CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 213	**Date: JUNE 29, 2007**
	Change Request 5630

SUBJECT: Various Benefit Integrity Revisions

I. SUMMARY OF CHANGES: Various benefit integrity (BI) sections in chapter 4 of the PIM and overpayments exhibits were revised to reflect updates and clarifications.

NEW / REVISED MATERIAL
EFFECTIVE DATE: July 30, 2007
IMPLEMENTATION DATE: July 30, 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	4/4.2.2/Program Safeguard Contractor Benefit Integrity Unit
R	4/4.2.2.4/Procedural Requirements
R	4/4.2.2.6/Benefit Integrity Security Requirements
R	4/4.3/Medical Review for Benefit Integrity Purposes
R	4/4.4.1/Requests for Information From Outside Organizations
N	4/4.8.2/Production of Medical Records and Documentation for an Appeals Case File
R	4/4.18.3/Referral to Quality Improvement Organizations
R	Exhibit 7/Sample Letter for On-Site Reviews
R	Exhibit 7.3/Part A Sample Letter Notifying the Provider of the Results, and Request for Repayment of Overpayments
R	Exhibit 7.4/Part B Sample Letter Notifying the Provider of the Results, and Request for Repayment of Overpayments

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: 213	Date: June 29, 2007	Change Request: 5630

SUBJECT: Various Benefit Integrity Revisions

EFFECTIVE DATE: July 30, 2007

IMPLEMENTATION DATE: July 30, 2007

I. GENERAL INFORMATION

A. Background: Various benefit integrity (BI) sections in chapter 4 of the PIM and overpayment exhibits were revised to reflect updates and clarifications.

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	
5630.1	For workload reporting purposes, the PSC shall only identify as proactive, those investigations and cases that the PSC self-initiated.											PSCs
5630.2	The PSC BI unit shall notify the OIG if parties without a need to know are asking inappropriate questions regarding any investigations.											PSCs
5630.3	The PSC shall refer all requests from the press related to the Medicare Integrity Program to the CMS contracting officer for approval prior to release. This includes, but is not limited to, contractor initiated press releases, media questions, media interviews, and Internet postings.											PSCs
5630.4	The PSC shall meet (in-person or telephone call) when needed with DOJ to enhance coordination with them on current or pending cases.											PSCs
5630.5	The PSC shall have access to the information											

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	
	contained in the provider tracking systems from medical review for comparison to PSC findings.											PSCs
5630.6	If law enforcement requests the PSC to perform medical review on all investigations the PSC initiates, the PSC shall only perform medical review if it deems it necessary on a case-by-case basis.											PSCs
5630.7	If law enforcement requests the PSC to perform medical review on all investigations the PSC initiates, the PSC shall inform the primary GTL, associate GTL, and SME of such requests.											PSCs
5630.8	PSCs shall follow the revisions to Priority I requests in section 4.4.1 G and H.											PSCs
5630.9	When the PSC denies a claim and the provider, supplier, physician or beneficiary appeals the denial, the AC or MAC shall request the medical records and documentation that the PSC used in making its determination.	X	X	X	X	X	X					
5630.10	The PSC shall assemble the case file and send it to the AC within 7 calendar days or the MAC within 5 calendar days.											PSCs
5630.11	The PSC shall include any position papers or rationale and support for its decision so that the appeals adjudicator can consider it during the appeals process.											PSCs
5630.12	Since the provider may receive the case file, the PSC shall consult with law enforcement before including any sensitive information relative to a potential fraud investigation.											PSCs
5630.13	If the PSC would like to be notified of an ALJ hearing on a particular case, the PSC shall put a cover sheet in the case file before sending it to the AC or MAC.											PSCs
5630.14	When the PSC puts a cover sheet on the case file to be notified of an ALJ hearing, the PSC shall ensure that the cover sheet states the PSC would like to be notified of an ALJ hearing and list a contact name with a phone											

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	
	and fax number where the contact can be reached.											PSCs
5630.15	The PSC shall ensure that the cover sheet includes the language, "PLEASE DO NOT REMOVE" to ensure it stays on the case file should the file be sent to the QIC.											PSCs
5630.16	If the PSC receives a notice of hearing, the PSC shall contact the QIC immediately.											PSCs
5630.17	PSCs may participate in an ALJ hearing, but they shall work with the QIC in preparation for the hearing.											PSCs
5630.18	PSCs shall never invoke party status.											PSCs
5630.19	If the PSC participates in a hearing, it shall be as a non-party.											PSCs
5630.20	If the PSC receives a notice that appears contrary to this instruction, the PSC shall contact the QIC and their Primary GTL, Associate GTL, and SME immediately.											PSCs
5630.21	The PSC shall coordinate the review of Part A acute care inpatient hospital claims and long term care hospital PPS claims (i.e., long term acute care, not SNFs) for benefit integrity purposes with the QIO to determine any QIO involvement with the claims.											PSCs
5630.22	If the PSC's review does not involve the extrapolation of an overpayment and results in single claims denials, the PSC shall refer these claims to the QIO for payment determination.											PSCs
5630.23	If an overpayment determination was otherwise based on extrapolation, then the PSC shall refer the overpayment determination to the AC or MAC for issuance of a demand.											PSCs
5630.24	PSC BI units shall submit any identified program vulnerabilities in the appropriate narrative in the PSC monthly cost report in addition to sending the vulnerabilities to the vulnerability address in PIM chapter 4, §4.31.											PSCs

III. PROVIDER EDUCATION TABLE

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	
	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 (MAC)*****:**

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.

4.2.2 - Program Safeguard Contractor Benefit Integrity Unit

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

The PSC BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The PSC BI unit:

- Prevents fraud by identifying program vulnerabilities.

- Proactively identifies incidents of potential fraud that exist within its service area and takes appropriate action on each case.

- Investigates (determines the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.

- Explores all available sources of fraud leads in its jurisdiction, including the MFCU and its corporate anti-fraud unit.

- Initiates appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.

- Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions (see PIM, chapter 4, §§4.18ff, 4.19ff, and 4.20ff).

- Refer any necessary provider and beneficiary outreach to the POE staff at the AC or MAC.

Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

The PSC BI units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices.

The PSC BI units shall pursue leads through data analysis (PSCs shall follow chapter 2, §2.3 for sources of data), the Internet, the Fraud Investigation Database (FID), news media, etc. Proactive (self-initiated) leads may be generated and/or identified by any internal PSC, AC, or MAC component, not just the PSC BI units (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment). *For workload reporting purposes the PSC shall only identify as proactive, those investigations and cases that the PSC self-initiated and any proactive leads the PSC pursues that were received from the AC or MAC that did not originate from a complaint.*

The PSC BI units shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, i.e., reviewing data for inexplicable aberrancies (other than the expected) and relating the aberrancies to specific providers, identifying "hit and run" providers, etc. PSC BI units shall meet periodically with staff

from their respective internal components and PSCs shall also meet with AC and MAC staff to discuss any problems identified that may be a sign of potential fraud.

Fraud leads from any external source (e.g., law enforcement, CMS referrals, beneficiary complaints) are considered to be reactive and not proactive. However, taking ideas from external sources, such as non-restricted fraud alerts and using them to look for unidentified aberrancies within PSC data is proactive.

4.2.2.4 - Procedural Requirements

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

Contractors shall provide written procedures for personnel in various contractor components (claims processing, MR, beneficiary services, POE, intermediary audit, etc.) to help identify potential fraud situations. Include provisions to ensure that personnel shall:

- Refer potential fraud cases promptly to the PSC BI unit.

- Forward complaints alleging fraud through the second-level screening staff to the PSC BI unit.

- Maintain confidentiality of referrals to the PSC.

- Forward to the PSC BI unit documentation of the details of telephone or personal contacts involving fraud issues discussed with providers or provider staff, and retain such information in individual provider files.

In addition, PSC BI units shall ensure the performance of the functions below and have written procedures for these functions:

- Keep educational/warning correspondence with providers and other fraud documentation concerning specific issues in individual provider files (refer to §4.2.2.4.2 for retention of this documentation), so that PSCs are able to retrieve such documentation easily.

- Maintain communication and information flowing between the PSC BI unit, and the DME PSC, AC, or MAC MR staff, and as appropriate, intermediary or MAC audit staffs.

- Communicate with the DME PSC, AC or MAC medical review staff on all findings of overutilization and coordinate with the AC or MAC provider outreach and education (POE) staff to determine what, if any, education has been provided before any BI investigation is pursued.

- Obtain and share information on health care fraud issues/fraud investigations among carriers, DME MACs, DMERCs fiscal intermediaries (including rural home health intermediaries (RHHIs)), A/B MACs, PSCs, CMS, and law enforcement.

- Serve as a reference point for law enforcement and other organizations and agencies to contact when they need help or information on Medicare fraud issues and do not know whom to contact.

- Coordinate and attend fraud-related meetings/conferences and inform all appropriate parties about these meetings/conferences. These meetings/conferences include, but are not limited to, health care task force meetings and conference calls.

- Distribute fraud alerts to the appropriate parties. Share PSC BI unit findings on fraud alerts with PSCs within the appropriate jurisdiction and CMS.

- Work with the Primary GTL, Associate GTL, and SME to develop and organize external programs and perform training as appropriate for law enforcement, ombudsmen, grantees (e.g., Harkin Grantees or Senior Medicare Patrol) and other CMS health care partners (e.g., AoA, State MFCU).

- Serve as a resource to CMS as necessary. For example, serve as a resource to CMS on the FID, including FID training.

- Help to develop fraud-related outreach materials (e.g., pamphlets, brochures, videos) in cooperation with beneficiary services and/or provider relations departments of the ACs and MACs, for use in their training. Submit written outreach material to the Primary GTL, Associate GTL, and SME for clearance.

- Assist in preparation and development of fraud-related articles for AC and MAC newsletters/bulletins. The PSC BI unit shall send CMS CO a copy of these newsletters/bulletins to the following address:

  Centers for Medicare & Medicaid Services (CMS)
  Re: Newsletter/Bulletin Articles
  Division of Benefit Integrity Management Operations
  Mail Stop C3-02-16
  7500 Security Boulevard
  Baltimore, Maryland 21244

- Provide resources and training for the development of internal and new hire fraud training.

- Take appropriate administrative action on cases not accepted by OIG or other investigative agencies. At a minimum, provide information for recovery of identified overpayments and other corrective actions discussed in PIM, chapter 3, §§8ff and 9ff.

- Subject to the requirements in PIM, chapter 4, §4.4.1, provide support to law enforcement agencies for investigation of potential fraud and abuse, including investigations for which an initial referral to law enforcement did not originate from the PSC BI unit.

- Properly prepare and document cases referred to OIG/OI; two copies of a summary report of investigation shall be included with each fraud referral made to the OIG. The referral format listed in PIM Exhibits 16.1 and 16.2 shall be followed, unless

written guidance is provided by the applicable OIG/OI office and approved by the Primary GTL, Associate GTL, and SME. PSC BI units shall maintain files on the written guidance provided by the OIG/OI.

- Meet (in-person or telephone call) quarterly, or more frequently if necessary, with OIG agents to discuss pending or potential cases.

- Meet (in-person or telephone) *when needed* with DOJ to enhance coordination with them on current or pending cases.

- Furnish all available information upon request to OIG/OI with respect to excluded providers requesting reinStatement.

- Report to the Primary GTL, Associate GTL, and SME all cases that have been identified where a provider consistently fails to comply with the provisions of the assignment agreement.

- Maintain documentation on the number of investigations alleging fraud, the number of cases referred to OIG/OI (and the disposition of those cases), processing time of investigations, and types of violations referred to OIG (e.g., item or service not received, unbundling, waiver of co-payment).

- Conduct investigations (including procedures for reviewing questionable billing codes) and make beneficiary contacts (see PIM, chapter 4, §4.7.1 for details concerning investigations).

- Coordinate and communicate with the MR unit within your organization if a DME PSC, and coordinate and communicate with the MR units in the ACs and MACs if an A/B PSC to avoid duplication of work.

- Obtain approval from the Primary GTL, Associate GTL, and the OI field office before making an unannounced visit where fraud is suspected, and ensure that any other appropriate investigative agency is consulted with regard to the plan. PSC BI unit staff shall never engage in covert operations (e.g., undercover or surveillance activities). If OIG does not give approval, discuss this with the Primary GTL who will make the final decision.

- Obtain approval by e-mail, letter, or telephone call, and express any concerns (if a telephone call, follow up with a letter or e-mail) to the Primary GTL when the PSC BI unit is asked to accompany the OI or any other law enforcement agency going onsite to a provider for the purpose of gathering evidence in a fraud case (e.g., executing a search warrant). However, law enforcement must make clear the role of PSC BI unit personnel in the proposed onsite visit. The potential harm to the case and the safety of PSC BI unit personnel shall be thoroughly evaluated. PSC BI unit personnel shall properly identify themselves as PSC BI unit employees, and under no circumstances shall they represent themselves as law enforcement personnel or special agents. Lastly, under no

circumstances shall PSC BI unit personnel accompany law enforcement in situations where their personal safety is in question.

The ACs and MACs ensure the performance of the functions below and have written procedures for these functions:

- Ensure no payments are made for items or services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (see PIM, chapter 4, §4.19ff for exceptions).

- Ensure all instances where an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported to the OIG (see PIM, chapter 4, §4.19ff).

Ensure no payments are made for an excluded individual or entity who is employed by a Medicare provider or supplier.

4.2.2.6 – Benefit Integrity Security Requirements

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

To ensure a high level of security for the PSC BI function, the PSCs shall develop, implement, operate, and maintain security policies and procedures that meet and conform to the requirements of the Business Partners Security Manual (BPSSM) and the Core Security Requirements (CSR) and its operational appendices (A, B, C, and D). The BPSSM is located at:

http://www.cms.hhs.gov/manuals/downloads/117_systems_security.pdf and the CSR is at http://www.cms.hhs.gov/it/security. Further, the PSCs shall adequately inform and train all PSC employees to follow PSC security policies and procedures so the information the PSC obtains is confidential.

Note that data PSCs collect in the administration of PSC contracts belong to CMS. Thus, PSCs collect and use individually identifiable information on behalf of the Medicare program to routinely perform the business functions necessary for administration of the Medicare program, such as, medical review and program integrity activities to prevent fraud and abuse. Consequently, any disclosure of individually identifiable information without prior consent from the individual to whom the information pertains, or without statutory or contract authority, requires CMS' prior approval.

This section discusses broad security requirements that PSCs shall follow. Most requirements listed below are in the BPSSM or CSRs and are included by reference. There are several exceptions. The first is requirement A (concerning PSC BI Unit Operations), which addresses several broad requirements; CMS has included requirement A here for emphasis and clarification. Two others are in requirement B (concerning sensitive information) and requirement G (concerning telephone security). Requirements B and G relate to security issues that are not systems related and are not in the BPSSM.

A. Program Safeguard Contractor Benefit Integrity Unit Operations

- The PSCs shall conduct their activities in areas not accessible to the general public.

- The PSC BI unit shall completely segregate itself from all other operations. Segregation shall include floor to ceiling walls and/or other measures described in CSR 2.2.6 that prevent unauthorized persons access to or inadvertent observation of sensitive and investigative information. The only exception to this requirement is that PSCs may co-locate PSC MR and PSC BI units in the same building and same office space. However, PS BI units shall keep all PSC BI unit information confidential and secure and shall share PSC BI unit information with PSC MR units only on need-to-know basis.

- Other requirements regarding PSC BI unit operations shall include sections 3.1, 3.1.2, 3.10.2, 4.1.1.2, 4.2, 4.2.5, and 4.2.6 of the BPSSM.

B. Handling and Physical Security of Sensitive and Investigative Material

See the BPSSM section 3.8 for definitions of sensitive and investigative material.

In addition, the PSCs shall follow the requirements provided below:

- Establish a policy that employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need-to-know. This may include:

    - Appropriate CMS personnel,

    - Staff from the PSC, AC, or MAC medical review and/or benefit integrity unit staff,

    - PSC, AC, or MAC audit unit staff,

    - PSC, AC, or MAC data analysis staff,

    - PSC, AC, or MAC senior management, or

    - PSC, AC, or MAC corporate counsel.

- The CSRs require that:

    - The following workstation security requirements are specified and implemented: (1) what workstation functions can be performed, (2) the manner in which those functions are to be performed, (3) and the physical attributes of the surrounding of a specific workstation or class of workstation that can access CMS sensitive information. CMS requires that for PSCs all the local workstations as well as the workstations used at home comply with these requirements.

    - If PSC employees are authorized to work at home on sensitive data, they are required to observe the same security practices that they observe at the office. These should address such items as viruses, VPNs, and protection of sensitive data as printed documents.

    - Users are prohibited from installing desktop modems.

    - The connection of portable computing or portable network devices on the CMS claims processing network is restricted to approved devices only. Removable hard drives and/or a FIPS-approved method of cryptography shall be employed to protect information residing on portable and mobile information systems.

    - For alternate work site equipment controls, (1) only CMS Business Partner owned computers and software are used to process, access, and store sensitive

information; (2) a specific room or area that has the appropriate space and facilities is used; (3) means are available to facilitate communication with their managers or other members of the Business Partner Security staff in case of security problems; (4) locking file cabinets or desk drawers; (5) "locking hardware" to secure IT equipment to larger objects such as desks or tables; and (6) smaller Business Partner-owned equipment is locked in a storage cabinet or desk when not in use. If wireless networks are used at alternate work sites, wireless base stations are placed away from outside walls to minimize transmission of data outside of the building.

Alternate work sites are those areas where employees, subcontractors, consultants, auditors, etc. perform work associated duties. The most common alternate work site is an employee's home. However, there may be other alternate work sites such as training centers, specialized work areas, processing centers, etc.

- Ensure the mailroom, general correspondence, and telephone inquiries procedures maintain confidentiality whenever the PSC receives correspondence, telephone calls, or other communication alleging fraud. Further, all internal written operating procedures shall clearly State security procedures.

- Direct mailroom staff not to open PSC BI unit mail in the mailroom, unless the PSC has requested the mailroom do so for safety and health precautions. Alternately, if mailroom staff opens PSC BI unit mail, mailroom staff shall not read the contents.

- For mail processing sites separate from the PSC, the PSCs shall minimize the handling of PSC BI unit mail by multiple parties before delivery to the PSC BI unit.

- The PSCs shall mark mail to CO or another PSC, "personal and confidential," and address it to a specific person.

- Where more specialized instructions do not prohibit PSC BI unit employees, PSC BI employees may retain sensitive and investigative materials at their desks, in office work baskets, and at other points in the office during the course of the normal work day. Regardless of other requirements, the employee shall restrict access to sensitive and investigative materials, and PSC staff shall not leave such material unattended.

- PSC staff shall safeguard all sensitive or investigative material when in transit.

- The PSC BI units shall maintain a controlled filing system (see PIM, chapter 4, §4.2.2.4.1).

C. Designation of a Security Officer

The Security Officer shall take such action as is necessary to correct breaches of the security standards and to prevent recurrence of the breaches. In addition, the Security Officer shall document the action taken and maintain that documentation for at least seven years. Actions shall include:

- Within one hour of discovering a security incident, clearly and accurately report the incident following BPSSM requirements for reporting of security incidents. For purposes of this requirement, a security incident is the same as the definition in section 3.6, Incident Reporting and Response, of the BPSSM.

- Specifically, the report shall address the following where appropriate:

  - Types of information about beneficiaries shall at a minimum address whether the compromised information includes name, address, HICN, and date of birth.

  - Types of information about providers shall at a minimum address if the compromised information includes name, address, and provider ID.

  - Whether law enforcement is investigating any of the providers with compromised information, and

  - Police reports.

- Provide additional information that CMS requests within 72 hours of the request.

- If CMS requests, issue a Fraud Alert to all CMS Medicare contractors listing the HICNs and provider IDs that were compromised within 72 hours of the discovery that the data was compromised.

- Within 72 hours of discovery of a security incident, when feasible, review all security measures and revise them if necessary so they are adequate to protect data against physical or electronic theft.

See section 3.1, of the BPSSM and Attachment 1 to this manual section (Letter from Director, Office of Financial Management, concerning security and confidentiality of PSC data) for additional requirements.

D. Staffing of the Program Safeguard Contractor Benefit Integrity Unit and Security Training

The PSC shall perform thorough background and character reference checks, including at a minimum credit checks, for potential employees to verify their suitability for employment with the PSC BI unit. Specifically, background checks shall at least be at level 2 (moderate risk – people with access to sensitive data at CMS – level 5 risk). The PSC may require investigations above a level 2 if the PSC believes the higher level is required to protect sensitive information.

At the point the PSC makes a hiring decision for a PSC BI unit position and prior to the selected person starting work, the PSC shall require the proposed candidate to fill out a conflict of interest declaration as well as a confidentiality Statement.

Annually, the PSC shall require existing employees to complete a conflict of interest declaration as well as a confidentiality Statement.

The PSC shall not employ temporary employees, such as those from temporary agencies, and students (non-paid or interns) in the PSC BI unit.

The PSC shall thoroughly explain to and discuss with employees special security considerations under which the PSC BI unit operates at least once a year. Further, this training shall emphasize that in no instance shall employees disclose sensitive or investigative information even in casual conversation.

See sections 2.0 of the BPSSM and CSRs 1.1.1-1.1.5, 1.1.7, 1.4.1, 1.6.4, 5.6.1, 5.6.3, and 6.3.4 for additional training requirements.

E. Access to Information

See section 2.3.4 of the BPSSM for requirements regarding access to PSC information.

The PSC BI unit shall notify the OIG if parties without a need to know are asking inappropriate questions regarding any investigations. The PSC shall refer all requests from the press related to the Medicare Integrity Program to the CMS contracting officer for approval prior to release. This includes, but is not limited to, contractor initiated press releases, media questions, media interviews, and Internet postings.

F. Computer Security

See section 4.1.1 of the BPSSM for the computer security requirements.

G. Telephone Security

The PSC BI units shall implement phone security practices. The PSC BI units shall discuss investigations and cases only with those individuals that have a need to know the information, and shall not divulge information to individuals not personally known to the PSC BI unit involved in the investigation of the related issue.

Additionally, the PSC BI units shall only use CMS, OIG, DOJ, and FBI phone numbers that they can verify. To assist with this requirement, PSC management shall provide PSC BI unit staff with a list of the names and telephone numbers of the individuals of the authorized agencies that the PSC BI units deal with and shall ensure that this list is properly maintained and periodically updated.

Employees shall be polite and brief in responding to phone calls, but shall not volunteer any information or confirm or deny that an investigation is in process. However, PSC BI units shall not respond to questions concerning any case the OIG, FBI, or any other law

enforcement agency is investigating. The PSC BI units shall refer such questions to the OIG, FBI, etc., as appropriate.

Finally, the PSC BI units shall transmit sensitive and investigative information via facsimile (fax) lines only after the PSC has verified that the receiving fax machine is secure. Unless the fax machine is secure, PSC BI units shall make arrangements with the addressee to have someone waiting at the receiving machine while the fax is transmitting. The PSC shall not transmit sensitive and investigative information via fax if the sender must delay a feature, such as entering the information into the machine's memory.

4.3 – Medical Review for Benefit Integrity Purposes

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

As Stated in PIM, chapter 1,section 1.1, the CMS' national objectives and goals as they relate to medical review are as follows: 1) Increase the effectiveness of medical review payment safeguard activities; 2) Exercise accurate and defensible decision making on medical review of claims; 3) Place emphasis on reducing the paid claims error rate by notifying the individual billing entities (i.e., providers, suppliers, or other approved clinicians) of medical review findings and making appropriate referrals to provider outreach and education (POE); and 4) Collaborate with other internal components and external entities to ensure correct claims payment, and to address situations of potential fraud, waste, and abuse.

The statutory authority for the MR program includes sections 1812, 1816, 1832, 1833(e), 1842, 1842(a)(2)(B), 1861, 1862(a), 1862(a)(1), 1861, and 1874 of the Social Security Act (the Act). In addition, the regulatory authority for the MR program rests in 42 CFR 421.100 for intermediaries and 42 CFR 421.200 for carriers. Refer to PIM, chapter 3, for detailed information about the statutory and regulatory authorities.

The focus of the MR *program* is to reduce the error rate through medical review and provider notification and feedback, whereas medical review for BI purposes focuses on addressing situations of potential fraud, waste and abuse.

Data analysis is an essential first step in determining whether patterns of claims submission and payment indicate potential problems. Such data analysis may include simple identification of aberrancies in billing patterns within a homogeneous group, or much more sophisticated detection of patterns within claims or groups of claims that might suggest improper billing or payment. The contractor's ability to make use of available data and apply innovative analytical methodologies is critical to the success of both MR and MR for BI purposes. See PIM, chapter 2 in its entirety for MR and BI data analysis requirements.

The PSC BI units and DME PSC, AC, and A/B MAC MR units shall have ongoing discussions and close working relationships regarding situations identified that may be signs of potential fraud. Intermediaries and A/B MACs shall also include the cost report audit unit in the ongoing discussions. AC and A/B MAC medical review (MR) staff shall coordinate and communicate with their associated PSC BI units to ensure coordination of efforts, to prevent inappropriate duplication of review activities, and to assure contacts made by the AC or MAC are not in conflict with benefit integrity related activities.

A. Referrals from the Medical Review Unit to the Benefit Integrity Unit

If a provider appears to have knowingly and intentionally furnished services that are not covered, or filed claims for services not furnished as billed, or made any false Statement on the claim or supporting documentation to receive payment, the DME PSC, AC, or MAC MR unit personnel shall discuss this with the PSC BI unit. If the PSC BI unit

agrees that there is potential fraud, the MR unit shall then make a referral to the PSC BI unit for investigation. Provider documentation that shows a pattern of repeated misconduct or conduct that is clearly abusive or potentially fraudulent despite provider education and direct contact with the provider to explain identified errors shall be referred to the PSC BI unit.

B. Referrals from the Benefit Integrity Unit to the Medical Review Unit and Other Units

The PSC BI units are also responsible for preventing and minimizing the opportunity for fraud. The PSC BI units shall identify procedures that may make Medicare vulnerable to potential fraud and take appropriate action.

The PSC BI unit may request the AC or A/B MAC to install a prepayment edit or auto-denial edit.

The PSC shall work with its own nurses to perform MR for BI reviews.

C. Benefit Integrity/Medical Review Determinations

When MR staff are reviewing a medical record for MR purposes, their focus is on making a coverage and/or coding determination. However, when PSC staff are performing BI-directed medical review, their focus may be different (e.g., looking for possible falsification). The PIM, chapter 3, §§ 3.4-3.4.3 outlines the procedures to be followed by both MR and MR for BI staff to make coverage and coding determinations.

1. The PSC shall maintain current references to support medical review determinations, including but not limited to:

- Code of Federal Regulations;
- CMS Internet Only Manuals (IOMs);
- Local coverage determinations (LCDs) and/or local medical review policies (LMRPs) from the affiliated contractor (AC) or MAC;
- Internal review guidelines (sometimes defined as desktop procedures); and
- The review staff shall be familiar with the above references and able to track requirements in the internal review guidelines back to the statute or manual.

2. The PSC shall have specific review parameters and guidelines established for the identified claims. Each claim shall be evaluated using the same review guidelines. The claim and the medical record shall be linked by identification of patient name, HIC number, diagnosis, ICN, and procedure. The PSC shall have access to *the information contained in the* provider tracking systems from medical review *for comparison to PSC findings*. The information on the tracking systems should be used for comparison to PSC findings. The PSC shall also consider that the medical review department may have established internal guidelines. (See PIM chapter 3, §3.4.4.)

3. The PSC shall evaluate if the provider specialty is reasonable for the procedure(s) being reviewed. As examples, one would not expect to see chiropractors billing for cardiac care, podiatrists for dermatological procedures, and ophthalmologists for foot care.

4. The PSC shall evaluate\determine if there is evidence in the medical record that the service submitted was actually provided and if so, if the service was medically reasonable and necessary. The PSC shall also verify diagnosis and match to age, gender, and procedure.

5. The PSC shall determine if patterns and/or trends exist in the medical record which may indicate potential fraud, waste or abuse. Examples include, but are not limited to:

- The medical records tend to have obvious or nearly identical documentation

- In reviews that cover a sequence of codes (Evaluation & Management codes, therapies, radiology, etc.), there may be evidence of a trend to use the high ends codes more frequently than would be expected

- In a provider review, there may be a pattern of billing more hours of care than would normally be expected on a given workday

6. The PSC shall evaluate the medical record for evidence of alterations including, but not limited to: obliterated sections, missing pages, inserted pages, white out, and excessive late entries.

7. The PSC shall document errors found and communicate these to the provider in a written format when the provider review does not find evidence of potential fraud. A referral may be made to the POE staff at the AC or MAC for additional provider education and follow-up, if appropriate.

8. The PSC shall downcode or deny, in part or in whole, depending upon the service under review when medical records do not support services billed by the provider.

9. The PSC shall thoroughly document the rationale utilized to make the medical review decision.

D. Quality Assurance

Quality assurance activities shall ensure that each element is being performed consistently and accurately throughout the PSC's MR for BI program. In addition, the PSC shall have in place procedures for continuous quality improvement. Quality Improvement builds on quality assurance in that it allows the contractor to analyze the outcomes from their program and continually improve the effectiveness of their processes.

1. The PSC shall assess the need for internal training on changes or new instructions (through minutes, agendas, sign-in sheets, etc.) and confirm with staff that they have participated in training as appropriate. The PSC staff shall have the ability to request training on specific issues.

2. The PSC shall evaluate internal mechanisms used to determine whether staff members have correctly interpreted the training (training evaluation forms, staff assessments) and demonstrated the ability to implement the instruction (internal quality assessment processes).

3. The PSC shall have an objective process to assign staff to review projects, ensuring that the correct level of expertise is available. For example, situations dealing with therapy issues may include review by an appropriate therapist or use of a therapist as a consultant to develop internal guidelines. Situations with complicated or questionable medical issues, or where no policy exists, may require a physician consultant (medical director or outside consultant).

4. The PSC shall develop a system to address how it will monitor and maintain accuracy in decision-making (inter-reviewer reliability) as referenced in PIM, chapter 1, §1.2.3.4.

5. When the PSC evaluation results identify the need for prepayment edit placement at the AC or A/B MAC, the PSC shall have a system in place to evaluate the effectiveness of those edits on an ongoing basis as development continues.

4.4.1 - Requests for Information From Outside Organizations

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

Federal and State and local law enforcement agencies may seek beneficiary and provider information to further their investigations or prosecutions of individuals or businesses alleged to have committed health care fraud and other crimes for which medical records may be sought as evidence. When these agencies request that a PSC BI unit disclose beneficiary records or provider information, the responsive disclosure shall comply with applicable Federal law as required by the HIPAA Business Associate provision of the PSC BI unit's contract. Federal law will dictate whether, and how much, requested information can be disclosed and disclosure will be contingent on the purpose for which it is sought, and whether information is sought about beneficiaries or providers. Certain general information, for example, which does not include specific beneficiary identifiers may be shared with a broader community (including private insurers), such as the general nature of how fraudulent practices were detected, the actions being taken, and aggregated data showing trends and/or patterns.

In deciding to share information voluntarily or in response to outside requests, the PSC BI unit shall carefully review each request to ensure that disclosure would not violate the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) and/or the Privacy Rule (45 CFR, Parts 160 and 164) implemented under the HIPAA. Both the Privacy Act and the Rule seek to strike a balance that allows the flow of health information needed to provide and promote high quality health care while protecting the privacy of people who seek this care. In addition, they provide individuals with the right to know with whom their personal information has been shared and this, therefore, necessitates the tracking of any disclosures of information by the PSC BI unit. PSC BI unit questions concerning what information may be disclosed under the Privacy Act or Privacy Rule shall be directed to regional office Freedom of Information Act (FOIA)/privacy coordinator. Ultimately, the authority to release information from a Privacy Act System of Records to a third party rests with the system manager/business owner of the system of records.

The HIPAA Privacy Rule establishes national standards for the use and disclosure of individuals' health information (also called protected health information) by organizations subject to the Privacy Rule (which are called "covered entities"). As a "business associate" of CMS, PSCs are contractually required to comply with the HIPAA Privacy Rule. The Privacy Rule restricts the disclosure of any information, in any form, that can identify the recipient of medical services unless that disclosure is expressly permitted under the Privacy Rule. Two of the circumstances in which the Privacy Rule allows disclosure are for "health oversight activities" (45 CFR 164.512(d)) and "law enforcement purposes" (45 CFR 164.512 (f)), provided the disclosure meets all the relevant prerequisite procedural requirements in those subsections. Generally, protected health information may be disclosed to a health oversight agency (as defined in 45 CFR 164.501) for purposes of health oversight activities authorized by law, including administrative, civil, and criminal investigations necessary for appropriate oversight of the health care system (45 CFR 164.512(d)). The Department of Justice (DOJ), through its United States Attorneys' Offices and its headquarters-level litigating divisions, the

FBI, the Department of Health and Human Services Office of Inspector General (DHHS - OIG), and other Federal, State, or local enforcement agencies, are acting in the capacity of health oversight agencies when they are investigating fraud against Medicare, Medicaid, or other health care insurers or programs.

The Rule also permits disclosures for other law enforcement purposes that are not health oversight activities but involve other specified law enforcement activities for which disclosures are permitted under HIPAA, which include a response to grand jury or administrative subpoenas and court orders, and for assistance in locating and identifying material witnesses, suspects, or fugitives. The complete list of circumstances that permit disclosures to a law enforcement agency is detailed in 45 CFR 164.512(f). Furthermore, the Rule permits covered entities, and business associates acting on their behalf, to rely on the representation of public officials seeking disclosures of protected health information for health oversight or law enforcement purposes provided that the identities of the public officials requesting the disclosure have been verified by the methods specified in the Rule (45 CFR 164.514(h)).

The Privacy Act of 1974 protects information about an individual that is collected and maintained by a Federal agency in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency. This includes, but is not limited to, information about educational background, financial transactions, medical history, criminal history, or employment history that contains a name or an identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voiceprint or a photograph. A "system of records" is any group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. For example, Medicare beneficiary data used by the PSC BI unit are maintained in a CMS "system of records" covered by the Privacy Act.

Information from some systems of records may be released only if the disclosure would be consistent with "routine uses" that CMS has issued and published. Routine uses specify who may be given the information and the basis or reason for access that must exist. Routine uses vary by the specified system of records, and a decision concerning the applicability of a routine use lies solely in the purview of the system's manager for each system of records. In instances where information is released as a routine use, the Privacy Act and Privacy Rule remain applicable. The Federal Register system of records notices maintained by CMS may be found on the Web site at http://www.cms.hhs.gov/privacyact/tblsors.asp. For example, the Department of Health and Human Services has published a routine use which permits the disclosure of personal information concerning individuals to the Department of Justice, as needed for the evaluation of potential violations of civil or criminal law and for detecting, discovering, investigating, litigating, addressing, or prosecuting a violation or potential violation of law, in health benefits programs administered by CMS. See 63, Fed. Reg. 38414, (July 16, 1998).

A. Requests from Private, Non-Law Enforcement Agencies

Generally, PSC BI units may furnish information on a scheme (e.g., where it is operating, specialties involved). Neither the name of a beneficiary or suspect can be disclosed. If it is not possible to determine whether or not information is releasable to an outside entity, PSCs shall contact their Primary Government Task Leader (GTL), Associate GTL, and SME for any further guidance.

B. Requests from Program Safeguard Contractors

The PSC BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to any PSC, AC, or MAC. PSCs, ACs, and MACs are "business associates" of CMS under the Privacy Rule and thus are permitted to exchange information necessary to conduct health care operations. If the request concerns cases already referred to the OIG/OI, PSC BI units shall refer the requesting PSC BI unit to the OIG/OI.

C. Requests for Information from Qualified Independent Contractors

When a qualified independent contractor (QIC) receives a request for reconsideration on a claim arising from a PSC review determination, it shall first coordinate with the AC *or* MAC to obtain any and all records and supporting documentation that the PSC provided to the AC or MAC in support of the AC's or MAC's first level appeals activities (redeterminations). As necessary, the QIC may also contact the PSC to discuss materials obtained from the AC or MAC and/or obtain additional information to support the QIC's reconsideration activities. The QIC shall send any requests to the PSC for additional information via electronic mail, facsimile, and/or telephone.

NOTE: Individually identifiable beneficiary information shall not be included in an e-mail.

These requests should be minimal. The QIC shall include in its request a name, phone number, and address to which the requested information shall be sent and/or follow-up questions shall be directed. The PSC shall document the date of the QIC's request and send/transmit the requested information within 7 calendar days of the date of the QIC's request. The date of the QIC's request is defined as the date the phone call is made (if a message is left, it is defined as the date the message was left) or the date of the e-mail request.

If a QIC identifies a situation of potential fraud and abuse, they shall immediately refer all related information to the appropriate PSC for further investigation. Refer to PIM, Exhibit 38, for QIC task orders and jurisdictions.

D. Quality Improvement Organizations and State Survey and Certification Agencies

The PSC BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to the QIOs and State survey and certification agencies. The functions QIOs perform for CMS are required by law, thus the Privacy Rule permits disclosures to them. State Survey and Certification Agencies are required by law to perform inspections, licensures, and other activities necessary for appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards, thus the Privacy Rule permits disclosures to them. If the request concerns cases already referred to the OIG/OI, PSC BI units shall refer the requestor to the OIG/OI.

E. State Attorneys General and State Agencies

The PSC BI units may furnish requested specific information on ongoing fraud investigations to State Attorneys General and to State agencies. Releases of information to these entities in connection with their responsibility to investigate, prosecute, enforce, or implement a State statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See subsection H below and PIM Exhibit 25, for guidance on how requests should be structured to comply with the Privacy Rule. PSC BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSC BI units shall refer the requestor to the OIG/OI.

F. Request from Medicaid Fraud Control Units

Under current Privacy Act requirements applicable to program integrity investigations, PSC BI units may respond to requests from Medicaid fraud control units (MFCUs) for information on current investigations. Releases of information to MFCUs in connection with their responsibility to investigate, prosecute, enforce, or implement a State statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). See subsection H below for further information regarding the Privacy Act requirements. If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See subsection H below and PIM Exhibit 25, for guidance on how requests should be structured to comply with the Privacy Rule. PSC BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSC BI units shall refer the requestor to the OIG/OI.

G. Requests from OIG/OI for Data and Other Records

The PSC BI units shall provide the OIG/OI with requested information, and shall maintain cost information related to fulfilling these requests. Such requested information may include law enforcement requests for voluntary refund data (refer to chapter 4, §4.16

for information on voluntary refunds). If major/costly systems enhancements are required to fulfill a request, the PSCs shall discuss the request with the Primary GTL, Associate GTL, and SME before fulfilling the request. These requests generally fall into one of the following categories:

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider. *The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) days when the information or material is contained in the PSC BI unit's files unless an exception exists as described below.*

The PSC BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested. If the PSC BI unit's files do not contain the full amount of information or material requested, the PSC BI unit shall inform the requestor, what, if any, portion of the request can be provided within thirty (30) days.

When the (30) day timeframe cannot be met due to lack of available information or material in the PSC BI unit's files, the PSC BI unit shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The need to notify the requesting office shall occur when the PSC BI unit is required to coordinate with other contractors to obtain the requested information or material. The PSC BI unit shall follow up with other contractors, and document all communication with contractors, to ensure that the request is not delayed unnecessarily. The PSC BI unit shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

If the request requires that the PSC BI unit access National Claims History (NCH) using Data Extract Software (DESY), the thirty (30) day timeframe for Priority I requests does not apply.

Priority II – This type of request is less critical than a Priority I request. Development requests may require review or interpretation of numerous records, extract of records from retired files in a warehouse or other archives, or soliciting information from other sources. Based on the review of its available resources, the PSC BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSC BI units shall respond to such requests within 45 calendar days, when possible. If that timeframe cannot be met, the PSC BI unit shall notify the requesting office within the 45-day timeframe, and include an estimate of when all requested information will be supplied. The PSC shall document all communication with the requesting office regarding the delay. The 45-day timeframe applies to all requests with the exception of those that require DESY access to national claims history (NCH). If the request requires coordination with other contractors and the timeframe cannot be met, the PSC shall

communicate with the contractors to ensure the request is not delayed unnecessarily. The PSC shall document these communications with other contractors.

Disclosures of information to the OIG/OI shall comply with the Privacy Rule and Privacy Act. To comply with the Privacy Act, the OIG/OI must make all data requests using the form entitled, Office of Inspector General, Office of Investigations Data Use Agreement (see Exhibit 37). In order for CMS to track disclosures that are made to law enforcement and health oversight agencies, PSCs and Medicare contractor BI units shall send a copy of all requests for data to the CMS Privacy Officer at the following address:

Centers for Medicare & Medicaid Services
Director of Division of Privacy Compliance Data Development
and CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Boulevard
Baltimore, Maryland 21244

The information sought in the request is required to be produced to the Office of Investigations pursuant to the Inspector General Act of 1978, 5 U.S.C. App. The information is also sought by the Office of Inspector General in its capacity as a health oversight agency, and this information is necessary to further health oversight activities. Disclosure is therefore permitted under the Health Insurance Portability and Accountability Act (HIPAA) Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.501; 164.512(a); and 164.512(d). If the OIG provides language other than the above, the PSC shall contact the Primary GTL, Associate GTL, and SME.

H. Procedures for Sharing CMS Data With the Department of Justice

In April 1994, CMS entered into an interagency agreement with the DHHS Office of the Inspector General and the DOJ that permitted CMS contractors (PSCs) to furnish information, including data, related to the investigation of health care fraud matters directly to DOJ that previously had to be routed through OIG (see PIM Exhibit 35). This agreement was supplemented on April 11, 2003, when in order to comply with the HIPAA Privacy Rule, DOJ issued procedures, guidance, and a form letter for obtaining information (see PIM Exhibit 25). CMS and DOJ have agreed that DOJ requests for individually identifiable health information will follow the procedures that appear on the form letter (see PIM Exhibit 25). The 2003 form letter must be customized to each request. The form letter mechanism is not applicable to requests regarding Medicare Secondary Payer (MSP) information, unless the DOJ requester indicates he or she is pursuing an MSP fraud matter.

The PIM, Exhibit 25, contains the entire document issued by the DOJ on April 11, 2003. PSC BI units shall familiarize themselves with the instructions contained in this document. Data requests for individually identifiable protected health information related to the investigation of health care fraud matters will come directly from those individuals at FBI or DOJ who are involved in the work of the health care oversight agency

(including, for example, from an FBI agent, AUSAs, or designee such as an analyst, auditor, investigator, or paralegal). For example, data may be sought to assess allegations of fraud; examine billing patterns; ascertain dollar losses to the Medicare program for a procedure, service, or time period; determine the nature and extent of a provider's voluntary refund(s); or conduct a random sample of claims for medical review. The law enforcement agency should begin by consulting with the appropriate Medicare contractor (usually the PSC, but possibly also the carrier, fiscal intermediary, MAC, or CMS) to discuss the purpose or goal of the data request. Requests for cost report audits and/or associated documents shall be referred directly to the appropriate FI or MAC.

The PSC BI units shall discuss the information needed by DOJ and determine the most efficient and timely way to provide the information. When feasible, the PSC BI unit will use statistical systems to inform DOJ of the amount of dollars associated with their investigation, and the probable number of claims to expect from a claims level data run. PSC BI units shall obtain and transmit relevant statistical information to DOJ (as soon as possible but no later than five (5) working days) and advise DOJ of the anticipated volume, format, and media to be used (or alternative options, if any) for fulfilling a request for claims data.

The DOJ will confirm whether a request for claims data remains necessary based on the results of statistical analysis. If so, DOJ will discuss with CMS issues involving the infrastructure and data expertise necessary to analyze and further process the data that CMS will provide to DOJ.

If DOJ confirms that claims data are necessary, DOJ will prepare a formal request letter to the PSC BI unit with existing DOJ guidance (Exhibit 25).

The PSC BI units will provide data to DOJ, when feasible in a format to be agreed upon by the PSC BI units and DOJ. Expected time frames for fulfilling DOJ claims level data requests will depend on the respective source(s) and duration of time for which data are sought with the exception of Emergency Requests which require coordination with Headquarters DOJ and CMS staff, these are as follows:

Emergency Requests - Require coordination with Headquarters DOJ and CMS staff.

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider. *The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) days when the information or material is contained in the PSC BI unit's files unless an exception exists as described below.*

The PSC BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested. If the PSC BI unit's files do not contain the full amount of information or material requested, the PSC BI unit shall inform the requestor, what, if any, portion of the request can be provided within thirty (30) days.

When the (30) day timeframe cannot be met due to lack of available information or material in the PSC BI unit's files, the PSC BI unit shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The need to notify the requesting office shall occur when the PSC BI unit is required to coordinate with other contractors to obtain the requested information or material. The PSC BI unit shall follow up with other contractors, and document all communication with contractors, to ensure that the request is not delayed unnecessarily. The PSC BI unit shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

If the request requires that the PSC BI unit access National Claims History (NCH) using Data Extract Software (DESY), the thirty (30) day timeframe for Priority I requests does not apply.

Priority II Requests – This type of request is less critical than a Priority I request. Development requests may require review or interpretation of numerous records, extract of records from retired files in a warehouse or other archives, or soliciting information from other sources. Based on the review of its available resources, the PSC BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSC BI units shall respond to such requests within 45 calendar days, when possible. If that timeframe cannot be met, the PSC BI unit shall notify the requesting office within the 45-day timeframe, and include an estimate of when all requested information will be supplied. The PSC shall document all communication with the requesting office regarding the delay. The 45-day timeframe applies to all requests with the exception of those that require DESY access to national claims history (NCH). If the request requires coordination with other contractors and the timeframe cannot be met, the PSC shall communicate with the contractors to ensure the request is not delayed unnecessarily. The PSC shall document these communications with other contractors.

Once the format is agreed upon, the law enforcement agency will send the signed 2003 form letter, identifying the appropriate authority under which the information is being sought and specifying the details of the request to the PSC BI unit. A request for data that is submitted on the 2003 form letter is considered to be a Data Use Agreement (DUA) with CMS. In order for CMS to track disclosures that are made to law enforcement and health oversight agencies, PSC BI units shall send a copy of all requests for data to the CMS Privacy Officer at the following address:

Centers for Medicare & Medicaid Services
Director of Division of Privacy Compliance Data Development
and CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Blvd.
Baltimore, MD. 21244

The CMS has established a cost limit of $200,000 for any individual data request. If the estimated cost to fulfill any one request is likely to meet or exceed this figure, a CMS representative will contact the requestor to explore the feasibility of other data search and/or production options. Few, if any, individual DOJ requests will ever reach this threshold. In fact, an analysis of DOJ requests fulfilled by CMS' central office over the course of 1 year indicates that the vast majority of requests were satisfied with a minimum of expense. Nevertheless, CMS recognizes that PSC BI units may not have sufficient money in their budgets to respond to DOJ requests. In such cases, PSCs shall contact their Primary GTLs, Associate GTLs, and SMEs.

I. Law Enforcement Requests for Medical Review

The PSC BI units shall not send document request letters or go on site to providers to obtain medical records solely at the direction of law enforcement. However, if law enforcement furnishes the medical records and requests the PSC BI unit to review and interpret medical records for them, the PSC BI unit shall require law enforcement to put this request in writing. At a minimum, this request shall include the following information:

The nature of the request (e.g., what type of service is in question and what should the reviewer be looking for in the medical record)

The volume of records furnished

Due date
Format required for response

The PSC shall present the written request to the Primary GTL, Associate GTL, and SME prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the PSC has resources to fulfill the request. If so, the request may be approved.

If law enforcement requests the PSC to perform medical review on all investigations the PSC initiates, the PSC shall only perform medical review if it deems it necessary on a case-by-case basis. The PSC shall inform the GTL, Associate GTL, and SME of such requests by law enforcement.

J. Law Enforcement Requests for PSC Audits of Medicare Provider Cost Reports Relating to Fraud

If law enforcement requests the PSC to perform an audit of a Medicare provider's cost report for fraud, the PSC shall consult with the AC or MAC to inquire if an audit of the cost report has already been performed. The PSC shall also consult with the Primary GTL, Associate GTL, and SME. The PSC shall provide the Primary GTL, Associate GTL, and SME with the basis for the law enforcement request and a detailed cost estimate to complete the audit. If the Primary GTL, Associate GTL, and SME approve

the audit, the PSC shall perform the audit within the timeframe and cost agreed upon with law enforcement.

K. Requests from Law Enforcement for Information Crossing Several PSC Jurisdictions

If a PSC receives a request from law enforcement for information that crosses several PSC jurisdictions, the PSC shall respond back to the requestor specifying that they will be able to assist them with the request that covers their jurisdiction. However, for the information requested that is covered by another PSC jurisdiction, the PSC shall provide the requestor with the correct contact person for the inquiry, including the person's name and telephone number. Furthermore, the PSC shall inform the requestor that the Director of the Division of Benefit Integrity Management Operations at CMS CO is the contact person in case any additional assistance is needed. The PSC shall also copy their GTLs and SMEs on their response back to law enforcement for these types of cross jurisdictional requests.

L. Privacy Act Responsibilities

The 1994 Agreement and the 2003 form letter (see PIM Exhibits 35 and 25 respectively) are consistent with the Privacy Act. Therefore, requests that appear on the 2003 form letter do not violate the Privacy Act. The Privacy Act of 1974 requires Federal agencies that collect information on individuals that will be retrieved by the name or another unique characteristic of the individual to maintain this information in a system of records.

The Privacy Act permits disclosure of a record, without the prior written consent of an individual, if at least one of twelve disclosure provisions apply. Two of these provisions, the "routine use" provision and/or another "law enforcement" provision, may apply to requests from DOJ and/or FBI.

Disclosure is permitted under the Privacy Act if a routine use exists in a system of records.

Both the Intermediary Medicare Claims Records, System No., 09-70-0503, and the Carrier Medicare Claims Records, System No. 09-70-0501, contain a routine use that permits disclosure to:

"The Department of Justice for investigating and prosecuting violations of the Social Security Act to which criminal penalties attach, or other criminal statutes as they pertain to Social Security Act programs, for representing the Secretary, and for investigating issues of fraud by agency officers or employees, or violation of civil rights."

The CMS Utilization Review Investigatory File, System No. 09-70-0527, contains a routine use that permits disclosure to "The Department of Justice for consideration of criminal prosecution or civil action."

The latter routine use is more limited than the former, in that it is only for "consideration of criminal or civil action." It is important to evaluate each request based on its applicability to the specifications of the routine use.

In most cases, these routine uses will permit disclosure from these systems of records; however, each request should be evaluated on an individual basis.

Disclosure from other CMS systems of records is not permitted (i.e., use of such records compatible with the purpose for which the record was collected) unless a routine use exists or one of the 11 other exceptions to the Privacy Act applies.

The law enforcement provision may apply to requests from the DOJ and/or FBI. This provision permits disclosures "to another agency or to an instrumentality of any jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought."

The law enforcement provision may permit disclosure from any system of records if all of the criteria established in the provision are satisfied. Again, requests should be evaluated on an individual basis.

To be in full compliance with the Privacy Act, all requests must be in writing and must satisfy the requirements of the disclosure provision. However, subsequent requests for the same provider that are within the scope of the initial request do not have to be in writing. PSCs shall refer requests that raise Privacy Act concerns and/or issues to the Primary GTL, Associate GTL, and SME for further consideration.

M. Duplicate Requests for Information

The DOJ and the OIG will exchange information on cases they are working on to prevent duplicate investigations. If the PSC BI unit receives duplicate requests for information, the PSC BI unit shall notify the requestors. If the requestors are not willing to change their requests, the PSC BI unit shall ask the Primary GTL, Associate GTL, and SME for assistance.

N. Reporting Requirements

For each data request received from DOJ, PSC BI units shall maintain a record that includes:

The name and organization of the requestor

The date of the written request (all requests must be in writing)

The nature of the request

Any subsequent modifications to the request

Whether the Primary GTL, Associate GTL, and SME had to intervene on the outcome (request fulfilled or not fulfilled)

The cost of furnishing a response to each request.

4.8.2 – Production of Medical Records and Documentation for an Appeals Case File

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

When the PSC denies a claim and the provider, supplier, physician or beneficiary appeals the denial, the AC or MAC shall request the medical records and documentation that the PSC used in making its determination. The PSC shall assemble the case file and send it to the AC within 7 calendar days or the MAC within 5 calendar days. The PSC shall include any position papers or rationale and support for its decision so that the appeals adjudicator can consider it during the appeals process. However, PSCs shall be aware that an appeals case file is discoverable by the appellant. This means that the appellant can receive a complete copy of the case file. Since the provider may receive the case file, the PSC shall consult with law enforcement before including any sensitive information relative to a potential fraud investigation.

If the PSC would like to be notified of an ALJ hearing on a particular case, the PSC shall put a cover sheet in the case file before sending it to the AC or MAC. The cover sheet shall State that the PSC would like to be notified of an ALJ hearing and list a contact name with a phone and fax number where the contact can be reached. The cover sheet shall also include language stating, "PLEASE DO NOT REMOVE" to ensure it stays on the case file should the file be sent to the QIC. If the PSC receives a notice of hearing, the PSC shall contact the QIC immediately.

The QICs are tasked with participating in ALJ hearings; therefore, they are the primary Medicare contractor responsible for this function. PSCs may participate in an ALJ hearing, but they shall work with the QIC to ensure that duplicative work is not being performed by both the PSC and the QIC in preparation for the hearing. PSCs shall never invoke party status. If the PSC participates in a hearing, it shall be as a non-party. An ALJ cannot require participation in a hearing, whether it is party or non-party. If a PSC receives a notice that appears contrary to this instruction, the PSC shall contact the QIC and their primary GTL, associate GTL, and SME immediately.

4.18.3 - Referral to Quality Improvement Organizations

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

Communication with the QIO is essential to discuss the potential impact of efforts to prevent abuse as well as efforts to ensure quality and access. More specifically, CMS expects dialogue between PSCs and the QIO to:

- Ensure that an LCD does not set up obstacles to appropriate care
- Articulate the program safeguard concerns or issues related to QIO activities
- Be aware of QIO initiatives (e.g., a QIO project to encourage Medicare beneficiaries to get eye exams), so they do not observe an increase in utilization and label it overutilization

The PSCs should continue exchanging additional information such as data analysis methods, data presentation methods, and successful ways to interact with providers to change behavior. This includes special projects that PSCs and the QIO have determined to be mutually beneficial.

It is essential that the PSC manager maintain an ongoing dialogue with his/her counterpart(s) at other PSCs, particularly in contiguous States. This ensures that a comprehensive investigation is initiated in a timely manner and prevents possible duplication of investigation efforts.

The PSCs should maintain an ongoing dialogue with the QIOs. Intermediaries or MACs may make referrals to the QIO for review of inpatient claims when outpatient claims reveal a problem provider. If the PSC refers a provider to the State licensing agency or medical society, i.e., those referrals that need immediate response from the State licensing agency, it should also send a copy of the referral to the QIO. Also, PSCs shall notify the QIO on utilization and quality issues for Part A providers and physicians that are suspected of fraud and of referrals to OIG/OI.

The PSC shall coordinate the review of Part A acute care inpatient hospital claims and long term care hospital PPS claims (i.e., long term acute care, not SNFs) for benefit integrity purposes with the QIO *to determine any QIO involvement with the claims*. The PSC shall follow the definition of acute care inpatient prospective payment system (PPS) hospital found in PIM Chapter 1, §1.1.2 (http://www.cms.gov/manuals/108_pim/pim83c01.pdf). If the PSC investigation indicates a need to review Part A acute care inpatient PPS hospital medical records or long term care hospital PPS claim medical records, the PSC shall request the medical records directly from the provider and have them sent directly to the PSC. Upon receipt of the records, the PSC shall perform a billing and document review of the medical record. The PSC shall also review the medical records for medical necessity, as well as, any indications of potential fraud and abuse.

If the PSC's review does not involve the extrapolation of an overpayment and results in single claims denials, the PSC shall refer these claims to the QIO for payment determination. If an overpayment determination was otherwise based on extrapolation, then the PSC shall refer the overpayment determination to the AC or MAC for issuance of a demand.

If after the PSC reviews the Part A acute care inpatient PPS hospital claims or long term care hospital PPS claims and medical records, the PSC determines that potential fraud and abuse is likely, the PSC shall coordinate the case with law enforcement (per Law Enforcement Memorandum of Understanding). If law enforcement accepts the case, law enforcement may then coordinate directly with the QIO for any further medical review.

The PSC shall not involve the QIO in reviews at other types of hospitals.

Exhibit 7 - Sample Letter for On-Site Reviews

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

DATE:

PROVIDER NAME: CONTRACTOR NAME:

PROVIDER ADDRESS: CONTRACTOR ADDRESS:

OPENING

Dear _______:

Thank you for your cooperation during the comprehensive medical review conducted at your facility on ___________. Based on this review we have determined that you have been overpaid. We hope the following information answers any questions you may have.

REASON FOR REVIEW

This review was conducted because our analysis of your billing data showed that your facility utilized ________ services at a rate of 50 percent more than that of your peer group.

HOW THE OVERPAYMENT WAS DETERMINED

A random sample of ________ claims processed from 01/01/98 to 06/30/98 was selected for review to determine if the services billed were reasonable and necessary and that all other requirements for Medicare coverage were met. Medical documentation for the selected claims was reviewed by our medical review staff.

Our review found that some services you submitted were not reasonable and necessary as required by the Medicare statute or did not meet other Medicare coverage requirements.

WHY YOU ARE RESPONSIBLE

You are responsible for the overpayment if you knew or had reason to know that service(s) were not reasonable or necessary, and/or you did not follow correct procedures or use care in billing or receiving payment.

The attachment identifies the specific claims that have been determined to be fully or partially non-covered, the specific reasons for denial, an explanation of why you are responsible for the incorrect payment and the amount of the overpayment.

WHAT YOU SHOULD DO

Please return the amount of the overpayment to us by ________ and no interest charge will be assessed. Make the check payable to Medicare Part A and send it with a copy of this letter to:

Intermediary's Address

IF YOU DO NOT REFUND WITHIN 30 DAYS:

If you repay the overpayment within 30 days, you will not have to pay any interest charge.

However, if you do not repay the amount within 30 days, interest will accrue from the date of this letter at the rate of _____ percent for each *full* 30-day period *that payment is not made on time*.

On ________ we will automatically begin to recoup the overpayment amount against your pending claims. Recouped payments will be applied to the accrued interest first and then to the principal. If you believe that recoupment should not be put into effect, submit a Statement within 15 days of the date of this letter to the above address, giving the reason(s) why you feel this action should not be taken. *We will review your documentation. However, this is not an appeal of the overpayment determination, and it will not delay recoupment.*

For copies of the applicable laws and regulations, please contact us at the address shown in our letterhead, to the attention of the __________ Department.

APPEAL RIGHTS:

If you disagree with the overpayment decision, you may file an appeal. An appeal is a review performed by people independent of those who have reviewed your claim so far. The first level of appeal is called a redetermination. You must file your request for a redetermination within 120 days of the date you receive this letter. Unless you show us otherwise, we assume you received this letter 5 days after the date of this letter. Please send your request for a redetermination to:

Address to which redetermination request should be sent

GENERAL PROBLEMS IDENTIFIED IN THE REVIEW AND/OR CORRECTIVE ACTIONS TO BE TAKEN

This review has shown that you are not following national Medicare guidelines in submitting claims for necessary and reasonable ________ services. In addition, you have not followed the Provider Bulletins and letters sent to you regarding local medical review policies and specific problems that we have identified with your billing practices. Your future claims for _______ will be suspended for prepayment review until you correct your billing.

If you have any questions regarding this matter, please contact _________ at ___________.

Thank you in advance for your prompt attention to this matter.

Sincerely,

7.3 - Exhibit: Part A Sample Letter Notifying the Provider of the Results, and Request Repayment of Overpayments

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

DATE:

PROVIDER NAME: **INTERMEDIARY NAME:**
PROVIDER ADDRESS: **INTERMEDIARY ADDRESS:**
PROVIDER NUMBER:
OPENING:

Dear XXXXXX:

Thank you for your cooperation during the comprehensive medical review conducted at your facility on ___________. Based on this review, we have reopened claims in accordance with the reopening procedures at 42 CFR 405.750 and have determined that you have been overpaid in the amount of ____________. We hope the following information answers any questions you may have.

REASON FOR REVIEW

This review was conducted because our analysis of your billing data showed that you may be billing inappropriately for services. (Include in this paragraph any additional details on why the provider was selected for the review.)

HOW THE OVERPAYMENT WAS DETERMINED

A randomly selected sample of ________ claims processed from ________ to ________ was selected for review to determine if the services billed were reasonable and necessary and that all other requirements for Medicare coverage were met. Medical documentation for the selected claims was reviewed by our medical review staff.

Based on the medical documentation reviewed for the selected claims, we found that some services you submitted were not reasonable and necessary, as required by the Medicare statute, or did not meet other Medicare coverage requirements. Along with our claims payment determination, we have made limitation on liability decisions for denials of those services subject to the provisions of §1879 of the Social Security Act (the Act). Those claims for which we determined that you knew, or should have known, that the services were noncovered have been included in the results of this review. In addition, we have made decisions as to whether or not you are without fault for the overpayment

under the provisions of §1870 of the Act. Those claims for which you are not without fault have been included in the results of this review. We projected our findings from the claims that we reviewed to the universe of claims processed during the time frame mentioned above.

TOTAL OVERPAYMENTS

(List the aggregate overpayments)

Be advised that this overpayment amount is based on your interim payment rate in effect at the time the review was done. Further adjustments may be made when your cost report is settled.

GENERAL PROBLEMS IDENTIFIED IN THE REVIEW AND/OR CORRECTIVE ACTIONS TO BE TAKEN

This review has shown that you are not following published Medicare guidelines and policies in submitting claims for necessary and reasonable ________ services. (Reference any provider specific education that occurred regarding these services.) Because of these identified problems, your future claims for _______ may be subject to prepayment review until you correct your billing.

WHY YOU ARE RESPONSIBLE

You are responsible for the overpayment if you knew or had reason to know that service(s) were not reasonable and necessary, and/or you did not follow correct procedures or use care in billing or receiving payment, and you are found to be not without fault under §1870 of the Act.

A list of the specific claims that have been determined to be fully or partially noncovered, the specific reasons for denial, identification of denials that fall under §1879 of the Act and those that do not, the determination of whether you are without fault under §1870 of the Act, an explanation of why you are responsible for the incorrect payment, and the amount of the overpayment is attached. (Enclose a list of the specific claims from the sample that have been found not to be covered. See the example within this exhibit.)

The sampling methodology used in selecting claims for review and the method of overpayment estimation is attached. (Enclosed an explanation of the sampling methodology.)

WHAT YOU SHOULD DO

Please return the amount of the overpayment to us by (insert date, 15 days from date of letter). However, you may request an extended repayment schedule in accordance with 42 CFR 401.607(c). Please contact (name of contact person at the FI/RHHI) on (phone

number of contact person) to discuss repayment options for the full amount of the overpayment determined by the projection of errors found on the ___claim sample.

INTEREST

If you refund the overpayment within 30 days, you will not have to pay any interest charge. If you do not repay the amount within 30 days, interest will accrue from the date of this letter at the rate of _____ percent for each *full* 30-day period *that payment is not made on time*. Medicare charges interest on its outstanding Part A debts in accordance with §1815(d) of the Act and 42 CFR 405.378.

RECOUPMENT AND YOUR RIGHT TO SUBMIT A REBUTTAL STATEMENT

As provided in regulations at 42 CFR 401.607(a) and 405.370-375, on (insert date provided in above paragraph captioned, "What You Should Do"), we will automatically begin to recoup the overpayment amount against your pending and future claims. If you do not repay the debt within 30 days, we will apply your payments, and amounts we recoup, first to accrued interest and then to principal. Also, in accordance with the Debt Collection Improvement Act, we may refer your debt to the Department of Treasury for offset against any monies payable to you by the Federal Government.

You have the right to submit a rebuttal Statement in writing within fifteen days from the date of this letter. Your rebuttal Statement should address why the recoupment should not be put into effect on the date specified above. You may include with this Statement any evidence you believe is pertinent to your reasons why the recoupment should not be put into effect on the date specified above. Your rebuttal Statement and evidence should be sent to:

FI Name, Address, Telephone #, and Fax #

Upon receipt of your rebuttal Statement and any supporting evidence, we will consider and determine within fifteen days whether the facts justify continuation, modification, or termination of the overpayment recoupment. We will send you a separate written notice of our determination that will contain the rationale for our determination. However, recoupment will not be delayed beyond the date Stated in this notice while we review your rebuttal Statement. *This is not an appeal of the overpayment determination, and it will not delay recoupment based on §1893(f)(2) of the Act.* If put into effect, the recoupment will remain in effect until the earliest of the following: (1) the overpayment and any assessed interest are liquidated; (2) we obtain a satisfactory agreement from you to liquidate the overpayment; (3) *a valid and timely appeal is received; or (4)* on the basis of subsequently acquired evidence, we determine that there is no overpayment.

If you choose not to submit a rebuttal Statement, the recoupment will automatically go into effect on (insert same date as provided in paragraph captioned, "What You Should Do "). Whether or not you submit a rebuttal Statement, our decisions to recoup or delay recouping, to grant or refuse to grant an extended repayment schedule, and our response

to any rebuttal Statement are not initial determinations as defined in 42 CFR 405.704, and thus, are not appealable determinations. (See also, 42 CFR 401.625 and 405.375(c).)

YOUR RIGHT TO CHALLENGE OUR DECISIONS

This letter serves as our revised determination of the claims listed in the Attachment. If you disagree with this determination, you *may* request a *redetermination* within *120* days of the date you receive this letter (*unless you can show us otherwise,* receipt is presumed to be five (5) days from the date of this letter). You have the right to raise the same issues under this procedure as you would have in the context of non-sampling claims determinations under Part A and overpayment recovery. (See 42 CFR 405.701, et seq.) You may ask for a *redetermination* of the denials for which you are determined to be liable under §1879 of the Act or for which the beneficiary is determined to be liable under §1879 of the Act, but declined, in writing, to exercise his/her appeal rights, and determinations for which you are found to be not without fault under §1870 of the Act. You may also challenge the validity of the sample selection and the validity of the statistical projection of the sample results to the universe. (Refer to the appeals procedure in your Provider Manual § __________ for further details.)

If you have any questions regarding this matter, please contact _________ at ___________. (Provide correspondence address.)

Thank you in advance for your prompt attention to this matter.

Sincerely,

Enclosures

7.4 - Exhibit: Part B Sample Letter Notifying the Provider of the Results, and Request Repayment of Overpayments

(Rev.213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

SAMPLE LETTER--MEDICARE PART B

DATE:

PROVIDER NAME: **INTERMEDIARY NAME:**
PROVIDER ADDRESS: **INTERMEDIARY ADDRESS:**
PROVIDER NUMBER:
OPENING:

Dear XXXXX:

Thank you for your cooperation during the comprehensive medical review conducted at your facility on ____________. Based on this review, we have reopened claims in accordance with the reopening procedures at 42 CFR 405.841 and have determined that you have been overpaid in the amount of ____________. We hope the following information answers any questions you may have.

REASON FOR REVIEW

This review was conducted because our analysis of your billing data showed that you may be billing inappropriately for services. (Include in this paragraph any additional details on why the provider was selected for the review.)

HOW THE OVERPAYMENT WAS DETERMINED

A randomly selected sample of ________ claims processed from ________ to ________ was selected for review to determine if the services billed were reasonable and necessary and that all other requirements for Medicare coverage were met. Medical documentation for the selected claims was reviewed by our medical review staff.

Based on the medical documentation reviewed for the selected claims, we found that some services you submitted were not reasonable and necessary, as required by the Medicare statute, or did not meet other Medicare coverage requirements. Along with our claims payment determination, we have made limitation on liability decisions for denials of those services subject to the provisions of §1879 of the Social Security Act (the Act). Those claims for which we determined that you knew, or should have known, that the services were noncovered have been included in the results of this review. In addition, we have made decisions as to whether or not you are without fault for the overpayment under the provisions of §1870 of the Act. Those claims for which you are not without fault have been included in the results of this review. We projected our findings from the

claims that we reviewed to the universe of claims processed during the time frame mentioned above.

GENERAL PROBLEMS IDENTIFIED IN THE REVIEW AND/OR CORRECTIVE ACTIONS TO BE TAKEN

This review has shown that you are not following published Medicare guidelines and policies in submitting claims for necessary and reasonable ________ services. (Reference any provider specific education that occurred regarding these services.) Because of these identified problems, your future claims for _______ may be subject to prepayment review until you correct your billing.

WHY YOU ARE RESPONSIBLE

You are responsible for the overpayment if you knew or had reason to know that service(s) were not reasonable and necessary, and/or you did not follow correct procedures or use care in billing or receiving payment, and you are found to be not without fault under §1870 of the Act.

A list of specific claims that have been determined to be fully or partially noncovered, the specific reasons for denial, identification of denials that fall under §1879 of the Act and those that do not, the determination of whether you are without fault under §1870 of the Act, an explanation of why you are responsible for the incorrect payment, and the amount of the overpayment is attached. (Enclosed a list of the specific claims and an explanation of fault for each. See the example within this exhibit.)

An explanation of the sampling methodology used in selecting claims for review and the method of overpayment estimation is attached. (Enclose an explanation of the sampling methodology.)

WHAT YOU SHOULD DO

Please return the overpaid amount to us by _______________(date) and no interest charge will be assessed. Make the check payable to Medicare Part B and send it with a copy of this letter to:

___________________Address

IF YOU DO NOT REFUND IN 30 DAYS

In accordance with 42 CFR 405.378, simple interest at the rate of _______ will be charged on the unpaid balance of the overpayment beginning on the 31st day. Interest is calculated in 30-day periods and is assessed for each full 30-day period that payment is not made on time. Thus, if payment is received 31 days from the date of final determination, one 30-day period of interest will be charged. Each payment will be

applied first to accrued interest and then to principal. After each payment, interest will continue to accrue on the remaining principal balance at the rate of ______.

We must request that you refund this amount in full. If you are unable to make refund of the amount at this time, advise this office immediately so that we may determine if you are eligible for an extended repayment schedule. (See enclosure for details.) Any extended repayment schedule (where one is approved) would run from the date of this letter.

RECOUPMENT AND YOUR RIGHT TO SUBMIT A REBUTTAL STATEMENT

If payment in full is not received by (specify a date 40 days from the date of the notification), payments to you will be withheld until payment in full is received, an acceptable extended repayment request is received, or a valid and timely appeal is received.

You have the right to submit a rebuttal Statement in writing within fifteen days from the date of this letter. Your rebuttal Statement should address why the recoupment should not be put into effect on the date specified above. You may include with this Statement any evidence you believe is pertinent to your reasons why the recoupment should not be put into effect on the date specified above. Your rebuttal Statement and evidence should be sent to:

Carrier Name, Address, Telephone #, and Fax #

Upon receipt of your rebuttal Statement and any supporting evidence, we will consider and determine within 15 days whether the facts justify continuation, modification or termination of the overpayment recoupment. We will send you a separate written notice of our determination that will contain the rationale for our determination. However, recoupment will not be delayed beyond the date Stated in this notice while we review your rebuttal Statement. *This is not an appeal of the overpayment determination, and it will not delay recoupment based on §1893(f)(2) of the Act.* If put into effect, the recoupment will remain in effect until the earliest of the following: (1) the overpayment and any assessed interest are liquidated; (2) we obtain a satisfactory agreement from you to liquidate the overpayment; (3) *a valid and timely appeal is received; or (4)* on the basis of subsequently acquired evidence, we determine that there is no overpayment.

Whether or not you submit a rebuttal Statement, our decisions to recoup or delay recouping, to grant or refuse to grant an extended repayment schedule, and our response to any rebuttal Statement are not initial determinations as defined in 42 CFR 405.803, and thus, are not appealable determinations. (See also, 42 CFR 401.625 and 405.375(c).)

YOUR RIGHT TO CHALLENGE OUR DECISIONS

This letter serves as our revised determination of the claims listed in the attachment. If you disagree with this determination, you *may* request a *redetermination* within *120 days*

of the date of this letter *(unless you show us otherwise, receipt is presumed to be five (5) days from the date of this letter)*. You have the right to raise the same issues under this procedure as you would have in the context of non-sampling claims determinations of Part B services billed to the Fiscal Intermediary, and overpayment recovery. (See 42 CFR 405.801, et seq. and 42 CFR 405.701, et seq.) You may ask for a *redetermination* of the denials for which you are determined to be liable under §1879 of the Act or for which the beneficiary is determined to be liable under §1879 of the Act, but declined, in writing, to exercise his/her appeal rights, and determinations for which you are found to be not without fault under §1870 of the Act. You may also challenge the validity of the sample selection and the validity of the statistical projection of the sample results to the universe. (Refer to the appeals procedure in your Provider Manual Section __________ for further details.)

IF YOU HAVE FILED A BANKRUPTCY PETITION

If you have filed a bankruptcy petition or are involved in a bankruptcy proceeding, Medicare financial obligations will be resolved in accordance with the applicable bankruptcy process. Accordingly, we request that you immediately notify us about this bankruptcy so that we may coordinate with both the Centers for Medicare & Medicaid Services and the Department of Justice so as to assure that we handle your situation properly. If possible, when notifying us about the bankruptcy, please include the name the bankruptcy is filed under and the district where the bankruptcy is filed.

If you have any questions regarding this matter, please contact _________ at ___________. (Provide correspondence address.)

Thank you in advance for your prompt attention to this matter.

Sincerely,

Enclosures