CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 501	**Date: January 9, 2014**
	Change Request 8429

Transmittal 486, dated September 6, 2013, is rescinded and replaced by Transmittal 501, dated January 9, 2014, to restore PIM section 3.3.1.1 regarding the timeliness requirements related to ZPIC referrals and timed-out ADR denials remanded back to MR from appeals. This section was inadvertently omitted from Transmittal 486. All other information remains the same.

SUBJECT: Complex Medical Review

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to address issues noted in the GAO Report 13 522. This change will require contractors to include inter-rater reliability assessments in their QI process.

EFFECTIVE DATE: October 7, 2013
IMPLEMENTATION DATE: October 7, 2013

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	3/3.3.1.1/Complex Medical Review

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 obliged 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

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-08	Transmittal: 501	Date: January 9, 2014	Change Request: 8429

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SUBJECT: Complex Medical Review

EFFECTIVE DATE: October 7, 2013
IMPLEMENTATION DATE: October 7, 2013

I. GENERAL INFORMATION

A. Background: This will be a Program Integrity Manual (PIM) change in concordance with the GAO Report 13 522. It will require contractors to include inter-rater reliability assessments in their QI process.

B. Policy: This will be a Program Integrity Manual (PIM) change in concordance with the GAO Report 13 522. It will require contractors to include inter-rater reliability assessments in their QI process.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
8429.1	Contractors shall establish a Quality Improvement process.	X	X	X	X								CERT, RA
8429.2	Contractors shall attend the annual medical review training conference as directed by the CMS.	X	X	X	X								CERT, RA
8429.3	Contractors shall include inter-rater reliability assessments in their QI process and shall report these results as directed by CMS.	X	X	X	X								CERT, RA

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Other
		A	B	HHH					
	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): Debbie Skinner, 4107867480 or Debbie.Skinner@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

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 do 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.

3.3.1.1 - Complex Medical Review

(Rev.501, Issued: 01-09-14, Effective: 10-07-13, Implementation: 10-07-13)

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

A. Credentials of Reviewers

The MACs, CERT, and ZPICs shall ensure that complex reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs and LPNs) or physicians, unless this task is delegated to other licensed health care professionals. Recovery Auditors shall ensure that the credentials of their reviewers are consistent with the requirements in the Recovery Auditor SOW.

During a complex review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians or physician specialists) for advice. The MACs, CERT, and ZPICs shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e., speech therapy claim, physical therapy). Recovery Auditors shall follow guidance related to calling upon other healthcare professionals as outlined in the Recovery auditor SOW.

The CERT and Recovery Auditors shall ensure that complex reviews for the purpose of making coding determinations are performed by certified coders. MACs are encouraged to make coding determinations by using certified coders. ZPICs have the discretion to make coding determinations using certified coders.

B. Credential Files

The MACs, CERT, Recovery Auditors, and ZPICs shall maintain a credentials file for each reviewer (including consultants, contract staff, subcontractors, and temporary staff) who performs complex reviews. The credentials file shall contain at least a copy of the reviewer's active professional license.

C. Quality Improvement (QI) Process

The MACs, CERT, and *Recovery Auditors* shall establish a Quality Improvement (QI) process that verifies the accuracy of MR decisions made by licensed health care professionals. *The MACs, CERT, and Recovery Auditors shall attend the* annual *medical review* training *conference as directed by the CMS.*
The MACs, CERT, and Recovery Auditors shall include inter-rater reliability assessments in their QI process and shall report these results as directed by CMS.

D. Advanced Beneficiary Notice (ABN)

The MACs, CERT, Recovery Auditors and ZPICs shall request as part of the ADR, during a complex medical record review, a copy of any mandatory ABNs, as defined in IOM 100-04, Medicare Claims Processing Manual Chapter 30 *section* 50.3.1. If the claim is determined not to be reasonable and necessary, the contractor will perform a face validity assessment of the ABN in accordance with the instructions stated in IOM 100-04 Medicare Claims Processing Manual chapter 30 *section* 50.6.3.

The Face Validity assessments do not include contacting beneficiaries or providers to ensure the accuracy or authenticity of the information. Face Validity assessments will assist in ensuring that liability is assigned in accordance with the Limitations of Liability Provisions of *section* 1879 of the Social Security Act.

E. MAC Funding Issues

The MAC complex medical review work performed by medical review staff for purposes other than MR (e.g., appeals) shall be charged, for expenditure reporting purposes, to the area requiring medical review services.

All complex review work performed by MACs shall:

- Involve activities defined under the Medicare Integrity Program (MIP) at Section 1893(b)(1) of the Act;

- Be articulated in its medical review strategy; and,

- Be designed in such a way as to reduce its Comprehensive Error Rate Testing (CERT) error rate or prevent the contractor's error rate from increasing.

The MACs shall be mindful that edits suspending a claim for manual review to check for issues other than inappropriate billing (i.e. completeness of claims, conditions of participation, quality of care) are not medical review edits as defined under Section 1893(b)(1) of the Act and cannot be funded by MIP. Therefore, edits resulting in work other than that defined in Section1893 (b) (1) shall be charged to the appropriate Program Management activity cost center.

F. Review Timeliness Requirement

For Prepayment Reviews

When a MAC receives requested documentation for prepayment review within 45 calendar days, the MAC shall do the following within 60 calendar days of receiving the requested documentation: 1) make and document the review determination, and 2) enter the decision into the Fiscal Intermediary Shared System (FISS), Multi-Carrier System (MCS), or the VIPS Medicare System (VMS).

When a ZPIC receives all documentation requested for prepayment review within 45 calendar days, the ZPIC shall make and document the review determination and notify the MAC of its determination within 60 calendar days of receiving all requested documentation.

For prepayment reviews, the MAC shall count day one as the date each new medical record is received in the mailroom. Each new medical record received would have an independent 60-day review time period associated with it.

For Postpayment Reviews

The MAC or Recovery Auditor shall make a review determination, and mail the review results notification letter to the provider within 60 calendar days of receiving the requested documentation, provided the documentation is received within 45 calendar days of the date of the ADR.

The MAC has the option to either:

- Begin counting the 60 days at the receipt of each medical record in the mailroom. Each new medical record would have an independent 60 day time period associated with it; or

- Wait until all requested medical documentation is received in the mailroom. The date on which the last of the requested medical documentation is received would represent the beginning of the 60 day time period.

For claims associated with any referrals to the ZPIC for BI investigation, MACs shall stop counting the 60-day time period on the date the referral is made. The 60-day time period will be restarted on the date the MAC receives requested input from the ZPIC or is notified by the ZPIC that the referral has been declined.

For claims sent to MR for reopening by the contractor appeals department, in accordance with Pub. 100-04, chapter 34, §10.3, begin counting the 60 days from the time the medical records are received in the MR department.

G. Auto Denial of Claim Line Item(s) Submitted with a GZ Modifier

Effective for dates of service on and after July 1, 2011, all MACs, PSCs and ZPICs shall automatically deny claim line(s) items submitted with a GZ modifier. Contractors shall not perform complex medical review on claim line(s) items submitted with the GZ modifier. The GZ modifier indicates that an ABN was not issued to the beneficiary and signifies that the provider expects denial due to a lack of medical necessity based on an informed knowledge of Medicare policy. All MACs shall make all language published in educational outreach materials, articles, and on their Web sites, consistent to state all claim line(s) items submitted with a GZ modifier shall be denied automatically and will not be subject to complex medical review. See Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 20.9.1.1. under paragraph F “GZ Modifier” for codes and the MSN to be used when automatically denying claim line(s) items submitted with a GZ modifier.