The Notice Period -- moves existing language from Chapter 1.

Chapter 13, Section 7.4.4, Final LMRP Web Site Requirements -- moves existing language from Chapter 1. Reminds contractors that they must ensure that no draft or retired LMRPs appear on LMRP.net.

Chapter 13, Section 8, The LMRP Advisory Process -- moves existing language from Chapter 1.

Chapter 13, Section 8.1, The Carrier Advisory Committee -- moves existing language from Chapter 1.

Chapter 13, Section 8.1.1, Purpose of the CAC -- moves existing language from Chapter 1.

Chapter 13, Section 8.1.2, Membership on the CAC -- moves existing language from Chapter 1.

Chapter 13, Section 8.1.3, Role of CAC Members -- moves existing language from Chapter 1.

Chapter 13, Section 8.1.4, CAC Structure and Process -- moves existing language from Chapter 1. Clarifies that contractors may (but are not required to) prepare a version of the CAC minutes that may be placed on their Web site. Eliminates the provision in which contractors were required to submit their CAC minutes to Central Office via hardcopy or email to MROperations@cms.hhs.gov.

Chapter 13, Section 8.2, Durable Medical Equipment Regional Carrier (DMERC) -- Advisory Process (DAP) -- moves existing language from Chapter 1.

Chapter 13, Section 9, Provider Education Regarding LMRPs -- moves existing language from Chapter 1.

Chapter 13, Section 10, Application of LMRP -- moves existing language from Chapter 1.

Chapter 13, Section 11 -- is reserved for future use.

Chapter 13, Section 12, Retired LMRPs -- moves existing language from Chapter 1.

These instructions should be implemented within your current operating budget.

NOTE: Red italicized font identifies new material.

Medicare Program Integrity Manual

Chapter 1 - Overview of Medical Review (MR) and Benefit Integrity (BI) and Medicare Integrity Program-Provider Education and Training (MIP-PET) Programs

---

Table of Contents
(Rev. 24, 04-05-02)

……..
Sections that remain unchanged:
1
1.1
1.2
2
…….
Sections that are deleted from chapter 1:
2.1 - 2.7.7
……
Sections that remain unchanged:
3-end
…….

Medicare Program Integrity Manual

Chapter 13 - Local Medical Review Policy

Table of Contents
(Rev. 24, 04-05-02)

---

1 - Medicare Policies - (Rev. 24, 04-05-02)

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 LMRPs to apply the provisions of the Act.

1.1 - National Coverage Decisions (NCDs) - (Rev. 24, 04-05-02)

NCDs are developed by CMS to describe the circumstances for Medicare coverage 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, FIs, Quality Improvement Organizations (QIOs, formerly known as Peer Review Organizations or PROs), Program Safeguard Contractors (PSCs) and beginning 10/1/01are 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://www.CMS.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 PM-PET activity. Within 30 calendar days of after an NCD is issued by CMS, contractors shall either publish the NCD on the contractor Web site or link to the NCD from the contractor website. In addition, the NCD shall be included, as soon as possible in a provider bulletin. The contractor shall not solicit comments on national coverage decisions. Contractors must amend affected LMRPs in accordance with §4C.

The contractor shall apply NCDs to individual claims. 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.

Requirements for prerequisite therapies listed in NCD (e.g., "conservative treatment has been tried, but failed") must be followed when deciding whether to cover a service.

National Coverage Decisions 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's internal 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 FR Notice entitled "Procedures for Making Coverage Decisions" and is located at http://www.CMS.gov/coverage/8a1.htm. If CMS decides to accept the request, information is posted on the coverage website at http://www.CMS.gov/coverage. National Coverage Requests may contain Technology Assessments (e.g.,http://www.CMS.gov/coverage/8b3-x2.htm). 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 (e.g., CIM, Medicare Carriers Manual (MCM), Medicare Intermediary Manual (MIM), or PM) within 180 days of the end of the calendar quarter in which the memo was posted on the Web. (An example of a Coverage Decision Memo can be found at http://www.CMS.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. 24, 04-05-02)

Coverage provisions in interpretive manuals are those coverage instructions published by CMS other than NCDs. These instructions are used to further define when and under what circumstances services may be covered (or not covered). For example, Chapter 2 of MCM and Chapter 2 of MIM describe coverage and limitations for specific services. Once published, the coverage provision in an interpretive manual is binding on all carriers, FIs, QIOs (formerly known as PROs), PSCs and M+C Organizations.

When a new coverage provision in an interpretive manual is published, the contractor shall notify the provider community as soon as possible of the change and corresponding effective date. This is a PM-PET activity. Within 30 calendar days of the new provision being issued by CMS, contractors shall either publish the coverage provision on the contractor Web site or link to the coverage provision from the contractor website. In addition, the coverage provision shall be included, as soon as possible in a provider bulletin. The contractor shall not solicit comments on coverage provisions in interpretive manuals. Contractors must amend affected LMRPs in accordance with §4C.

The contractor shall apply coverage provisions in interpretive manuals to individual claims that are selected for review. When making individual claim determinations, contractors have no authority to 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") must be followed when deciding whether to cover a service.

1.3 - Local Medical Review Policy - (Rev. 24, 04-05-02)

LMRP specifies under what clinical circumstances a service is covered (including under what clinical circumstances it is considered to be reasonable and necessary) and correctly coded. It is an administrative and educational tool to assist providers in submitting correct claims for payment. LMRPs outline how contractors will review claims to ensure that they meet Medicare coverage and coding requirements. Contractors

publish LMRP to provide guidance to the public and medical community within a specified geographic area. LMRP explain when a service will be considered covered and correctly coded. Contractors develop LMRPs by considering medical literature, the advice of local medical societies and medical consultants and public comments. If a contractor develops an LMRP, its LMRP applies only within the area it services. While another contractor may come to a similar decision, CMS does not require it to do so.

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

The contractor shall use the format specified in PIM Exhibit 6, for all LMRPs.

Contractors must ensure that LMRPs present an objective and positive statement and do not malign (directly or indirectly) any segment of the medical community. LMRPs do not address fraud and contractors should not use terms such as "fraud" and "fraudulent" in their LMRPs. For example, the following sentence would be inappropriate in an LMRP. "If, on postpay review this carrier finds that XYZ procedure was billed to Medicare after the effective date of this LMRP, 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."

2 - Articles - (Rev. 24, 04-05-02)

Contractors may include in provider bulletins, websites, and educational materials general discussion regarding practice standards, existing NCDs, PMs issued by CMS, coverage provisions in an interpretive manual and existing LMRPs.

3 - Individual Claim Determinations - (Rev. 24, 04-05-02)

Contractors may review claims on either a prepayment or postpayment basis regardless of whether a NCD, coverage provision in an interpretive manual, or LMRP 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 and/or correctly coded. A service may be covered by a contractor if it meets all of the conditions listed in §5.1, Coverage Provisions in LMRPs below.

4 - When To Develop New/Revised LMRP - (Rev. 24, 04-05-02)

The use of LMRP 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 MUST Develop New/Revised LMRP

Contractors shall develop LMRPs when they have identified an item or 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.

B -- Contractors MAY Develop New/Revised LMRP

Contractors may develop LMRPs 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 LMRP across all its jurisdictions even if data analysis indicates that the problem exists only in one state.*

- *LMRP is needed to assure **beneficiary access** to care.*

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

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

C -- Contractors Must REVIEW LMRP

Within 90 Days
Contractors must review and appropriately revise affected LMRP 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 interpretive manual,*

- *a change to national payment policy,*

Within 120 Days
Contractors must review and appropriately revise affected LMRP within 120 days of the publication of an update to the ICD-9 or HCPCS coding systems.

Annually

Effective October 2001, to ensure that all LMRPs remain accurate and up-to-date at all times, at least annually, contractors must review and appropriately revise LMRPs based upon CMS NCD, coverage provisions in interpretive manuals, national payment policies and national coding policies. If an LMRP has been rendered useless by a superceding national policy, it must be retired. This process must include a review of the policies at www.LMRP.net and on the contractors Web site.

5 - Content of an LMRP - (Rev. 24, 04-05-02)

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

*The LMRP must 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 may not use that as a basis to develop LMRP 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 must allow for individual consideration **unless** the LMRP supports automatic denial for some or all of those other diagnoses/conditions.*

5.1 - Coverage Provisions in LMRPs - (Rev. 24, 04-05-02)

A service may be covered by a contractor if it meets all of the following conditions:

- *It is one of the benefit categories described in title XVIII of The Act;*
- *It is not excluded by title XVIII of The Act other than 1862(a)(1); and*
- *It is reasonable and necessary under 1862(a)(1) of the Act.*

A - Benefit Category

In order to be covered under Medicare, a service must be one of the benefits described in title XVIII of the Act and it must meet the definition of that benefit category listed in CMS's Manual, e.g., (See MIM, §§3101ff). A list of Medicare benefit categories can be found at www.CMS.gov/medicare/mip/index_ar.htm (scroll to or click on "I. Benefit Category Reviews").

B - Statutory Exclusions on Grounds Other Than Section 1862(a)(1)

*In order to be covered under Medicare, a service must not be excluded by title XVIII of the Act, **other than** by §1862(a)(1). Such exclusions include, but are not limited to, routine physical checkups, immunizations, cosmetic surgery, hearing aids, eyeglasses, routine foot care for certain patients, and most dental care.*

C - Reasonable and Necessary

In order to be covered under Medicare, a service must be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LMRP for the service is considered reasonable and necessary under 1862(a)(1). 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/or 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) 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 intraocular lens.*

5.2. - Coding Provisions in LMRPs - (Rev. 24, 04-05-02)

In its LMRP, a contractor may describe the national and/or local coding rules that pertain to a given service.

It is important to note that the presence and use of billing codes (e.g., HCPCS, revenue codes, RUGs, etc.), either describing a specific category of product/service or describing products/services not otherwise classified (e.g., E1399, "DME, miscellaneous), does not automatically guarantee coverage or payment. Once the appropriate billing code for a service has been identified, contractors must still determine if the service meets Medicare coverage criteria and how much to pay for that service.

The Statistical Analysis DMERC (SADMERC) has responsibility for providing coding advice and assigning DMEPOS products and services to HCPCS codes. The SADMERC does not provide coverage determinations, nor do they impart to the DMERC any direction to pay or review claims containing any given HCPCS code.

5.3 - Documentation Provisions in LMRPs - (Rev. 24, 04-05-02)

[Reserved For Future Use]

5.4 - Least Costly Alternative - (Rev. 24, 04-05-02)

"Least costly alternative" is a national policy provision that must be applied by contractors when determining payment for all durable medical equipment (DME). (See Medicare Carriers Manual (MCM) §2100.2.) Contractors have the discretion to apply this principle to payment for non-DME services as well.

5.5 - Use of Absolute Words in LMRPs - (Rev. 24, 04-05-02)

Contractors may use phrases such as "rarely medically necessary" or "not usually medically necessary" in proposed LMRPs 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 LMRPs) during prepay review, they may not do so via automated review if documentation is submitted with the claim but instead must manually review such claims."

When strong clinical justification exists, contractors may also develop LMRPs that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in LMRPs, 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.

5.6 - LMRP Requirements That Alternative Service Be Tried First – (Rev. 24, 04-05-02)

Contractors may incorporate into LMRPs the concept that use of an alternative item or service precedes the use of another item/service. This approach is termed a "prerequisite." Contractors must base any requirement on evidence that a particular alternative is safe, more effective, or more appropriate for a given condition without exceeding the patients' medical needs. Prerequisites must 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 must 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 LMRPs. As an alternative, contractors may use phrases in proposed LMRPs like "the provider should consider..."

6 - LMRP Format - (Rev. 24, 04-05-02)

Any newly developed policies as of February 1, 2001 must use the standard format listed in Exhibit 6. Contractors must forward new, revised, and final LMRPs to Julie.Berkey@TrailBlazerHealth.com no later than 2 business days after the start of the notice period. See Exhibit 6.1 for submission requirements for LMRPs. Contractor policies will not be accepted if not forwarded as required in Exhibit 6.1.

All new LMRPs must be written in HyperText Markup Language (HTML). The LMRPs on your Web site must be in HTML. This does not prohibit a contractor from writing policies in a word processing application and then translating them into HTML. Contractors must specify in the HTML title the contractor name and topic of the LMRP. If needed, contractors may use their initials for their name in the HTML title field. "Title" refers to

the HTML tag called "title" in the source code of HTML. A sample HTML format is located at www.medicarecmd.net. Contractors are encouraged to use this HTML sample. Contractors may alter the appearance of the HTML file to meet their own Web site needs, e.g., change the background color.
Contractors are encouraged to put existing LMRPs into these formats.

6.1 - AMA Current Procedural Terminology (CPT) Copyright Agreement - (Rev. 24, 04-05-02)

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 must display the AMA copyright notice in the body of each LMRP. Contractors must use a point and click license on a computer screen or Web page any time CPT codes are used on the Internet. Contractors should refer to Program Memorandum AB-00-126 for further guidance.

7 - LMRP Development Process - (Rev. 24, 04-05-02)

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

- *Contact the CMD facilitation contractor, other contractors, the local carrier or intermediary, the DMERC (if applicable), www.LMRP.net or QIOs (formerly PROs) to inquire if a policy which addresses the issue in question already exists;*
- *Adopt or adapt an existing LMRP, 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 LMRP includes developing a draft LMRP based on review of medical literature and the contractor's understanding of local practice.

A -- Multi-State Contractors

A contractor with LMRP jurisdiction for 2 or more states is strongly encouraged to develop uniform LMRP across all its jurisdictions. However, carriers must continue to maintain and utilize CACs in accordance with the §7 below.

7.1 - Evidence Supporting LMRPs - (Rev. 24, 04-05-02)

Contractor LMRPs must be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LMRPs. The initial action in gathering evidence to support LMRPs must always be a search of published

scientific literature for any available evidence pertaining to the item/service in question. In order of preference, LMRPs 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 must be evaluated before a conclusion is reached.

LMRPs, which challenge the standard of practice in a community and specify that an item is never reasonable and necessary, must 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. - LMRPs That Require A Comment and Notice Period – (Rev. 24, 04-05-02)

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

- *All **New LMRP***

- *Revised LMRP that **Restricts** Existing LMRP - Examples: adding non-covered indications to an existing LMRP ; deleting previously covered ICD-9 codes.*

- ***Revised LMRP that makes a Substantive Correction** - If the contractor identifies an error published in an LMRP that substantively changes the reasonable and*

necessary intent of the LMRP, then the contractor must extend the comment and/or notice period by an additional 45 calendar days.

7.3 - LMRPs that Do Not Require a Comment and Notice Period – (Rev. 24, 04-05-02)

When a comment and notice period is unnecessary, contractors may immediately publish a revised LMRP electronically (e.g., Web site, email) and publish a print copy at a later date. In the following situations, the comment and notice processes are unnecessary:

- ***Revised LMRP that Liberalizes Existing LMRP*** *- For example, a revised LMRP expands the list of covered indications/diagnoses. The revision effective date may be retroactive.*

- ***Revised LMRP Being Issued for Compelling Reasons*** *- MUST OBTAIN RO APPROVAL - For example, a highly unsafe procedure/device.*

- ***Non-Substantive Correction*** *- For example, typographical or grammatical errors that do not substantially change the LMRP. The revision effective date may be retroactive.*

- ***Revised LMRP that makes a Clarification*** *-For example, adding information that clarifies the LMRP but does not restrict the LMRP. The revision effective date may be retroactive.*

- ***Non-discretionary Coverage/Payment/Coding Update****s - Contractors must update LMRPs 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.*

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

7.4 - LMRP Comment & Notice Process - (Rev 24, 04-05-02)

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

In addition, contractors 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 LMRP. Contractors notify providers of the LMRP effective date. New LMRP may **not** be implemented retroactively.*

7.4.1 - The Comment Period - (Rev. 24, 04-05-02)

A -- When The Comment Period Begins

For LMRPs 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 may distribute these draft LMRPs to the CAC members via hardcopy or via email.

For LMRPs 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 LMRPs to medical providers and organizations via:

- *Hardcopy mailing of the entire draft LMRP,*
- *Hardcopy mailing of the title and Web address of the draft LMRP, or*
- *E-mail containing the title and Web address of the draft LMRP.*

B-- When The Comment Period Ends

Contractors must 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 LMRP Distribution

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

- *Appropriate groups of health professionals and provider organizations that may be affected by the LMRP;*
- *Representatives of 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 LMRP Web site Requirements);*

- *RO, associate regional administrator, for distribution to the appropriate regional staff (e.g., coverage experts, reimbursement experts). The RO staff will review the LMRPs for any operational concerns; and*

- *The appropriate Advisory process:*

  - *The CAC, for carriers (See §8.1)*

  - *The DAP, for DMERCs (See §8.2)*

Contractors should make an effort to ensure that providers who have a history of billing for the service are informed of the proposed LMRP and have an opportunity to comment.

Contractors should encourage commentors to submit evidence-based data, professional consensus opinions or any other relevant information.

Contractors must indicate in each distribution the date the comment period ends.

D -- Draft LMRP Open Meetings

Contractors must provide open meetings for the purpose of discussing draft LMRPs. Carriers must 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 must provide other means for attendance (e.g., telephone conference) and accept written or e-mail comments. Written and e-mail comments must 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 LMRP, including providers, physicians, vendors, manufacturers, beneficiaries, and caregivers) can make presentations of information related to draft policies. Contractors must 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 LMRP is to be specifically discussed.

7.4.2 - Draft LMRP Web site Requirements - (Rev. 24, 04-05-02)

A - Draft LMRP on the Contractor Web site

Contractors must post draft LMRPs on the contractor's Web site. This Web site must 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.

LMRP Status Page

Contractors must post to the their Web site an LMRP status page that includes the draft LMRP title, date of release of draft LMRP for comment, e-mail and postal address for comments to be sent, end date for comment period, current status (see the following status indicators), actual date of release of final LMRP, and Web site link to final LMRP.

LMRP Status Indicators
D = draft under development; not yet released for comments
C = draft LMRP released for comment
E = formal comment period has ended; comments now being considered
F = final new/revised LMRP has been issued.

Comment/Response Document

Contractors must post to their Web site a summary of comments received concerning the draft LMRP with the contractor's response. The comment/response document needs to be posted on the Web for 3 - 6 months.

B - Draft LMRP on www.draftLMRP.net

For each LMRP the contractor posts for comments, the contractor must also complete a draft LMRP form on www.draftLMRP.net. The form must be completed within 2 business days of the draft LMRP being posted to the contractor Web site.

7.4.3 - The Notice Period - (Rev. 24, 04-05-02)

When a new or revised LMRP requires comment and notice (see §7.2), contractors must ensure that the effective date follows a minimum notice period of 45 calendar days.

A -- When The Notice Period Begins

Contractors must make final LMRPs public via a special bulletin, update to a provider manual, or inclusion in a newsletter.

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 LMRP is the 46th calendar date after the notice period began.

7.4.4 - Final LMRP Web site Requirements - *(Rev. 24* , 04-05-02*)*

A -- Final LMRP on the Contractor Web site

Contractors must post all final LMRPs on their Web site. Every contractor Website must contain all final LMRPs for that contractor (i.e. the number of LMRPs on LMRP.net should equal the number of final LMRPs on the contractor Web site).

Contractors who are an intermediary and a carrier within the same corporation must have separate Web pages for the LMRPs. Contractors must notify all providers via a bulletin article of the contractor LMRP Web address. Contractors must advise providers without access to the Web via the bulletin to request a hard copy of the LMRP.

B -- Final LMRPs on www.LMRP.net

Contractors must update www.LMRP.net when they issue a new or revised LMRP. Contractors must ensure that no draft LMRPs or retired LMRPs appear on LMRP.net.

8 - The LMRP Advisory Process - (Rev. 24, 04-05-02)

8.1 - The Carrier Advisory Committee - (Rev. 24, 04-05-02)

Carriers must establish one CAC per State. Where there is more than one carrier in a State, the carriers must 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 LMRPs 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 within a single region may establish a single CAC with permission from the RO. In order to obtain a waiver from the RO, contractors must obtain consensus agreement from all CAC members within the region.

8.1.1 - Purpose of the CAC - (Rev. 24, 04-05-02)

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 LMRP 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 must clearly communicate to CAC members that the focus of the CAC is LMRPs 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 must review all draft LMRPs, the final implementation decision about LMRPs rests with the CMD.
The CMD jointly develops the agenda with the co-chair representing the CAC to include concerns about LMRPs and local administrative issues.

8.1.2 - Membership on the CAC - (Rev. 24 , 04-05-02)

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

8.1.3 - Role of CAC Members - (Rev. 24, 04-05-02)

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

- Disseminate proposed LMRPs 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. 24, 04-05-02)

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 LMRPs developed by the CMD. The 45-calendar-day comment process required for all LMRPs starts when the proposed LMRP is distributed to the committee members. (See PIM Chapter 13 §7.4.1
Co-chairs present all proposed LMRPs to the CAC for discussion. If the need arises to develop and implement LMRPs before the next scheduled meeting, they solicit comments from committee members by mail or e-mail.

D - Staff Participation

The Director of Medicare Operations must 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.*

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 must 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 LMRP. 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)

may 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 may (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 must 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 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 LMRPs 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 LMRP development.

8.2 - Durable Medical Equipment Regional Carrier (DMERC) Advisory Process (DAP) - (Rev. 24, 04-05-02)

The DMERC must 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 may 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 Medical Review Policy (RMRP) 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 LMRPs - (Rev. 24, 04-05-02)

Contractors must educate the provider community on new or significantly revised LMRPs (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 LMRP - (Rev. 24, 04-05-02)

Contractors may apply LMRPs to claims on either a prepayment or postpayment basis. If a contractor decides to enforce an LMRP on a prepayment basis, the contractor must design an MR edit. (See PIM Chapter 3, §5) Contractors have flexibility to add, alter, or eliminate MR edits at any time.

Contractors must apply LMRPs prepayment or postpayment prospectively when conducting MR-directed claim reviews with dates of service on or after the effective date of the policy. Contractors should not apply a LMRP retroactively to claims processed prior to the effective date of the policy. However, if NCD, coverage provisions in interpretive manuals and LMRP fail to address an issue of coverage for a given claim, contractors make coverage determinations based on the information provided.

[Section 11 is being reserved for future use]

12 - Retired LMRPs - (Rev. 24, 04-05-02)

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