CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 210	Date: JUNE 15, 2007
	Change Request 5626

SUBJECT: High Risk Areas

I. SUMMARY OF CHANGES: Certain situations may contribute to emerging or widespread anomalies that may lead to potential fraud and abuse. As a result, instructions are required for identifying high risk areas and implementing necessary activities.

NEW / REVISED MATERIAL
EFFECTIVE DATE: July 16, 2007
IMPLEMENTATION DATE: July 16, 2007

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/Table of Contents
R	4/4.28/Joint Operating Agreement
N	4/4.32/Designation of High Risk Areas
N	4/4.32.1/Actions Taken in High Rise Areas

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 210	Date: June 15, 2007	Change Request: 5626

SUBJECT: High Risk Areas

EFFECTIVE DATE: July 16, 2007
IMPLEMENTATION DATE: July 16, 2007

I. GENERAL INFORMATION

A. Background: Certain situations may contribute to emerging or widespread anomalies that may lead to potential fraud and abuse. As a result, instructions are required to identify and take action in these high risk areas.

B. Policy: N/A

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5626.1	Program safeguard contractors (PSCs) shall include high risk areas in the JOA between PSCs and affiliated contractors (ACs) and PSCs and Medicare Administrative Contractors (MACs).											PSCs
5626.2	The PSCs shall identify an area as high risk in coordination with the ACs and MACs through the JOA process.											PSCs
5626.3	When the PSCs identify a potential high risk area, they shall submit in overnight mail service a written request for approval to the CMS Director of the Division of Benefit Integrity and Management Operations (DBIMO), which includes: • the name of the PSC • contact name • phone number • e-mail address and • the justification for identifying an area as high risk.											PSCs

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5626.4	The MAC or the AC shall notify its project officer or contract manager of the PSC's request for a designation as a high risk fraud and abuse area concurrent with the PSC's request for approval from the Director of DBIMO.	X	X	X	X	X	X					
5626.5	Prior to effectuating any action/implementation plans in high risk areas, the PSCs shall work jointly with the ACs and MACs through the JOA process to develop a proposal of activities.											PSCs
5626.6	The PSCs shall submit in overnight mail service a written request for approval on action/implementation plans to the CMS Director of DBIMO, which includes: • the name of the PSC • contact name • phone number • e-mail address and • an explanation of the action /implementation plans proposed.											PSCs
5626.7	The MAC or the AC shall work with its project officer or contract manager to determine the specific support functions needed for ongoing and proposed project activities.	X	X	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	None.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Downin, Kimberly.Downin@cms.hhs.gov
Post-Implementation Contact(s): Kimberly Downin, Kimberly.Downin@cms.hhs.gov

VI. FUNDING

A. ***For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):***

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. ***For Medicare Administrative Contractors (MACs):***

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

Medicare Program Integrity Manual
Chapter 4 –Benefit Integrity

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(Rev. 210, 06-15-07)

4.28 - Joint Operating Agreement

(Rev. 210: Issued: 06-15-07; Effective/Implementation Dates: 07-16-07)

A Joint Operating Agreement (JOA) is a document developed by the PSC and the AC and the PSC and the MAC that delineates the roles and responsibilities for each entity specific to a Task Order.

As it applies to the PSC's task order, the JOA shall, at a minimum:

- Include a description and documentation of process/workflows that illustrate how the PSC and AC and the PSC and the MAC intend to interact with one another to complete each of the tasks outlined in the Task Order on a daily basis

- Establish responsibility for who shall request medical records/documentation(s) not submitted with the claim.

- Ensure that the AC and MAC communicates to the PSC any interaction with law enforcement on requests for cost report information

- Establish responsibility for how medical documentation that has been submitted without being requested shall be stored and tracked

- Establish responsibility for how medical documentation that has been submitted without being requested shall be provided to the PSC if documentation becomes necessary in the review process

- Mitigate risk of duplicate medical documentation requests

- Ensure that there is no duplication of effort by the PSC and the AC and the PSC and the MAC (e.g., the AC and MAC must not re-review PSC work)

- Identify the JOA participants

- Describe the roles and responsibilities of the PSC and the AC and the PSC and the MAC

- Clearly define dispute resolution processes

- Describe communication regarding CMS changes

- Include systems information

- Include training and education

- Include complaint screening and processing (including the immediate referral by

the AC and MAC second-level screening staff of provider complaints and immediate advisements to the PSC)

- Include data analysis
- Include suspension of payment
- Include overpayments processing
- Include data to evaluate PSC edit effectiveness via a monthly report from the AC and the MAC
- Include excluded providers
- Include voluntary refunds
- Include incentive Reward Programs
- Include appeals
- Include provider enrollment
- Include system edits and audits
- Include requests for information
- Include FOIA and Privacy Act responsibilities
- Include interaction with law enforcement
- Include fraud investigations
- Include prepayment reviews
- Include postpayment reviews
- Include coordination on LCDs (applicable only to JOAs between DME PSCs and DME MACs
- Include Harkin Grantees
- Include OIG Hotline referrals
- Include Self-Disclosures
- Include consent settlements

- Include coordination on Provider Outreach and Education
- Include securing email information
- Include JOA workgroup meetings
- *Include coordination on identifying high risk areas*
- *Include coordination on action/implementation plans to address the problems identified in high risk areas*
- *Include deactivation and/or revocation of PINs (refer to chapter 10 of the PIM)*
- Contain other items identified by CMS, the PSC, and/or AC, and/or MAC

4.32 – Designation of High Risk Areas

(Rev. 210: Issued: 06-15-07; Effective/Implementation Dates: 07-16-07)

The PSCs shall identify an area as high risk in coordination with the ACs and MACs through the JOA process. High risk areas may be identified by emerging or widespread anomalies that may lead to potential fraud and abuse in, for example, claim type, provider type, and geographic area. This may be demonstrated by such situations, including but not limited to:

- *Sudden changes in billing;*
- *Spike billing;*
- *Billing by inappropriate specialties;*
- *Billing of inappropriate diagnoses;*
- *Increased beneficiary complaints;*
- *Compromised beneficiary identities;*
- *Compromised provider identities;*
- *Geographical changes in billing;*
- *High CERT rate;*
- *Identity Theft (provider and beneficiary);*
- *Beneficiary Recruitment (capping);*
- *High, "out of the norm," UPIN/PIN utilization that accounts for a disproportionate share of the "ordered" services for a provider or groups of providers;*
- *Billing for claims for deceased patients in which the date of services is after the patients' date of death;*
- *Billing for Part B services during an inpatient, Part A institutional stay;*
- *Billing for ordered services (IDTF, clinical laboratory, DME, etc.) in which the ordering physician has no billing relationship for the patient (implying lack of clinical relationship for the ordering physician and beneficiary); and*

- *Billing for deceased physicians or other clinical practitioners or billings for "ordered" services based upon the UPIN/NPI of a deceased physician or clinical practitioner.*

When the PSCs identify a potential high risk area, they shall submit in overnight mail service a written request for approval to the CMS Director of the Division of Benefit Integrity Management Operations (DBIMO) who will coordinate with other CMS components on the designation of areas as high risk. The request shall include the name of the PSC, a contact name, phone number, e-mail address, and the justification for identifying an area as high risk.

The MAC or the AC shall notify its project officer or contract manager of the PSC's request for designation as a "high risk fraud and abuse" area concurrent with the PSC's request for approval to the Director of DBIMO.

Refer to chapter 10, §§20.1 and 20.2 of the PIM for provider enrollment guidance regarding high risk areas.

4.32.1 – Actions Taken in High Risk Areas

(Rev. 210: Issued: 06-15-07; Effective/Implementation Dates: 07-16-07)

Prior to effectuating any action/implementation plans in high risk areas, the PSCs shall work jointly with the ACs and MACs through the JOA process to develop a proposal of activities. The PSCs shall submit in overnight mail service a written request for approval on these plans to the CMS Director of DBIMO who will coordinate with other CMS components. The request shall include the name of the PSC, a contact name, phone number, e-mail address, and an explanation of the action/implementation plans proposed. This list is not all inclusive, but PSCs can propose the implementation of the following actions in designated high risk areas:

- *Edits recommended by the PSC;*
- *Selected and/or 100% auto-denials;*
- *Expanded beneficiary complaint acknowledgement;*
- *Increase in the frequency of Medicare Summary Notices (MSNs);*
- *Beneficiary requested edits;*
- *Greater proactive coordination with the qualified independent contractors (QICs) and the Office of Medicare Hearings and Appeals (OMHA); and*
- *Increase in beneficiary, provider, and congressional outreach.*
- *Supporting the CMS field office (if geographically appropriate);*
- *Provider enrollment (provider risk designation, site visits, validation of reassignment of benefits and enrollment);*
- *Complaint screening and acknowledgement; and*
- *Prepayment MR edits and local MUEs.*

The MAC or the AC shall work with its project officer or contract manager to determine the specific support functions needed for ongoing and proposed project activities.

Refer to chapter 10, §§20.1 and 20.2 of the Program Integrity Manual (PIM) for approval authority related to provider enrollment activities in high risk areas.