CHANGE REQUEST 1485

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
1	Table of Contents	---	---
1	2	---	---
1	2.1	---	---
1	2.3	---	---
1	2.3.1	---	---
1	2.3.2	---	---
1	2.3.3	---	---
1	2.3.4	---	---

NEW/REVISED MATERIAL--EFFECTIVE/IMPLEMENTATION DATE: July 11, 2001

This transmittal replaces PIM Chapter 1, Sections 2, 2.1, and sections 2.3 up through and including 2.3.4.

This transmittal does **NOT** replace section 2.2.

Sections 2.3.5 through the end of the chapter remain unchanged.

Nothing in this manual revision supercedes or eliminates requirements described in Transmittal AB-00-116 (The "LMRP Openess" PM, Change Request 1021)

Although this transmittal contains some changes that are effective October 1, 2001, it does not contain any of the changes that will be needed as a result of Section 522 of the Benefits Improvements and Protection Act of 2000. These BIPA 522 changes will be communicated to contractors via a sepaate transmittal.

Chapter 1, Section 2, The Medicare MR Program – adds the word "contractors" to a sentence. Clarifies that not all Medicare contractors perform all MR functions and the contractor requirements listed in this manual apply to contractors who have jurisdiction for those particular functions. Adds *new sub*-headings. Clarifies that the MR program addresses coverage and coding errors, not duplicate claims, Medicare Secondary Payor (MSP), and other types of claim errors. Clarifies that when the MR unit detects situations where a provider has repeatedly submitted claims in error, the contractor shall follow the requirements in Chapter 3 §1 Verifying Potential Errors & Taking Corrective Actions - Introduction.

Chapter 1, Section 2A, Quality of Care Issues -- Title of section has been added. State Medical Boards have been removed from the list on organizations responsible for quality of care issues since they are considered part of state licensing survey and certification agencies. Removes the requirement that contractors notify RO and CO of quality of care referrals.

Chapter 1, Section 2B, Goal of the MR Program -- clarifies that one way contractors meet the goal of the MR program is by providing guidance to the public and providers and other interested entities about when items and services will be eligible for payment. Adds langauge clarifying that providers may conduct self-audits to identify coverage and coding errors using the OIG Compliance Program Guidelines.

Chapter 1, Section 2C, MR Manager -- is a new section added to incorporate requirements listed in the 2001 Budget and Performance Requirements (BPR). This language requires contractors to name a MR manager that will act as the primary contact between the contractor and the Centers for Medicare and Medicaid Services (CMS) concerning the contractor's MR program.

Chapter 1, Section 2D, Annual MR Strategy -- is a new section added to incorporate requirements listed in the 2001 BPR. Removes the requirement that contractor perform certain types of review on CMS-specified percentages of claims. Requires contractors to determine the appropriate types and amounts of review for their jurisdiction. Requires contractor to disperse their workload evenly throughout the year. Removes the full-time CMD requirement for FIs, RHHIs, and DMERCs.

Chapter 1, Section 2E, Annual QI Program Report - is a new section added to incorporate requirements listed in the 2001 BPR and add new requirements for the QI Program and the QI Program Report.

Chapter 1, Section 2.1, National Coverage Decisions (NCDs), Coverage Provisions in Interpretive Manuals, Local Medical Review Policy (LMRP), and Individual Claim Determinations – eliminates the term National Coverage Policy (NCP) and replaces it with the term National Coverage Decision (NCD). Clarifies that "the act" refers to the Social Security Act.

Chapter 1, Section 2.1.A, National Coverage Decisions – replaces NCP with NCD. Adds language and examples to further define NCDs. States that NCDs should not be confused with National Coverage Requests or Coverage Decision Memos. Defines National Coverage Requests and links to an example. Defines Coverage Decision Memos, links to an example, and states that although contractors are not bound by Coverage Decision Memos, contractors may consider them when reviewing claims. However, in an effort to ensure that MR funds are not expended developing LMRP that will be superceded shortly by an NCD, it encourages contractors to consider Coverage Decision Memos posted on the CMS website.

Chapter 1, Section 2.1.B, Coverage Provisions in Interpretive Manuals – clarifies that contractors are bound by coverage provisions that appear in manuals other than the Coverage Issues Manual.

Chapter 1, Section 2.1.C, LMRP – adds PMs issued by CMS to the list of information contractors may include in websites and bulletins. Reminds contractors not to use the terms "fraud" or "fraudulent" in their LMRPs.

Chapter 1, Section 2.1.D, Individual Claim Determinations – replaces the term "NCP" with the terms "NCD" and "coverage provisions in interpretive manuals." Adds a requirement that contractors complete all prepay and postpay reviews within 60 days of receipt of medical records.

Chapter 1, Section 2.3, LMRP Development Process – adds a PIM reference to the DMERC Advisory Process (DAP); adds language encouraging multi-state contractors to develop uniform LMRP across all its jurisdictions but reminding such contractors to abide by the CAC rules in PIM Chapter 1, §2.7.1.

Chapter 1, Section 2.3.1, Identification of Services For Which a New or Revised LMRP is Needed – adds the term "new or revised" to the title of this section. Adds language clarifying that the underlying purpose of LMRP is to help avoid situations in which claims are paid or denied without a provider having full understanding of the basis for payment and denial. Requires contractors to develop LMRP if the contractor has identified an item or service that is never covered under certain circumstances and the contractor wishes to establish automated review. Incorporates Progressive Corrective Action Program Memorandum language by adding the phrase "validated widespread problem" to the list of instances when contractors may develop LMRP. Adds that a contractor may develop LMRP when the contractor has assumed the LMRP development work from another contractor and wants to create uniform LMRP across its multiple jurisdictions. Allows contractors to develop LMRP when frequent denials are issued or anticipated following routine or complex review. Requires contractors to review and appropriately revise affected LMRPs within 90 days of publication of a program instruction containing a national coverage determination or national payment policy. Adds an annual requirement that contractors review and revise/retire LMRPs as needed based upon CMS NCDs, coverage provisions in interpretive manuals and national payment policies. Requires contractors to keep www.LMRP.net current.

Chapter 1, Section 2.3.2, Techniques for Writing LMRPs – adds the term "new or revised" to the third paragraph and replaces the term "NCP" with the terms "NCD" and "national coverage provision in interpretive manuals."

Chapter 1, Section 2.3.2.1 - Evidence Supporting LMRP - is revised to clarify that less stringent evidence is needed when allowing for coverage of services that have lower risks of negative health effects on beneficiaries.

Chapter 1, Section 2.3.2.2 - Use of Absolute words in LMRP - replaces the term "NCP" with the terms "NCD" and "coverage provisions in interpretive manuals."

Chapter 1, Section 2.3.3.A, Benefit Category – adds a link to a list of Medicare benefit categories as currently listed in the Program Safeguard Contractor Statement of Work.

Chapter 1, Section 2.3.3.B, Statutory Exclusions on Grounds Other Than Section 1862(a)(1) – moves the exceptions to 1862(a)(1)(A) to section 2.3.3.C.

Chapter 1, Section 2.3.3.C, Reasonable and Necessary – moves the exceptions to 1862(a)(1)(A) from the section 2.3.3.B to this section. Adds the exception for routine clinical trial services.

Chapter 1, Section 2.3.4, Coding Provisions in LMRPs – Clarifies that the mere presence of a billing code (HCPCS, revenue code, RUG, etc.) does not guarantee Medicare coverage. Adds a description of the Statistical Analysis Durable Medical Equipment Regional Contractor (SADMERC) and points out that the SADMERC provides Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) coding advice not coverage advice to suppliers and contractors.

Redlining (*red italics font*) is used to indicate new material.

These instructions should be implemented within your current operating budget.

MEDICARE PROGRAM INTEGRITY MANUAL

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

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Table of Contents
(Rev. 8, 07-11-01)

2 – The Medicare MR Program (Rev. 8, 07-11-01)

The statutory authority for the MR program *includes* the following sections of the Social Security Act (the Act):

- Section 1833(e) that states, *in part* "...no payment shall be made to any provider... unless *there* has *been furnished* such information as *may be necessary* in order to determine the amounts due such provider....;"

- Section 1842*(a)*(2)(B) that requires contractors to "*assist in the application of* safeguards against unnecessary utilization of services furnished by providers*...;*"

- Section 1862(a)(1) that states no Medicare payment shall be made for *expenses incurred for* items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member;"

- The remainder of Section 1862(a) that describes all statutory exclusions from coverage;

- Sections *1812,* 1861, and 183*2* that describe the Medicare benefit categories; *and*

- *Sections 1874, 1816, 1842 that provide further authority.*

The regulatory authority for the MR program rests in:

- 42 CFR 421.100 for intermediaries

- 42 CFR 421.200 for carriers

CMS contracts with carriers, fiscal intermediaries (FIs), and program safeguard contractors (PSCs) to perform MR functions: analyze data, write local medical review policy, and review claims. All of these entities are referred to as Medicare "contractors." Not all Medicare contractors perform all MR functions. The contractor requirements listed in this manual apply to contractors who have responsibility for those particular functions. For example, if a contractor has a contract with CMS only to perform data analysis for all durable medical equipment, that contractor would not be required to comply with the LMRP requirements, or any requirements other than data analysis.

A -- Quality of Care Issues

Potential quality of care issues are not the responsibility of the MR unit but the responsibility of the PRO, State *licensing/survey and Certification* agency, or other appropriate entity in the service area. Contractors should refer quality of care issues to them. *See Chapter 3 §1 for a discussion of how contractors should handle situations where providers are non-compliant with Medicare conditions of participation.*

B -- Goal of MR Program

The goal of the medical review program is to *reduce payment error by identifying, and addressing billing errors concerning coverage and coding* made by providers. To achieve the goal of the MR program, contractors:

- *Proactively* identify *potential billing* errors *concerning Coverage & Coding made by providers* through analysis of data (e.g., profiling of providers, services, or beneficiary utilization) and evaluation of other information (e.g., complaints, enrollment and/or cost report data) (Chapter 2 describes these activities in further detail) and;

- Take action to prevent and/or address the identified error. Errors identified will represent a continuum of intent. (Chapter 3 describes these actions in further detail.)

- *Publish local medical review policy to provide guidance to the public and medical community about when items and services will be eligible for payment under the Medicare statute.*

Providers may conduct self-audits to identify coverage and coding errors using the OIG Compliance Program Guidelines at www.os.dhhs.gov/oig/modcomp/index.htm. *Contractors must follow transmittal AB-00-41 in handling any voluntary refunds that may result from these provider self-audits.*

Most errors do not represent fraud. Most errors are not acts that were committed knowingly, willfully, and intentionally. However, in situations where a provider has repeatedly submitted claims *in error*, the MR unit *shall follow the procedures listed in Chapter 3 §1*. For example, some errors will be the result of provider misunderstanding or failure to pay adequate attention to Medicare policy. Other errors will represent calculated plans to knowingly acquire unwarranted payment. Contractors are to take action commensurate with the error made. Contractors should evaluate the circumstances surrounding the error and proceed with the appropriate plan of correction. *See Chapter 3§1*.

C -- MR Manager

An effective MR program begins with the strategies developed and implemented by senior management staff. Contractors must name a MR point of contact that will act as the primary contact between the contractor and CMS concerning the contractor's MR program. The MR Manager will also have primary responsibility for oversight and implementation of the contractor's MR Quality Improvement Program (eff. 10/01) and primary responsibility for ensuring the timely submission of the MR Strategy, and MR QI Program Report.

D – Annual MR Strategy and Report

Contractors are required to develop and document a unique annual MR strategy within their jurisdiction. This strategy must be consistent with the goal of reducing the error rate. Under the Government Performance and Results Act (GPRA), CMS has a FY 2002 goal to reduce the Medicare fee for service paid claims error rate to 5 percent. Contractors are not requested to establish a baseline error rate or calculate a contractor specific error rate to be judged against the GPRA goal. The Comprehensive Error Rate Testing Program will eventually provide the baseline measurements.

When submitting the MR Strategy, the contractor shall:

- *Complete the following chart:*

CAFM II Activity Code	*BUDGET*	*PROJECTED WORKLOAD*		
		Workload 1	*Workload 2*	*Workload 3*
21001				
21002				
21003				
21007				
21008				
21030				
21031				
21032				
21100				

- *Identify, by job title, the number of FTEs for each CAFM II activity code and provide an employee list associated with direct costs;*

- *Identify the intended areas for focusing the contractors MR resources;*

- *Identify the processes that the contractor shall use to monitor spending in each MR activity code to ensure that spending is consistent with the allocated budget. This shall include the processes the contractor shall undertake to revise, amend the plan, when spending is over or under the budget allocation;*

- *Identify the process that assures the accuracy and the consistency of reporting workload for each CAFM II code and assesses the proper allocation of FTE/hrs that are required for each activity;*

- *Identify the data analysis process the contractor will employ in carrying out the MR program;*

- *Identify the provider educational processes the contractor will employ throughout the MR program;*

- *Contractors may perform automated, routine, and complex prepayment review and post-payment reviews. Contractors should determine the appropriate amount of review to be performed for each CAFM II code within the constraints of their budget. Consideration should be provided for the cost effectiveness of each tool, as well as the appropriateness of each tool for resolving identified problems in achieving the overall goal of reducing the claims payment error rate.*

- *In order to prevent "bunching," contractors should complete 20-30% of their workload for each MR activity code per quarter.*

- *Only in those instances where reviews cannot be automated and no clinician review is indicated shall the contractor conduct routine manual reviews.*

- *DMERCs, FI, and RHHI budgets should include funds for activities associated with providing advance determinations of Medicare coverage (ADMC) for certain customized items of DME (PIM Chapter 5, Section 7).*

- *DMERCs are now required to employ at least a part-time CMD.*

Beginning in *October* 2000, *an* MR Strategy should be submitted no later than November 1 to the appropriate RO and CO (MROperations@cms.hhs.gov). *This report is a description of the contractors MR strategy and must, at a minimum, include a discussion of the MR strategy*

requirements listed above. Effective 10/01, the MR Strategy should be updated as needed and updated MR Strategies should be sent with the budget request to the RO and CO (MROperations@cms.hhs.gov).

E –Annual QIP and Report

Contractors must assure the implementation of an effective QIP. The QIP goals are to assure that the decisions are accurate, consistent and the Medical Review Strategy is being implemented efficiently and effectively. The contractor is responsible for identifying problems or potential problems with each QI process. In response to problems or potential problems identified, a contractor must formulate an intervention to address the problem/potential problem and evaluate the impact/effectiveness of the intervention. In FY 2000, the top five overall problems identified through the Contractor Performance Evaluation process were workload management, effective data analysis, edit development and evaluation of edit effectiveness, and accurate review decisions. As such, contractors, in formulating their QIPs should give special attention to these five areas. At a minimum, contractor's MR QIP must:

- *Establish Quality Improvement coordinators within the organization structure.*
- *Assure that all QI processes are written and catalogued together in a single manual.*
- *Include oversight of policy development.*
- *Assure accurate, consistent, and defensible decision-making by the MR staff, including employing physician participation in determining the accuracy of medical review decisions and regularly testing and improving inter-reviewer reliability.*
- *Include oversight of the data analysis process to ensure the contractor uses a variety of local and national data sources. The QIP should identify potential aberrant patterns with appropriate translation of findings into a prioritized review strategy. The QIP should consider PCA, MR, appeals, and reversal findings and trends when considering changes in methodologies and procedures.*
- *Establish written methods for conducting objective assessment of all MR functions.*
- *Validate the appropriateness of the MR process.*
- *Assure that the MR system has the capacity to draw on special expertise when necessary for conducting medical review/claim determinations.*
- *Assure the internal education efforts are effective and efficient.*
- *Assure provider education efforts are effective and efficient. (Remedial provider education is a MIP PET activity.)*

- *Demonstrate proficient management practices, with written policies and procedures that are up-to-date to address identified problems and appropriate remedial action. One way the contractors can assure proficient management procedures is to become ISO 9000 certified[1] or to undergo a third party validation process. PSCs with task orders valued at $1million or moare must obtain ISO certification.*

- *Include a process that assures the accuracy and the consistency of reporting workload for each CAFM II code and assess the proper allocation of FTE/hrs that are required for each activity.*

- *Contractors must submit an updated QIP plan with their MR strategy and budget request.*

To the extent that a contractor has a corporate QIP that meets all or some of the MR QIP requirements, the contractor need not duplicate these processes, but must include a detailed description of its corporate QIP processes in the QIP Report. Contractors must submit an updated QIP plan to assess and monitor their MR Strategy with their budget request. Contractors must submit a semi-annual QIP Report entitled "MR QI Program" to the RO and CO (MROperations@cms.hhs.gov) no later than 30 days after the close of the 2nd and 4th quarters.

F - Reporting for Separate MR Sites

Contractors with multiple MR sites must separate track workload and funding for each site and report this data in the Remarks Section of CAFMII for each activity code.

2.1 – National Coverage *Decisions* (NC*D)*, *Coverage Provisions in Interpretive Manuals,* Local Medical Review Policy (LMRP), and Individual Claim Determinations (Rev. 8, 07-11-01)

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* manual*s*, and LMRPs to apply the provisions of the Act.

A. *NCD*

NC*Ds 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, Peer Review Organizations, Program Safeguard Contractors 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.hcfa.gov/pubforms/06_cim/ci50.htm#_1_56.

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(1) For more information concerning ISO 9000 certification, on the World Wide Web go to www.ASQ.org, or call 1-800-248-1946.

When *a* new NC*D* 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 website *or link to the NCD from the contractor website*. In addition, th*e* NC*D* 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 wit*h §2.3.1.

The contractor shall apply NC*Ds* to individual claims. When making individual *claim* determinations, contractors have no authority to deviate from NC*D* if absolute words such as "never" or "only if" are used in the policy.

Requirements for prerequisite therapies listed in NC*D* (e.g., "conservative treatment has been tried, but failed") must be adhered to when making decisions 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.hcfa.gov/coverage/8a1.htm. *If CMS decides to accept the request, information is posted on the coverage website at* http://www.hcfa.gov/coverage. *National Coverage Requests may contain Technology Assessments (e.g.,* http://www.hcfa.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 Carrier 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.hcfa.gov/coverage/8b3-a1.htm*.)*

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

B. Coverage Provisions in Interpretive Manuals

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, PROs, and PSCs.

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 website 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 §2.3.1.

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 adhered to when making decisions to cover a service.

C. LMRP

LMRP specifies whether 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 medial 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.

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

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 of coverage and coding policy 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 inflamatory if the word "fraudulent" were replaced with the word "noncovered."

D. Individual Claim Determinations

Contractor may review claim*s* on either a prepayment or postpayment basis regardless of whether a NC*D*, *coverage provision in an interpretive manual,* or LMRP exists for that service. However, automated denials cannot be made in the absence of NC*D, coverage provision in interpretive manual* or LMRP. 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* ***§2.3.3, Coverage Provisions in LMRPs*** *below.*

Contractors must complete prepay and postpay reviews within 60 days of receipt of medical records.

2.2 - Least Costly Alternative - (Rev. 3, 11-22-00)

"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 Carrier Manual (MCM) §2100.2.) Contractors have the discretion to apply this principle to payment for non-DME services as well.

2.3 – LMRP Development Process (Rev. 8, 07-11-01)

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. In addition, contractors solicit comments from the medical community. Carriers solicit comments from the Carrier Advisory Committee (CAC) (See PIM Chapter 1 §2.7 for further discussion of the CAC.) DMERCs solicit comments through the DMERC Advisory Process (DAP). *(See Chapter 1 §2.7.7 for further discussion of the DAP.)* Contractors respond to comments and, where appropriate, incorporate them into the final LMRP. Contractors notify providers of the LMRP effective date. (See PIM Chapter 1, §2.3.6) New LMRP may **not** be implemented retroactively. *(See Chapter 8 - Transmittal # AB-00-116)*

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, the contractor must continue to maintain and utilize CACs in accordance with the Chapter 1, § 2.7.1. Multi-state contractors may develop uniform LMRP across all its jurisdictions even if data analysis indicates that the problem exists only in one state.

2.3.1 – Identification of Services For Which a *New or Revised* LMRP is Needed (Rev. 8, 07-11-01)

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.

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 that supports automated review.

Contractors *may* develop LMRP*s when*:

- *a validated widespread problem* demonstrate*s* 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.*

- 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*

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

*In the instance that there is no LMRP for a given service, c*ontractors should continue to make individual claim determinations for those services. *Contractors must continue to develop edits for new providers and for new benefits to ensure correct coverage from the beginning as indicated in Chapter 3, §5.1.1.1. Contractors must ensure that their new provider edits and new benefit edits do not place an administrative burden on providers.*

Contractors must review and appropriately revise affected LMRP within 90 days of the publication of:

- *a program instruction containing a new or revised NCD,*

- *a program instruction containing a new or revised coverage provision in interpretive manual,*

- *a program instruction containing a change to national payment policy,*

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.

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's 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.

2.3.2 – Techniques for Writing LMRPs (Rev. 8, 07-11-01)

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

The LMRP must be clear, concise, 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.

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 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.

- **2.3.2.1 – Evidence Supporting LMRP*s* (Rev. 8, 07-11-01*)***

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.

LMRP*s*, which challenge the standard of practice in a community and specif*y* 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.

2.3.2.2 – Use of Absolute Words in LMRP*s* (Rev. 8, 07-11-01)

Contractors may use phrases such as "rarely medically necessary" or "not usually medically necessary" in proposed LMRP*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 documentation or 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 LMRP*s* that contain absolute words such as "is never covered" or "is only covered for". When phrases with absolute words are clearly stated in LMRP*s*, 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.

2.3.2.3 – LMRP Requirements That Alternative Service Be Tried First (Rev. 8, 07-11-01)

Contractors may incorporate into LMRP*s* 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 LMRP*s*. As an alternative, contractors may use phrases in proposed LMRP*s* like "the provider should consider..."

2.3.3 – Coverage Provisions in LMRPs (Rev. 8, 07-11-01)

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.hcfa.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, 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 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.

2.3.4. – Coding *Provisions* in LMRPs (Rev.8, 07-11-01)

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 categorized (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 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