CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 608	**Date: August 14, 2015**
	Change Request 8747

Note: This note is being re-sent to include the missing implementation date of September 14, 2015 on the Business Requirement document for CR 8747. All other information remains the same.

SUBJECT: Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-08. In some instances this required deletion of "9" or "ICD-9" in references to the International Classification of Diseases (ICD). Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE: ASC X12: January 1, 2012; ICD-10: Upon Implementation of ICD-10
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: ASC X12: September 14, 2015; ICD-10: Upon Implementation of ICD-10

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/3.2- Overview of Prepayment and Postpayment Reviews
R	3/3.2.3.7- Special Provisions for Lab Additional Documentation Requests
R	3/3.3- Policies and Guidelines Applied During Review
R	3/3.3.2.8- MAC Articles
R	3/3.4.1- Electronic and Paper Claims
R	3/3.4.1.3- Diagnosis Code Requirements
R	3/3.6.2.4- Coding Determinations
R	3/3.6.4- Notifying the Provider
R	4/4.7.1- Conducting Investigations
R	4/4.16- AC, MAC, PSC, and ZPIC Coordination on Voluntary Refunds
R	4/4.33- Recovery Audit Contractors (RACs)
R	5/5.2.3- Detailed Written Orders
R	6/Table of Contents
R	6/6.5.3- DRG Validation Review
R	6/6.5.5- Special Review Considerations
R	13/13.1.3- Local Coverage Determinations (LCDs)
R	13/13.4- When To Develop New/Revised LCDs
R	13/13.5.2- Coding Provisions in LCDs

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 608	Date: August 14, 2015	Change Request: 8747

Note: This note is being re-sent to include the missing implementation date of September 14, 2015 on the Business Requirement document for CR 8747. All other information remains the same.

SUBJECT: Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

EFFECTIVE DATE: ASC X12: January 1, 2012; ICD-10: Upon Implementation of ICD-10
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: ASC X12: September 14, 2015; ICD-10: Upon Implementation of ICD-10

I. GENERAL INFORMATION

A. Background: This CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-08. Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

B. Policy: CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-08. Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8747.1	A/B MACs, DME MACs, RACs, and ZPICs shall be aware of the updated language for ICD-10 and for ASC X12 in Pub. 100 - 08.	X	X	X	X					RACs, ZPICs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility		
		A/B MAC	DME	CED

		A	B	H H H	M A C	I
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s):

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Program Integrity Manual
Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

3.2 -Overview of Prepayment and Postpayment Reviews

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, as indicated.

A. Prepayment and Postpayment Review

Prepayment review occurs when a reviewer makes a claim determination before claim payment has been made. Prepayment review always results in an "initial determination"

Postpayment review occurs when a reviewer makes a claim determination after the claim has been paid. Postpayment review results in either no change to the initial determination or a "revised determination" indicating that an overpayment or underpayment has occurred.

B. Prepayment Edit Capabilities

Prepayment edits shall be able to key on a beneficiary's Health Insurance Claim Number (HICN), National Provider Identifier (NPI) and specialty code, service dates, and diagnosis or procedure code(s) (i.e., Healthcare Common Procedure Coding System [HCPCS] and/or International Classification of Diseases diagnoses codes), Type of Bill (TOB), revenue codes, occurrence codes, condition codes, and value codes.

The MAC systems shall be able to select claims for prepayment review using different types of comparisons. At a minimum, those comparisons shall include:

- Procedure to Procedure -permits contractor systems to screen multiple services at the claim level and in history.
- Procedure to Provider - permits selective screening of services that need review for a given provider.
- Frequency to Time- permits contractors to screen for a certain number of services provided within a given time period.
- Diagnosis to Procedure- permits contractors to screen for services submitted with a specific diagnosis. For example, the need for a vitamin B12 injection is related to pernicious anemia, absent of the stomach, or distal ileum. Contractors must be able to establish edits where specific diagnosis/procedure relationships are considered in order to qualify the claim for payment.
- Procedure to Specialty Code or TOB- permits contractors to screen services provided by a certain specialty or TOB.
- Procedure to Place of Service- permits selective screening of claims where the service was provided in a certain setting such as a comprehensive outpatient rehabilitation facility.

Additional MAC system comparisons shall include, but are not limited to the following:

- Diagnoses alone or in combination with related factors.
- Revenue linked to the health care common procedure coding system (HCPCS).

- Charges related to utilization, especially when the service or procedure has an established dollar or number limit.

- Length of stay or number of visits, especially when the service or procedure violates time or number limits.

- Specific providers alone or in combination with other parameters.

The MR edits are coded system logic that either automatically pays all or part of a claim, automatically denies all or part of a claim, or suspends all or part of a claim so that a trained clinician or claims analyst (routine review) can review the claim and associated documentation (including documentation requested after the claim is submitted) in order to make determinations about coverage and payment under Section 1862(a) (1) (A) of the Act. Namely, the claim is for a service or device that is medically reasonable and necessary to diagnose or treat an injury or improve the functioning of a malformed body member. All non-automated review work resulting from MR edits shall:

- Involve activities defined under the MIP at §1893(b)(1) of the Act;

- Be articulated in the MAC's medical review strategy;

- Be designed in such a way as to reduce the MAC's CERT error rate or prevent the MAC's CERT error rate from increasing, or;

Prevent improper payments identified by the Recovery Auditors.

3.2.3.7 - Special Provisions for Lab Additional Documentation Requests

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided upon implementation of ICD-10. ICD-9-CM is used for discharges and other services before that implementation.

When the MACs, CERT, Recovery Auditors and ZPICs send an ADR for a lab service, the following documentation shall be requested from the billing lab:

- The order for the service billed (including sufficient information to allow the reviewer to identify and contact the ordering provider);

- Verification of accurate processing of the order and submission of the claim; and

- Diagnostic or other medical information supplied to the lab by the ordering provider, including any *diagnosis* codes or narratives.

The contractor shall deny the claim if a benefit category, statutory exclusion, or coding issue is in question, or send an ADR to the ordering provider in order to determine medical necessity. The contractor shall review information from the lab and find it insufficient before the ordering provider is contacted. The contractor shall send an ADR to the ordering provider that shall include sufficient information to identify the claim in question.

If the documentation received does not demonstrate that the service was reasonable and necessary, the contractor shall deny the claim. These denials count as complex reviews. Contractor denial notices shall remind providers that beneficiaries cannot be held liable for these denials unless they have received proper liability notification before services were rendered, as detailed in CMS Pub. IOM 100-04, chapter 30.

The MACs, CERT and Recovery Auditors shall implement these requirements to the extent possible without shared systems changes.

3.3 - Policies and Guidelines Applied During Review

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, Recovery Auditors, Supplemental Medical Review Contractors (SMRCs) and ZPICs, as indicated.

A. Statutes, Regulations, the CMS' Rulings, National Coverage Determinations, Coverage Provisions in Interpretive Medicare Manuals, and Local Coverage Determinations

The primary authority for all coverage provisions and subsequent policies is the Social Security Act. In general, MACs, CERT, Recovery Auditors, SMRCs, and ZPICs shall apply the provisions of the Act according to the following hierarchy of documents in effect at the time the item(s) or service(s) was provided to make medical review decisions:

Social Security Act
Code of Federal Regulations
CMS' Rulings
National Coverage Determination (NCDs)
Coverage provisions in Interpretive Manuals or Internet Only Manuals (IOM) which includes Medical Review Guidance in the Medicare Program Integrity Manual
CMS coding policies
Technical Direction Letters (TDLs)*
The relevant MAC's Local Coverage Determination (LCDs)
The relevant MAC's local articles
AHA Coding Clinics.

*TDLs that contain MR guidance may provide an exception to this hierarchy.

B. Coding Guidelines

The MACs, CERT, Recovery Auditors, and ZPICs shall apply coding guidelines to services selected for review. All contractors shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology-4 (CPT) book, *International Classification of Diseases Guidelines (ICD),* CMS *HCPCS or ICD* policy or guideline requirements, LCDs, or MAC articles.

C. Internal Medical Review Guidelines

The MAC, CERT, Recovery Auditor, and ZPIC staffs have the discretion to develop detailed written review guidelines to guide staff during claim reviews. Internal MR guidelines shall specify the information to be reviewed by reviewers and the appropriate resulting determination. Recovery Auditors are required to develop written review guidelines in accordance with their SOW. The MACs, CERT, Recovery Auditors, and ZPICs shall make their internal MR guidelines available to their staff, as needed. Internal MR Guidelines shall not create or change the CMS policy.

3.3.2.8 - MAC Articles

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs.

A. General

The MACs have the discretion to publish articles communicating certain information to providers, such as any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. The MACs are required to enter articles that address LCDs, coding or medical review-related billing and claims considerations into the Medicare Coverage Database (MCD).

For the purposes of this manual, the term "publish" will be used to describe any form of dissemination including posting on a Web site, distributing at a seminar, e-mailing, or printing in a hardcopy bulletin. The MAC Medical Review Departments are responsible for the development of articles associated with new or revised LCDs and for entering those articles into the Medicare Coverage Database. Other widespread educational articles shall not be charged to MR.

The MAC medical review departments shall send articles to the appropriate department within the MAC for publishing. All newly created articles shall be posted on the MAC's Web site where duplicate copies can be obtained by providers/suppliers.

When NCDs or other coverage instructions issued by the CMS include specific conditions or parameters for covered services, the MACs have the discretion to develop and publish a list of covered codes associated with the coverage provision. MACs have the discretion to automate denials for codes not included on the list without the development of a LCD if the NCD indicates or states that no other condition or parameters will be covered.

MACs also have the discretion to:

- Publish definitions of procedure codes, lists of items that may be billed under a particular code, or minimum requirements that providers must meet in order to bill using a certain code.

- Publish a product classification list that instructs providers about which specific products meet the definitional requirements of a particular HCPCS code. Developing or revising an LCD for this article is unnecessary.

- Explain which off-labeled uses of the Food and Drug Administration (FDA) approved drugs are considered reasonable and necessary within the *diagnosis* codes that reflect such uses.

- Explain the benefit category decisions and publish a list of drugs/biologicals that are considered usually self-administered. MACs should enter their self-administered medication exclusion list into the Medicare Coverage Database. This database can be accessed at www.cms.gov/mcd.

- MACs have the discretion to explain which HCPCS code or group of codes properly describes a particular service.

- MACs have the discretion to publish State non-physician licensure information that governs services billed by the physician under the "incident to" provision.

The MACs shall ensure that articles do not conflict with NCDs, LCDs, policy, or coverage provisions in interpretive manuals. Although a comment and notice process is not required, MACs are encouraged to consult with stakeholders in the provider community when developing articles. MACs shall monitor comments about articles from clinician providers and respond to their concerns, as needed, by issuing revised or clarifying articles.

NOTE: Nothing in this section precludes the MACs or ZPICs from making individual claim determinations, even in the absence of an article or LCD.

3.4.1 - Electronic and Paper Claims

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs.

The Administrative Simplification Compliance Act (ASCA, Section 3 of Pub. L, 107-105, 42 CFR 424.32) requires that all Medicare claims be submitted electronically *using the ASC X12 837 institutional or professional claim formats* with few exceptions. MACs shall not require providers to submit paper claims when they are targeted for prepayment complex medical review. The MACs shall allow providers that qualify for an ASCA mandatory electronic billing exception to submit paper claims when they are targeted for prepayment review (See IOM Pub.100-04, chapter 24, §90 for exceptions).

A. Supporting Documentation Submitted with Claims

The MACs shall not require or request providers to submit supporting documentation with the initial claim(s) through MAC-developed forms, local policies, or any other communications with providers. The MACs shall only request supporting documentation through the ADR process or an alternate MAC process that permits matching the claim number to the submitted documentation.

The MACs shall match supporting documentation with claims as part of the ongoing medical review process. The MACs have the discretion to consider unsolicited documentation, but are not required to. The MACs shall inform providers in their jurisdiction if they allow supporting paper documentation to be submitted with the claim for medical review purposes.

The MACs may choose to suspend for medical review claims for lab services coded with one of the laboratory-negotiated rulemaking *diagnosis* "Codes that Do Not Support Medical Necessity (where documentation could result in payment)" only if identified as a prioritized problem in their medical review strategy, and consistent with PIM chapter 11, §11. In these cases, MACs shall continue to use the documentation submitted with the claim in order to determine whether the lab service was reasonable and necessary for that particular *diagnosis* code.

3.4.1.3 - Diagnosis Code Requirements

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs and ZPICs, as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided on and after the implementation of ICD-10-CM. ICD-9-CM is used for discharges and other services before the implementation of ICD-10-CM.

Section 1833(e) of the Act states that no payment should be made "under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person…." MACs and ZPICs should require submission of information, in accordance with the requirements below, that they deem necessary to make a claim determination and determine appropriate payment. Some provider types are required to submit diagnosis codes on all claims while other provider types are required to submit diagnosis codes only if such information is required by a LCD.

A. Claims Submitted by Physicians or Certain Non-Physician Practitioners Must Contain Diagnosis Codes.

Section 1842 (p) (1) of the Act states that for each claim submitted by physicians or certain non-physician practitioners (defined in 1842(b) (18) (C) of the Act) "shall include the appropriate diagnosis code (or codes)…." For claims submitted with invalid, truncated, or missing *diagnosis* codes, MACs and ZPICs shall classify the claim as rejected as unprocessable within the MCS. See the Claims Processing Manuals IOM Pub.100-04.

B. Claims Submitted by All Other Provider Types Must Contain Diagnosis Codes if required by a LCD

During a service-specific review to address potential abuse or overutilization, MACs and ZPICs should require that *diagnosis* codes be submitted with each claim for the targeted service. The diagnosis information is used to determine if the services are covered and correctly coded. MACs and ZPICs should require that ICD diagnosis codes be submitted by all non-physician billers with every claim for a targeted service only if such a requirement appears in a LCD for that service. This outreach shall occur via Web site, bulletin articles, etc.

For provider-specific reviews, MACs and ZPICs have the discretion to require submission of diagnosis codes to support that the reasonable and necessary criteria has been met on all claims submitted by individual non-physician providers who have been targeted because of unusual billing practices, fraud referrals, etc., even if no LCD exists requiring such codes. For claims submitted with invalid, truncated, or missing *diagnosis* codes, reviewers shall classify the claim as unable to be processed, and return the claim to the provider (RTP). See the Claims Processing Manual IOM Pub.100-04.

C. Requirements for Lab Claims

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) established three new and one revised Organ and Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multichannel tests there is a general presumption of medical necessity. If there is data or reason to suspect abuse of the panel codes, contractors may review these claims. Should contractors determine the need to develop a LCD for laboratory panel codes the MAC shall develop these policies at the panel code level. In some instances of perceived abuse of the panel codes, the contractors may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

3.6.2.4 - Coding Determinations

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, SMRC, Recovery Auditors, and ZPICs, as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided on and after the implementation of ICD-10-CM.. ICD-9-CM is used for discharges and other services before that date.

The MACs, CERT, SMRC, Recovery Auditors, and ZPICs shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology-4 (CPT-4), Coding Clinic for ICD, Coding Clinic for HCPCS, and any coding requirements listed in CMS manuals or MAC articles.

In certain situations, it is appropriate for contractors to up code or down code a claim (or items or services on a claim) and adjust the payment. When the medical record supports a higher or lower level code, the MACs, SMRC, CERT, ZPICs and Recovery Auditors shall not deny the entire claim but instead shall adjust the code and adjust the payment. The MACs, SMRC, CERT, ZPICs and Recovery Auditors shall up code or down code when it is possible to pay for the item or service actually provided without making a reasonable and necessary determination or if otherwise specified in applicable CMS medical review instructions. The MACs, SMRC, CERT, ZPICs and Recovery Auditors shall not substitute the payment amount of one item or service for a different item or service based on a reasonable and necessary determination.

Example situations where it is appropriate to up code or down code a claim are:

1. CBC with diff was ordered and billed but CBC without diff was provided;
2. X-ray with contrast was ordered and billed but X-ray without contrast was provided;
3. E&M level 3 was billed but the medical record supports level 2 (or other level);
4. PPS (DRG/RUG/HHRG) code was billed but the medical records supports a different code; and
5. Quantity of diabetic test strips exceeds limits; for example, quantity was provided for insulin treated but the patient was not insulin treated.

3.6.4 - Notifying the Provider

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to, MACs, Recovery Auditors, and ZPICs, as indicated.

A. General

At the conclusion of postpayment review, the MACs shall send a Review Results Letter to the provider even if no overpayment determination is made. If the MACs choose to send a Review Results Letter separately from the demand letter they shall do so within the timeframes listed in PIM chapter 3, §3.3.1.1F. Likewise, the Recovery Auditors shall issue a Review Results Letter for complex audits as outlined in their SOW requirements. ZPICs shall comply with the requirements listed below when issuing Review Results Letters.

Each Review Results Letter shall include:

- Identification of the provider or supplier—name, address, and NPI;
- Reason for conducting the review or good cause for reopening;
- A narrative description of the overpayment situation that states the specific issues involved in the overpayment as well as any recommended corrective actions;
- The review determination for each claim in the sample, including a specific explanation of why any services were determined to be non-covered, or incorrectly coded and if others were payable;
- A list of all individual claims that includes the actual non-covered amount, the reason for non-coverage, the denied amounts, under/overpayment amounts, the §1879 and §1870 of the Act determinations made for each specific claim, along with the amounts that will and will not be recovered from the provider or supplier;
- Any information required by PIM chapter 8, §8.4 for statistical sampling for overpayment estimation reviews;
- Total underpayment amounts;
- Total overpayment amounts that the provider or supplier is responsible for;
- Total overpayment amounts the provider or supplier is not responsible for because the provider or supplier was found to be without fault;
- MACs shall include an explanation that subsequent adjustments may be made at cost settlement to reflect final settled costs;

- An explanation of the procedures for recovery of overpayments including Medicare's right to recover overpayments and charge interest on debts not repaid within 30 days (not applicable to Recovery Auditors or ZPICs);

- The provider's or supplier's right to request an extended repayment schedule (not applicable to Recovery Auditors or ZPICs);

- The MACs and ZPICs shall include limitation of liability and appeals information in the provider notices;

- The MACs shall include appeals information in the provider notices;

- The MACs shall include the provider or supplier financial rebuttal rights under PIM chapter 3, §3.6.5; and,

- For MAC Review Results Letter only, a description of any additional corrective actions or follow-up activity the MAC is planning (i.e., prepayment review, re-review in 6 months).

If a claim is denied through prepayment review, the MACs and ZPICs are encouraged to issue a notification letter to the provider but may use a remittance notice to meet this requirement. However, if a claim is denied through postpayment review, the MAC and Recovery Auditor shall notify the provider by issuing a notification letter to meet this requirement. The ZPIC shall use discretion on whether to issue a notification letter.

The CERT contractor is NOT required to issue provider notices for claims they deny. Instead, the CERT contractor shall communicate sufficient information to the MAC to allow the MAC to develop an appropriate provider notice.

B. MACs

The MACs need provide only high-level information to providers when informing them of a prepayment denial via a remittance advice. In other words, the shared system remittance advice messages are sufficient notices to the provider. However, for complex review, the provider should be notified through the shared system, but the MAC shall retain more detailed information in an accessible location so that upon written or verbal request from the provider, the MAC can explain the specific reason the claim was denied as incorrectly coded or otherwise inappropriate.

C. Recovery Auditors

For overpayments detected through **complex** review, the Recovery Auditor shall send a review results letter as indicated in the Recovery Auditor SOW. In addition, the Recovery Auditor shall communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider and collect the overpayment.

For overpayments detected through **non-complex** review, the Recovery Auditor shall notify the provider as indicated in the Recovery auditor SOW and will communicate sufficient information to the MAC so that the MAC can send a Remittance Advice to the provider.

For underpayments, the Recovery Auditor shall notify the provider as indicated in the Recovery Auditor SOW. In addition, the Recovery Auditor shall communicate sufficient information to the MAC so that the MAC can send *a r*emittance *a*dvice to the provider and pay back the underpayment.

D. ZPICs

For overpayments detected through **complex** review, and after coordination between the ZPIC and OIG, the ZPIC shall send a review results letter (the MAC sends the demand letter). In addition, the ZPIC shall communicate sufficient information to the MAC so that the MAC can send a demand letter to the provider and collect the overpayment. The ZPIC shall use discretion on whether to send the review results letter.

E. Indicate in the Denial Notice Whether Records Were Reviewed

For claims where the MAC or ZPIC had sent an ADR letter and no timely response was received, they shall issue a denial and indicate in the provider denial notice, using remittance advice code N102/56900, that the denial was made without reviewing the documentation because the requested documentation was not received or was not received within the allowable time frame (§1862(a) (1) of the Act). This information will be useful to the provider in deciding whether to appeal the decision.

For claims where the reviewer makes a denial following complex review, the reviewer has the discretion to indicate in the denial notice, using remittance advice code N109 that the denial was made after review of submitted documentation. This includes those claims where the provider submits documentation along with the claim and the reviewer selects that claim for review.

Medicare Program Integrity Manual
Chapter 4 - Benefit Integrity

4.7.1 -Conducting Investigations
(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

When the complaint cannot be dismissed by the AC or MAC second-level screening staff as an error or a misunderstanding, unless otherwise advised by law enforcement, PSC or ZPIC *PI* units shall use one or more of the following investigative methods to determine whether or not there is a pattern of submitting false claims. (The list is not intended to be all-inclusive.)

- Review a small sample of claims submitted within recent months. Depending on the nature of the problem, the PSC or the ZPIC *PI* unit may need to request medical documentation or other evidence that would validate or cast doubt on the validity of the claims.

- Interview by telephone a small number of beneficiaries. Do not alarm the beneficiaries or imply that the provider did anything wrong. The purpose is to determine whether there appear to be other false claims or if this was a one-time occurrence.

- Look for past contacts by the PSC or the ZPIC *PI* unit, or the MR unit concerning comparable violations. Also, check provider correspondence files for educational/warning letters or for contact reports that relate to similar complaints. Review the complaint file. Discuss suspicions with MR and audit staff, as appropriate.

- Perform data analysis (PSCs and ZPICs shall follow Chapter 2, §2.3 for sources of data).

- Review telephone calls or written questionnaires to physicians, confirming the need for home health services or DME.

- Perform random validation checks of physician licensure.

- Review original CMNs.

- Perform an analysis of high frequency/high cost, high frequency/low cost, low frequency/low cost, and low frequency/high cost procedures and items.

- Perform an analysis of local patterns/trends of practice/billing against national and regional trends, beginning with the top 30 national procedures for focused medical review and other kinds of analysis that help to identify cases of fraudulent billings.

- Initiate other analysis enhancements to authenticate proper payments.

- Perform a compilation of documentation, e.g., medical records or cost reports.

Using internal data, PSC and ZPIC *PI* units may determine the following:

- Type of provider involved in the allegation and the perpetrator, if an employee of the provider.

- Type of services involved in the allegation.

- Places of service.

- Claims activity (including assigned and non-assigned payment data in the area of the fraud complaint).

- The existence of statistical reports generated for the Provider Audit List (PAL) or other MR reports, to establish if this provider's practice is exceeding the norms established by their peer group (review the provider practice profile).

- Whether there is any documentation available on prior complaints. Obtain the appropriate *ASC X12 837 institutional or professional claim formats,* Form CMS-1490*S*s, *1450s*, and/or 1500s, and/or attachments. Review all material available.

NOTE: Due to evidentiary requirements, do not write on these forms/documents in any manner.

After reviewing the provider's background, specialty and profile, PSC and ZPIC *PI* units decide whether the situation, is potential fraud or may be more accurately categorized as a billing error. For example, records indicate that a physician has billed, in some instances, both Medicare and the beneficiary for the same service. Upon review, a *PI* unit determines that, rather than attempting to be paid twice for the same service, the physician made an error in his/her billing methodology. Therefore, this would be considered a determination of improper billing, rather than fraud involving intentional duplicate billing.

The purpose of these activities is to decide whether it is reasonable to spend additional investigative resources. If there appears to be a pattern, the PSC or the ZPIC *PI* unit shall discuss it with OIG/OI at the onset of the investigation. The PSC or the ZPIC *PI* unit shall discuss with OIG/OI the facts of the investigation and obtain OIG's recommendation on whether or not the investigation should be further developed for possible case referral to OIG/OI.

Once a case has been referred to law enforcement, the PSC or the ZPIC *PI* unit shall not contact the provider or their office personnel. If there is belief that provider contact is necessary, the PSC or the ZPIC *PI* unit shall consult with OIG/OI. OIG/OI will consider the situation and, if warranted, concur with such contact.

Additionally, if the suspect provider hears that its billings are being reviewed or learns of the complaint and contacts the PSC or the ZPIC *PI* unit, they shall report such contact immediately to OIG/OI.

NOTE: If investigations do not result in a case, the PSC and the ZPIC *PI* unit shall take all appropriate action in order to prevent any further payment of inappropriate claims and to recover any overpayments that may have been made (the PSC and the ZPIC *PI* unit shall refer to chapter 3, §3.8ff for overpayments).

4.16 - AC, MAC, PSC, and ZPIC Coordination on Voluntary Refunds

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Voluntary refund checks payable to the Medicare program shall not be returned, regardless of the amount of the refund. The PSC and the ZPIC *PI* unit shall communicate with the AC or MAC staff responsible for processing voluntary refunds to obtain information on voluntary refund checks received. The PSC and the ZPIC *PI* unit shall perform an investigation on any voluntary refunds where there is suspicion of inappropriate payment or if a provider is under an active investigation.

Should the PSC and the ZPIC *PI* unit receive a voluntary refund check in error, the PSC and the ZPIC shall coordinate the transfer of voluntary refund checks to the AC or MAC through the JOA.

The ACs and MACs shall refer to the Financial Management Manual for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers.

Through the JOA, PSCs and ZPICs shall establish a mechanism whereby the AC or MAC notifies the PSC and the ZPIC on a regular basis of all voluntary refunds received by the AC or MAC. PSCs or ACs and

PSCs or MACs and ZPICs or ACs and ZPICS or MACs shall send one letter annually (calendar year) to any provider that submits a voluntary refund during that calendar year, advising the provider of the following:

> The acceptance of a voluntary refund in no way affects or limits the rights of the Federal Government or any of its agencies or agents to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.

The PSCs and ACs or the PSCs and MACs and the ZPICs or ACs and the ZPICS or MACs shall work out in the JOA whether the PSC or AC and the PSC or MAC and the ZPIC or AC and the ZPIC or MAC sends the above language. The ACs and MACs may send the language above on a voluntary refund acknowledgement letter or on a *r*emittance *a*dvice if this capability exists.

The PSC and the ZPIC *PI* units shall refer to chapter 4, §4.4.1G and H, for law enforcement requests for voluntary refund information

4.33 - Recovery Audit Contractors (RACs)

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

The CMS established the RAC Data Warehouse to track RAC activity and prevent conflicts between RAC reviews and other program integrity activities; this mission depends on timely and accurate information reporting by Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs) as well as by claims processing contractors and by the RACs themselves.

To prevent RAC interference with active investigations or cases, PSCs or ZPICs shall enter suppressions in the RAC Data Warehouse to temporarily mark entire providers or subsets of a provider's claims as off-limits to the RACs. Individual claims that have been previously reviewed (or that are part of an extrapolated settlement universe) shall be excluded to permanently block them from repeat reviews by a RAC.

The RAC Data Warehouse allows users to enter suppressions on any combination of provider ID, DRG, ICD procedure code, HCPCS code, state or ZIP code, although CMS requires that suppressions be tailored as narrowly as possible. PSCs and ZPICs shall suppress targeted procedure codes from specific providers associated with open investigations/cases; suppressions of one or more procedure codes across an entire geographic area may be considered in egregious situations of widespread fraud and abuse of specific codes or types of services (e.g., infusion therapy in South Florida).

In designated high-risk areas where particular categories of providers are under scrutiny by law enforcement, the PSC or ZPIC may also suppress at the provider level. Because geographic and/or provider-level suppressions have the potential to remove a large volume of claims from RAC review, the PSC or ZPIC shall provide CMS with appropriate justification for the suppression in the comments section of the Data Warehouse upload record.

The Data Warehouse can accept suppressions on rendering provider, supplier or institution ID; suppressions on referring, ordering, billing (for *A/B MAC (B) and DME MAC* claims) and attending providers (institutional claims) are not currently supported.

Whether suppressing an entire provider or only a portion of a provider's claims, the PSC or ZPIC shall indicate the nature of the provider being suppressed (hospital, individual physician, physician group, home health agency, etc.) in the provider type field using the codes specified in the Data Warehouse. The PSC or ZPIC shall also indicate the name of the provider being suppressed in the comment field, which can accommodate up to 256 characters.
When entering a suppression on a six-digit provider ID, the PSC or ZPIC shall also enter the provider's practice state. States are not required for NPIs, NSC numbers, alphanumeric PINs or PINs that are other than six digits long, but six-digit PINs potentially overlap with six-digit CMS institutional provider numbers.

Having the provider state will help CMS suppression reviewers differentiate between multiple providers with the same ID.

Specific suppression start and end dates are also mandatory; suppressions can extend up to three years into the past and one year forward from date of entry. (The start date is initially fixed at 10/1/2007, which is the earliest that RACs can go for their reviews.) Users will be notified as their suppressions approach their expiration dates and can renew them if necessary, although CMS expects users to release them sooner if the underlying investigations/cases are closed.

Once a suppression is lifted or expires, PSCs and ZPICs are also responsible for entering any necessary exclusions. Any claims for which the PSC/ZPIC has requested medical records shall be excluded to prevent re-review by a RAC, unless the PSC/ZPIC's review resulted in a full denial. In this case, exclusion is unnecessary because the provider will either appeal (the redetermination entity will enter the exclusion) or will allow the decision to stand (the RACs are unlikely to pursue zero-dollar claims).

Below are examples of suppressions and exclusions in various circumstances; this list is not all-inclusive and PSC/ZPIC staff may need to consult with their respective CMS COTR and/or CMS RAC liaison to determine the appropriate level of suppression or exclusion.

Suppression and/or Exclusion - Examples

- Suppressions of providers who are the subject of a law enforcement investigation should remain effective until the provider's case is returned from law enforcement as declined for prosecution and without a request for PSC or ZPIC administrative action. The suppression may be entered using one of the following methods:

Suppression at the provider and/or geographic level requires the user to supply detailed justification for each request, in addition to provider name/type, start/end dates and other fields as specified in the RAC Data Warehouse User's Guide. PSCs or ZPICs shall routinely monitor accepted suppression records to ensure that the suppressions remain relevant/appropriate and that they are ultimately released in a timely manner.

Suppression at the procedure code level for individual providers may be done without providing justification due to the narrower scope of the suppression. Suppressions at this level still require the user to supply a DRG, ICD procedure or HCPCS code, provider identifiers, start and end dates, and any additional information as defined in the RAC Data Warehouse User's Guide.

NOTE: The RACs can review claims paid as early as 10/1/2007, which is before NPI submission became mandatory. Therefore, PSCs and ZPICs are strongly encouraged to enter suppressions on both NPIs and legacy provider numbers for suppressions that cover the period of October 2007 through May 2008.

- Suppression/Exclusion for postpayment review where extrapolation may or may not be performed - if it is unknown at the time of review whether any overpayments that are identified will be extrapolated to the parent claim universe, the PSC or ZPIC shall enter a suppression on the relevant provider ID and service code(s). If the PSC/ZPIC does ultimately assess an extrapolated overpayment, the PSC or ZPIC shall release the suppression and exclude the entire universe. If the overpayment is computed based only on the sampled claims (ie, the overpayment is not projected to the entire universe), the PSC or ZPIC shall release the suppression and exclude only the sample claims that were actually reviewed.

- Exclusion for prepayment edits or clinically unlikely edits (CUEs) - claims that have been subjected to automated edits only are still eligible for RAC review and should generally not be excluded, although claims that have subsequently undergone complex review do require exclusion.

- Exclusion for prepayment review - even if a provider under investigation is subject to 100% prepayment review, a suppression will not be necessary because the RACs do not receive claim data in real time. However, the individual claims that were reviewed will need to be excluded. (This requirement

applies whether the provider was on 100% prepayment review or if only a lesser fraction of that provider's claims were being renewed.)

For access to the RAC Data Warehouse, contact the system administrators at rac@cms.hhs.gov. Current suppression/exclusion file layouts and the user's guide are available from the help desk staff or by download from the system itself.

The ZPICs and the PSCs shall have a JOA with the RACs. Refer to PIM Exhibit 44 for the JOA between the PSCs and the RACs and between the ZPICs and the RACs. If PSCs, ZPICs or RACs have any recommendations for modifying the JOA, they shall provide these modifications to their respective COTRs.

Medicare Program Integrity Manual
Chapter 5 -Items and Services Having Special DME Review Considerations

5.2.3 -Detailed Written Orders
(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Detailed written orders are required for all transactions involving DMEPOS. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section 3.4.1.1.B.)

All orders must clearly specify the start date of the order.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. (For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.)

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number.

If the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement.

The supplier must have a detailed written order prior to submitting a claim. For items listed in chapter 5 section 5.2.3.1, the detailed written order must be obtained prior to delivery. If a supplier does not have a faxed, photocopied, electronic or pen and ink signed detailed written order in their records before they submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals). For all other items (except those listed in section 5.2.3.1), if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.

Medical necessity information (e.g., *a* diagnosis code, narrative description of the patient's condition, abilities, limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

In other sections of this chapter, the term “order” or “written order” means “detailed written order” unless otherwise specified.

Medicare Program Integrity Manual
Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services

Table of Contents
(Rev.608, 08-14-15)

Medicare Program Integrity Manual
Chapter 6 - Intermediary MR Guidelines for Specific Services

6.5.3 - DRG Validation Review

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

The contractor shall perform DRG validation on PPS, as appropriate, reviewing the medical record for medical necessity and DRG validation. The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the beneficiary's medical record. Reviewers shall validate principal diagnosis, secondary diagnoses, and procedures affecting or potentially affecting the DRG.

NOTE: For PPS waived/excluded areas, review shall be performed appropriate to your area.

A. Coding

The contractor shall use individuals trained and experienced in ICD coding to perform the DRG validation functions. The validation is to verify the accuracy of the hospital's ICD coding of all diagnoses and procedures that affect the DRG.

The contractor shall base DRG validation upon accepted principles of coding practice, consistent with guidelines established for ICD coding, the Uniform Hospital Discharge Data Set data element definitions, and coding clarifications issued by CMS. The contractor shall not change these guidelines or institute new coding requirements that do not conform to established coding rules.

The contractor shall verify a hospital's coding in accordance with the coding principles reflected in the ICD Coding Manual. Contractors shall use the ICD version in place at the time the services were rendered, and the official National Center for Health Statistics and CMS addenda, which update the ICD Manual annually. The annual addenda are effective on October 1 of each year and apply to discharges occurring on or after October 1. The contractor shall use only ICD Manual volumes based on official ICD Addendum and updates when performing DRG validation.

Hospitals are not required to code minor diagnostic and therapeutic procedures (e.g., imaging studies, physical, occupational, respiratory therapy), but may do so at their discretion.

B. Diagnoses

Contractors shall ensure that the hospital reports the principal diagnosis and all relevant secondary diagnoses on the claim. The relevant diagnoses are those that affect DRG assignment. The hospital must identify the principal diagnosis when secondary diagnoses are also reported. When a comorbid condition, complication, or secondary diagnosis affecting the DRG assignment is not listed on the hospital's claim but is indicated in the medical record, insert the appropriate code on the claim form. If the hospital already reported the maximum number of diagnoses allowed on the claim form, delete a code that does not affect DRG assignment, and insert the new code.

The contractor is not required to code additional diagnoses on the claim as long as all conditions that affect the DRG are reflected in the diagnoses already listed, and the principal diagnosis is correct and properly identified. The hospital can list the secondary diagnoses in any sequence on the claim form because the GROUPER program will search the entire list to identify the appropriate DRG assignment.

- Principal Diagnosis -The contractor shall determine whether the principal diagnosis listed on the claim is the diagnosis which, after study, is determined to have occasioned the beneficiary's admission to the hospital. The principal diagnosis (as evidenced by the physician's entries in the beneficiary's medical record) (see 42 CFR 412.46) must match the principal diagnosis reported on the claim form. The principal diagnosis must be coded to the highest level of specificity. For example, a diagnosis from "Symptoms, Signs, and Ill-defined Conditions," may not be used as the principal diagnosis when the underlying cause of the beneficiary's condition is known.

- Inappropriate Diagnoses -The contractor shall exclude diagnoses relating to an earlier episode that have no bearing on the current hospital stay. Delete any incorrect diagnoses and revise the DRG assignment as necessary.

C. Procedures

The contractor shall ensure that the hospital has reported all procedures affecting the DRG assignment on the claim. If there are more procedures performed than can be listed on the claim, verify that those reported include all procedures that affect DRG assignment, and that they are coded accurately. See section 6.5.4 below for further detail on reviewing procedures.

6.5.5 -Special Review Considerations

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Refer to Pub. 100-04, chapter 3, §20 C. for information regarding handling of claims with DRG 468. This DRG represents a discharge with valid data but where the surgical procedure is unrelated to the principal diagnosis.

Refer to 100-04, chapter 3, §20.2.1, subsection D.9. for a description of questionable admission *diagnosis* codes. *A/B* MACs *(A)* may wish to consider including these diagnoses in their data analysis.

For a listing of diagnosis codes identified as “questionable admission” codes see the Medicare Code Editor (MCE) Web site at:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/01_overview.asp

Refer to 100-04, chapter 3, §20.2.1, subsection D.*9* for a description of diagnoses which are acceptable only when coded with a secondary diagnosis. *A/B* MACs *(A)* may wish to include these diagnoses in their data analysis as the MCE will not reject them when they are billed with a secondary diagnosis.

For a listing of diagnosis codes that are acceptable only when coded with a secondary diagnosis see the MCE Website at:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY_14_Definition_of-Medicare_Code_Edits_V_31_Manual.pdf

Medicare Program Integrity Manual
Chapter 13 -Local Coverage Determinations

13.1.3 - Local Coverage Determinations (LCDs)
(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term "local coverage determination" (LCD). An LCD is a decision by a Medicare administrative contractor (MAC) whether to cover a particular item or service on a MAC-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the item or service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist of only "reasonable and necessary" information, while LMRPs may also contain benefit category and statutory exclusion provisions.

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

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

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

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

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

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

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

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

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

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

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

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

13.4 - When To Develop New/Revised LCDs

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

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

A. Contractors Shall Develop New/Revised LCDs

Contractors shall develop LCDs when they have identified 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 LCD

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

A validated widespread problem demonstrates a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume items or services. Multi-state contractors may develop uniform LCDs across all its jurisdictions even if data analysis indicates that the problem exists only in one state.

- An LCD is needed to assure beneficiary access to care.
- A contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCDs across its multiple jurisdictions; or is a multi-state contractor undertaking an initiative to create uniform LCDs across its jurisdiction; or
- Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

C. Contractors Shall Review LCD

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

Within 90 Days

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

- A new or revised NCD;
- A new or revised coverage provision in an interpretive manual; or
- A change to national payment policy. Within 120 Days

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

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

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

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

Annually

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

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

13.5.2 - Coding Provisions in LCDs

(Rev.608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

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