CMS Manual System

Pub 100-08 Medicare Program Integrity

Transmittal 144

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: MARCH 31, 2006

Change Request 4247

SUBJECT: Various Benefit Integrity (BI) Revisions

I. SUMMARY OF CHANGES: Various revisions have been made to the BI sections in chapter 4, of the PIM, to reflect updates and clarifications.

NEW/REVISED MATERIAL
EFFECTIVE DATE: May 1, 2006
IMPLEMENTATION DATE: May 1, 2006

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:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/4.2/The Medicare Fraud Program
R	4/4.4.1/Requests for Information From Outside Organizations
R	4/4.11.2.9/Closing Cases
R	4/4.16/AC and PSC Coordination on Voluntary Refunds
R	4/4.18.1.2/Immediate Advisements to the OIG/OI
R	Exhibits/Table of Contents
R	Exhibits/Exhibit 1/Definitions
R	Exhibits/Exhibit 16.1/OIG/OI Case Referral Fact Sheet Format
R	Exhibits/Exhibit 37/Office of Inspector General, Office of Investigations Data Use Agreement

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 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: 144	Date: March 31, 2006	Change Request 4247

SUBJECT: Various Benefit Integrity (BI) Revisions

I. GENERAL INFORMATION

A. Background: Various BI sections in chapter 4 of the PIM were revised to reflect updates and clarifications.

B. Policy: N/A

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements											Respo colum
			FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other	
		PSC					FISS	MCS	VMS	CWF		
4247.1	Any area in the AC that refers potential fraud and abuse to the PSC shall maintain a log of these referrals, and all areas within the Medicare contractor shall maintain a log of all potential fraud and abuse referrals to the Medicare contractor BI unit.		X	X	X	X						
4247.2	At a minimum, the above log shall include the following information: provider/physician/supplier name, beneficiary name, HIC number, nature of the referral, date the referral is forwarded to the PSC or Medicare contractor BI unit, name and contact information of the individual who made the referral, and the name of the PSC or Medicare contractor BI unit to whom the referral was made.		X	X	X	X						
4247.3	PSCs and Medicare BI units shall consider a case closed when no further action will be required of the PSC or Medicare contractor BI unit by law enforcement agency(ies) working	X				X						

Requirement Number	Requirements											Respo colum
			FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other	
		PSC					FISS	MCS	VMS	CWF		
	the case and when the law enforcement agency(ies) has ended all its activity on the case; and when all necessary administrative actions have been finalized (i.e., when the total amount calculated has been referred to the AC). Note that after a case is closed, it can still be updated to reflect any additional activity that takes place (i.e., recoupment of the overpayment by the AC).											
4247.4	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 one copy of all requests for data to the CMS Privacy Officer at the address specified in PIM Chapter, §4.4.1G.	X				X						
4247.4	ACs and Medicare contractors shall refer to the Financial Management Manual for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers.		X	X	X	X						
4247.5	PSCs and ACs shall work out in the JOA whether the PSC or the AC sends, at a minimum annually, the voluntary refund language in PIM Chapter 4, §4.16.	X										
4247.6	The PSC or Medicare contractor BI unit shall immediately advise the OIG/OI through a telephone communication to the Special Agent in Charge (SAC) or Assistant Special Agent in Charge (ASAC) when it receives the allegations specified in chapter 4, §4.18.1.2 of the PIM.	X				X						
4247.7	The PSC or Medicare contractor BI unit shall document the telephone conversation with the SAC or ASAC through a written communication (e.g., an e-mail or letter) to the SAC or ASAC.	X				X						

Requirement Number	Requirements	Respo colum									
			FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
		PSC					FISS	MCS	VMS	CWF	
4247.8	If the OIG requests a query on an immediate advisement and the requests becomes costly or requires major resources, the PSC shall discuss this with the GTL, Associate GTL, and SME; and the Medicare contractor BI units shall discuss this with the RO.	X				X					
4247.9	Refer to Exhibit I for changes in the following definitions: Closed Case, Office of Inspector General (OIG), Office of Investigations (OI), Suspension of Payment.	X				X					
4247.10	When completing the OIG/OI Case Referral Fact Sheet in Exhibit 16.1 in the PIM, the PSC and Medicare contractor BI unit shall indicate if the overpayment is actual, estimated, or projected.	X				X					
4247.11	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 address specified in the PIM, Chapter 4, §4.4.1.G.	X				X					
4247.12	Refer to Exhibit 37 for changes in the title and #s 2 and 3 of the text.	X				X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	None.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: May 1, 2006 **Implementation Date:** May 1, 2006 **Pre-Implementation Contact(s):** Kimberly Downin, Kimberly.downin@cms.hhs.gov **Post-Implementation Contact(s):** Kimberly Downin, Kimberly.downin@cms.hhs.gov	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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

4.2 - The Medicare Fraud Program

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

The primary goal of the PSC and the Medicare contractor BI unit is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped. Suspension and denial of payments and the recoupment of overpayments are an example of the actions that may be taken. All cases of potential fraud are referred to the Office of Inspector General (OIG), Office of Investigations field office (OIFO) for consideration and initiation of criminal or civil prosecution, civil monetary penalty, or administrative sanction actions. AC and Medicare contractor personnel conducting each segment of claims adjudication, Medical Review (MR), and professional relations functions shall be aware of their responsibility for identifying fraud and be familiar with internal procedures for forwarding potential fraud cases to the PSC and the Medicare contractor BI unit. Any area within the AC (e.g., medical review, enrollment, second level screening staff) that refers potential fraud and abuse to the PSC shall maintain a log of all these referrals, and all areas within the Medicare contractor shall maintain a log of all potential fraud and abuse referrals to the Medicare contractor BI unit. At a minimum, the log shall include the following information:

provider/physician/supplier name, beneficiary name, HIC number, nature of the referral, date the referral is forwarded to the PSC or Medicare contractor BI unit, name and contact information of the individual who made the referral, and the name of the PSC or Medicare contractor BI unit *to whom the referral was made*.

Preventing and detecting potential fraud involves a cooperative effort among beneficiaries, PSCs, ACs, Medicare contractors, providers, quality improvement organizations (QIOs), state Medicaid fraud control units (MFCUs), and Federal agencies such as CMS, the Department of Health and Human Services (DHHS), OIG, the Federal Bureau of Investigation (FBI), and the Department of Justice (DOJ).

Each investigation is unique and shall be tailored to the specific circumstances. These guidelines are not to be interpreted as requiring the PSCs and Medicare contractor BI units to follow a specific course of action or establishing any specific requirements on the part of the government or its agents with respect to any investigation. Similarly, these guidelines shall not be interpreted as creating any rights in favor of any person, including the subject of an investigation.

When the PSC or Medicare contractor BI unit has determined that a situation is not fraud, it shall refer these situations to the appropriate unit at the PSC, AC, or Medicare contractor.

4.4.1 - Requests for Information From Outside Organizations

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

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 or Medicare contractor 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 or Medicare contractor 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 or Medicare contractor 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 or Medicare contractor BI unit. PSC and Medicare contractor 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 and Medicare contractor BI units 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 or Medicare contractor 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, PSCs and Medicare contractor 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, Medicare contractors shall contact the CMS RO for further direction. Similarly, PSCs shall contact their Primary Government Task Leader (GTL), Associate GTL, and SME for any further guidance.

B. Requests from Medicare Contractors and Program Safeguard Contractors

The PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to any PSC, AC, or Medicare contractor BI unit. PSCs, ACs, and Medicare contractor BI units 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, PSCs or Medicare contractor BI units shall refer the requesting PSC or Medicare contractor 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 to obtain any and all records and supporting documentation that the PSC provided to the AC in support of the AC's first level appeals activities (redeterminations). As necessary, the QIC may also contact the PSC to discuss materials obtained from the AC 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 should not be given 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 any 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 PSCs and Medicare contractor 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, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

E. State Attorneys General and State Agencies

The PSCs and Medicare contractor 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. PSCs and Medicare contractor 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, PSCs and Medicare contractor 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, PSCs and Medicare contractor 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. PSCs and Medicare contractor 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, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

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

The PSCs and Medicare contractor 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, and the Medicare contractor BI units shall discuss the request and the cost with the RO 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. Information or material is obtained from the PSC's or Medicare contractor BI unit's files. Based on review of its available resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSCs and Medicare contractors BI units shall respond to such requests within 30 days whenever possible. If that timeframe cannot be met, the PSC or Medicare contractor BI unit shall notify the requesting office as soon as possible (but not later than 30 days) after receiving the request. PSCs and Medicare contractor BI units shall include an estimate of when all requested information will be supplied. This timeframe applies to all requests with the exception of those that require Data Extract Software System (DESY) access to NCH.

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 or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSCs and Medicare contractor BI units shall respond to such requests within 45 calendar days, when possible. If that timeframe cannot be met, the PSC or Medicare contractor BI unit shall notify the requesting office within the 45-day timeframe, and include an estimate of when all requested information will be supplied. This timeframe applies to all requests with the exception of those that require DESY access to national claims history (NCH).

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

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 and Medicare contractor BI units) 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. PSCs and Medicare contractor 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, 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.

The PSCs and Medicare contractor 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 and Medicare contractor 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. PSCs and Medicare 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 or Medicare contractor BI unit with existing DOJ guidance (Exhibit 25).

The PSCs and Medicare contractor BI units will provide data to DOJ, when feasible in a format to be agreed upon by the PSCs or Medicare contractor 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, as follows:

- PSC or Medicare contractor BI unit data requests that do not require coordination with other Medicare contractors and/or CMS shall be provided within 30 days of the request. (Changes to Exhibit 25 will be forthcoming by DOJ, but this timeframe and the timeframe below shall be followed and not the timeframe specified in the current Exhibit 25.)

- PSC or Medicare contractor BI unit data requests that require coordination with other Medicare contractors and/or CMS (except for the bullet directly below) shall be provided within 45 days of the request.

- PSCs or Medicare contractor BI units data requests that require Data Extract Software System (DESY) access to the National Claims History (NCH) files will have an undetermined response time.

Emergency requests require coordination with Headquarters DOJ and CMS staff.

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 or Medicare contractor 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, 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 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 PSCs and Medicare contractor BI units may not have sufficient money in their budgets to respond to DOJ requests. In such cases, Medicare contractor BI units are advised to submit to CMS a Supplementary Budget Request (SBR). PSCs shall contact their Primary GTLs, Associate GTLs, and SMEs. To facilitate CMS' ability to track the frequency and burden of DOJ requests, the Medicare contractor BI unit shall maintain and submit to CMS, on a quarterly basis, a log of DOJ data requests that has been itemized to show costs for filling each request. This report should be in the form of an Excel spreadsheet (see PIM Exhibit 26) and shall include, at a minimum, the following fields:

1. Medicare contractor name and identification number

2. Date of DOJ request

3. Nature of DOJ request and DOJ tracking number, if provided

4. Cost to fulfill request

5. Medicare contractor's capacity to fill request, including date of SBR submission, if necessary

The report shall be sent to the following address:

Director, Division of Benefit Integrity Management Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C3-02-16
Baltimore, Maryland 21244

I. Law Enforcement Requests for Medical Review

The PSCs and Medicare contractor 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 or Medicare contractor BI unit to review and interpret medical records for them, the PSC and Medicare contractor 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 dates

Format required for response

The PSC shall present the written request to the Primary GTL, Associate GTL, and SME and the Medicare contractor BI unit shall present the written request to their RO prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the request will be approved.

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 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, and Medicare contractor BI units shall refer requests to their CMS RO.

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 or Medicare contractor BI unit receives duplicate requests for information, the PSC or Medicare contractor BI unit shall notify the requestors. If the requestors are not willing to change their requests, the PSC or Medicare contractor BI unit shall ask the Primary GTL, Associate GTL, and SME (if a PSC) or CMS RO employee (if a Medicare contractor BI unit) for assistance.

N. Reporting Requirements

For each data request received from DOJ, PSCs and Medicare contractor 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 RO, 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

The Medicare contractor shall report the data to the RO when requested by the RO. This data will be used to assess budget requirements.

4.11.2.9 – Closing Cases

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

An active FID case shall be closed when *no further action will be required of the PSC or Medicare contractor BI unit by law enforcement agency(ies) working the case and when the law enforcement agency(ies) has ended all its activity on the case; and when all necessary administrative actions have been finalized (i.e., when the calculated overpayment has been referred to the AC for recoupment). Note that after a case is closed, it can still be updated to reflect any additional activity that takes place (i.e., recoupment of the overpayment by the AC).*

4.16 – AC and PSC Coordination on Voluntary Refunds

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

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

Should the PSC or Medicare contractor BI unit receive a voluntary refund check in error, the PSC shall coordinate the transfer of voluntary refund checks to the AC through the JOA, and the Medicare contractor BI unit shall transfer the check to the appropriate Medicare contractor staff.

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

Through the JOA, PSCs shall establish a mechanism whereby the AC notifies the PSC on a regular basis of all voluntary refunds received by the AC. Medicare

contractor BI units shall work with the appropriate area in the Medicare contractor to receive such notification. PSCs or ACs and Medicare contractor BI units shall send one letter annually (calendar year) to *any* provider *that* submit*s* a voluntary refund *during that calendar year*, advising the provider of the following:

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

The PSCs and ACs shall work out in the JOA whether the PSC or the AC sends the above language. The ACs may send the language above on a voluntary refund acknowledgement letter or on a Remittance Advice if this capability exists.

The PSCs and Medicare contractor BI units shall refer to Chapter 4, §4.4.1G and H for law enforcement requests for voluntary refund information.

4.18.1.2 - Immediate Advisements to the OIG/OI

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

The PSC or Medicare contractor BI unit shall immediately advise *the* OIG/OI *through a telephone communication to the Special Agent in Charge (SAC) or Assistant Special Agent in Charge (ASAC) and maintain internal documentation on these advisements* when it receives allegations with one or more of the following characteristics:

- Indications of PSC, AC, or Medicare contractor employee fraud.
- Cases involving an informant that is an employee or former employee of the suspect physician or supplier.
- Involvement of providers who have prior convictions for defrauding Medicare or who are currently the subject of an OIG fraud investigation.
- Situations involving the subjects of current program investigations.
- Multiple carriers involved with any one provider (OIFO coordinates activities with all involved carriers).
- Cases with, or likely to get, widespread publicity or involving sensitive issues.
- Allegations of kickbacks or bribes.
- Allegations of a crime by a federal employee.

- Indications that organized crime may be involved.

- Indications of fraud by a third-party insurer that is primary to Medicare.

For OIG Hotline complaints with one or more of the above characteristics, the PSC or Medicare contractor BI unit shall promptly telephone the SAC or ASAC and describe the nature of the allegations. This communication ensures that the SAC or ASAC knows about the allegations from the OIG Hotline and gives the PSC or Medicare BI unit an opportunity to request further direction (if such direction has not already been given) from the SAC. In addition, the PSC or Medicare contractor BI unit shall document the telephone conversation through a written communication (e.g., an e-mail or letter) to the SAC or ASAC. This approach ensures that Immediate Advisements are timely and provides an audit trail for the PSC or Medicare contractor BI unit.

The PSCs and Medicare contractor BI units shall not expend resources attempting to investigate the allegation until so directed by CMS and/or the OIG. For example, if a PSC or Medicare contractor BI unit receives an allegation of kickbacks, the PSC or Medicare contractor BI unit shall immediately advise the OIG of the allegation, but shall not initiate an independent PSC or Medicare contractor BI unit query until requested to do so by the OIG and guidance on the parameters of the query are provided by the OIG. *If the query requested by the OIG becomes costly or requires major resources or is outside the scope of the normal law enforcement requests (e.g., requesting the PSCs or Medicare contractor BI units to conduct an interview for the development of a kickback case), the PSCs shall discuss this with the GTL, Associate GTL, and SME before fulfilling the OIG query request; and the Medicare contractor BI units shall discuss this with the RO.*

When an "immediate advisement" is required, all available documentation received with the allegation shall be forwarded *to the OIG*, unless otherwise directed by OIG. However, the initial forwarding of the applicable information does not equate to the PSC or Medicare contractor BI unit completing the full referral package as defined in the PIM (see PIM Exhibit 16.1), and does not equate to a case referral to law enforcement.

Refer to the FID section of the PIM for entering immediate advisements into the FID.

Medicare Program Integrity Manual
Exhibits

Table of Contents
(Rev. 144, 03-31-06)

Exhibit 1 - Definitions

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

A

Abuse

Billing Medicare for services that are not covered or are not correctly coded.

Affiliated Contractor (AC)

A Medicare carrier, fiscal intermediary (FI), or other contractor such as a durable medical equipment regional carrier (DMERC), which shares some or all of the Program Safeguard Contractor's (PSC's) jurisdiction; Affiliated Contractors perform non-PSC Medicare functions such as claims processing.

B-C

Carrier

The Carrier is an entity that has entered into a contract with CMS to process Medicare claims under Part B for non-facility providers (e.g., physicians, suppliers, laboratories). Durable Medical Equipment Regional Carriers (DMERCs) are those carriers that CMS has designated to process DME, prosthetic, orthotic and supply claims.

Case

A case exists when the PSC or Medicare contractor BI unit has referred a fraud allegation to law enforcement, including but not limited to, documented allegations that: a provider, beneficiary, supplier, or other subject has a) engaged in a pattern of improper billing, b) submitted improper claims with actual knowledge of their truth or falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity.

Contractor

Contractor includes all intermediaries, carriers, DMERCs, RHHIs, and PSCs.

Centers for Medicare & Medicaid Services (CMS)

CMS administers the Medicare program. CMS's responsibilities include management of AC and Medicare contractor claims payment, managing PSC, AC, and Medicare contractor fiscal audit and/or overpayment prevention and recovery,

and the development and the monitoring of payment safeguards necessary to detect and respond to payment errors or abusive patterns of service delivery. CMS was formerly known as the Health Care Financing Administration (HCFA).

Closed Case

A FID case shall be closed when no further action will be required of the PSC or Medicare contractor BI unit by the law enforcement agency(ies) working the case and when the law enforcement agency(ies) has ended all its activity on the case*; and when all necessary administrative actions have been finalized (i.e., when the calculated overpayment has been referred to the AC for recoupment). Note that even after the case has been closed, it can still be updated to reflect any additional activity that takes place (i.e., recoupment of the overpayment by the AC).*

D-E

Department of Justice (DOJ)

Attorneys from DOJ and United States Attorney's Offices have criminal and civil authority to prosecute those providers who de-fraud the Medicare program.

Demand Bill or Demand Claim

A demand bill or demand claim is a complete, processable claim that must be submitted promptly to Medicare by the physician, supplier or provider at the timely request of the beneficiary, the beneficiary's representative, or, in the case of a beneficiary dually entitled to Medicare and Medicaid, a state as the beneficiary's subrogee. A demand bill or demand claim is requested usually, but not necessarily, pursuant to notification of the beneficiary (or representative or subrogee) of the fact that the physician, supplier or provider expects Medicare to deny payment of the claim. When the beneficiary (or representative or subrogee) selects an option on an advance beneficiary notice that includes a request that a claim be submitted to Medicare, no further demand is necessary; a demand bill or claim must be submitted.

F

Federal Bureau of Investigation (FBI)

Along with OIG, the FBI investigates potential health care fraud. Under a special memorandum of understanding, the FBI has direct access to contractor data and other records to the same extent as OIG.

Fraud

Fraud is the intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or some other person.

G-H

I

Inpatient hospital claims

An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. For benefit integrity purposes, claims for inpatient hospital services, hospital "swing" bed services, hospital-based ASC services, and procedures on the ASC list performed in the hospital outpatient hospital setting are reviewed by Quality Improvement Organizations, not intermediaries.

Intermediary

The intermediary is a public or private agency or organization that has entered into an agreement with CMS to process Medicare claims under both Part A and Part B for institutional providers (e.g., hospitals, SNFs, HHAs, hospices, CORFs, OPT, occupational therapy, speech pathology providers, and ESRD facilities). regional home health intermediaries (RHHIs) are those FIs that CMS has designated to process Medicare claims received from home health and hospice providers.

J-K-L

Local Medical Review Policy (LMRP)

The LMRPs are those policies used to make coverage and coding decisions in the absence of specific statute, regulations, national coverage policy, national coding policy, or as an adjunct to a national coverage policy.

M

Medicare Contractor (Benefit Integrity)

Medicare contractors include all intermediaries and carriers that have not transitioned their benefit integrity work to a PSC.

Medicare Contractor (Medical Review)

Medicare contractors include intermediaries and carriers that have not transitioned

their MR to a PSC.

Misrepresented

A deliberate false statement made, or caused to be made, that is material to entitlement or payment under the Medicare program.

N

Noncovered (Not Covered)

Noncovered services are those for which there is no benefit category, services that are statutorily excluded (other than §1862 (A)(1)(a)), or services that are not reasonable and necessary under §1862 (A)(1)(a).

O

Office of Audit Services (OAS)

The OAS conducts comprehensive audits to promote economy and efficiency and to prevent and detect fraud, abuse, and waste in operations and programs. OAS may request data for use in auditing aspects of Medicare and other Health and Human Service (HHS) programs and is often involved in assisting OIG/OI in its role in investigations and prosecutions.

Office of Counsel to the Inspector General (OCIG)

The OCIG is responsible for coordinating activities that result in the negotiation and imposition of Civil Monetary Penalties (CMPs), assessments, and other program exclusions. It works with the Office of Investigations (*OI*), Office of Audit Services (OAS), CMS, and other organizations in the development of health care fraud and exclusions cases.

Office of Inspector General (OIG)

The OIG investigates *referrals of* suspected fraud or abuse *in the Medicare program* and performs audits and inspections of CMS programs. In carrying out its responsibilities, OIG may request information or assistance from CMS, its PSCs, Medicare contractors, and QIOs. OIG has access to CMS's files, records, and data as well as those of CMS's contractors. OIG investigates fraud, develops cases, and has the authority to take action against individual health care providers in the form of CMPs and program exclusion, and to refer cases to the DOJ for criminal or civil action. OIG concentrates its efforts in the following areas:

- Conducting investigations of specific providers suspected of fraud, waste, or abuse for purposes of determining whether criminal, civil, or administrative remedies are warranted;

- Conducting audits, special analyses and reviews for purposes of discovering and documenting Medicare and Medicaid policy and procedural weaknesses contributing to fraud, waste, or abuse, and making recommendations for corrections;

- Conducting reviews and special projects to determine the level of effort and performance in health provider fraud and abuse control;

- Participating in a program of external communications to inform the health care community, the Congress, other interested organizations, and the public of OIG's concerns and activities related to health care financing integrity;

- Collecting and analyzing Medicare contractor, AC, Medicare contractor, and State Medicaid agency-produced information on resources and results; and,

- Participating with other government agencies and private health insurers in special programs to share techniques and knowledge on preventing health care provider fraud and abuse.

Office of Investigations (OI)

The Office of Investigations (OI), within OIG, is staffed with professional criminal investigators and is responsible for all HHS criminal investigations, including Medicare fraud. OIG/OI investigates allegations of fraud or abuse whether committed by PSCs, ACs, Medicare contractors, grantees, beneficiaries, or providers of service (e.g., fraud allegations involving physicians and other providers, contract fraud, and cost report fraud claimed by hospitals).

The OIG/OI presents cases to the United States Attorney's Office within the Department of Justice (DOJ) for civil or criminal prosecution. When a practitioner or other person is determined to have failed to comply with its obligations in a substantial number of *claims* or to have grossly and flagrantly violated any obligation in one or more instances, OIG/OI may refer the case to OCIG for consideration of one or both of the following sanctions:

- An exclusion from participation in the Medicare program or any State health care program as defined under §1128(h) of the Social Security Act (the Act);or

- The imposition of a monetary penalty as a condition to continued participation in the Medicare program and State health care programs.

Offset

The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

P

Program Safeguard Contractor (PSC)

The PSC is a contractor dedicated to program integrity that handles such functions as audit, medical review and potential fraud and abuse investigations consolidated into a single contract.

Providers

Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatientphysical therapy, comprehensive outpatient rehabilitation facility, renal dialysis facility, hospice, physician, non-physician practitioner, laboratory, supplier). For purposes of this manual, the term provider is generally used to refer to individuals or organizations that bill carriers, intermediaries, DMERCs, and RHHIs. If references apply to only specific providers (e.g., physicians), the specific provider will be identified.

Q- R

Quality Improvement Organization (QIO)

The Peer Review Improvement Act of 1982 established the Utilization and Quality Control Peer Review Organization (PRO) program. The PRO name has changed to Quality Improvement Organization. CMS contracts with independent physician organizations in each state to administer the QIO program. Their purpose is to ensure that the provisions of the Act are met. Under their contracts with CMS, QIOs are required to review the medical services provided to Medicare beneficiaries in settings such as acute care hospitals, specialty hospitals, or ambulatory surgical centers.

Recoupment

The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Reliable Information

Reliable information includes credible allegations, oral or written, and/or other material facts that would likely cause a non-interested third party to think that there is a reasonable basis for believing that a certain set of facts exists, for example, that claims are or were false or were submitted for non-covered or miscoded services. Reliable information of fraud exists if the following elements are found:

- **The allegation is made by a credible person or source**. The source is knowledgeable and in a position to know. The source experienced or learned of the

alleged act first hand, i.e., saw it, heard it, read it. The source is more credible if the source has nothing to gain by not being truthful. The source is competent; e.g., a beneficiary may not always be a credible source in stating that services received were not medically necessary. An employee of a provider who holds a key management position and who continues to work for the provider is often a highly credible source. The friend of a beneficiary who heard that the provider is defrauding Medicare may not be a particularly credible source;

- **The information is material**. The information supports the allegation that fraud has been committed by making it more plausible, reasonable, and probable (e.g., instructions handwritten by the provider delineating how to falsify claim forms).

- **The act alleged is not likely the result of an accident or honest mistake.** For example, the provider was already educated on the proper way to complete the form, or the provider should know that billing for a service not performed is inappropriate, or claims are submitted the same way over a period of time by different employees.

Reliable evidence includes but is not limited to the following:

- Documented allegations from credible sources that items or services were not furnished or received as billed;

- Billing patterns so aberrant from the norm that they bring into question the correctness of the payments made or about to be made;

- Data analysis that shows the provider's utilization to be well above that of its peers without any apparent legitimate rationale for this;

- Statements by beneficiaries and/or their families attesting to the provider's fraudulent behavior;

- Corroboration from provider employees (official and unofficial whistle blowers);

- Other sources, such as prepayment and postpayment review of medical records; or

- Recommendations for suspension by OIG/OI, FBI, Assistant U.S. Attorneys (AUSAs), or CMS, based on their finding that the provider has already received overpayments and continued payments should be made only after a determination that continued payment is appropriate.

S

Services

Medical care, items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital RPCH or SNF facilities. (42CFR 400.202). In other sections of Medicare manuals

and remittance advice records, the term item/service is used. However, throughout this manual we will use the term service to be inclusive of item/service. See §1861 of Title 18 for a complete description of services by each provider type.

Suspension of Payment

Suspension of payment is defined in the regulation 42CFR 405.370 as "the withholding of payment by the carrier or intermediary from a provider or supplier of an approved Medicare payment amount before a determination of the amount of overpayment exists." In other words, ACs or Medicare contractors have received, processed and approved claims *for payment* for a provider's items or services; however, the provider has not been paid and the amount of the *payment is withheld until such time as the overpayment has been determined and, if appropriate, the payment suspension has been terminated*.

T-U-V-W-X

16.1 - OIG/OI Case Referral Fact Sheet Format

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

Heading	Description of Information to Include
Subject's Name	Provider/Physician/Supplier/Individual/Corporation>
Allegation	Simply stated (kickback/false claims, etc.)
Source of Complaint	Simply stated - (beneficiary/competitor/OIG)
Contractor Investigator - (Contact person)	If the contact person is not the case investigator, include both the contact person and the investigator's names and telephone numbers. Also include the reference number, if applicable (OI case number if assigned by the RO.
Subject's Address	Home; and Office/Business
Corporate/Business Name Used	If other than subject's name
Overpayment *(Indicate if Actual, Estimated, or Projected)*	
History of Contact with OIG	List all contacts with OIG and note any guidance given

Exhibit 37 – *Office Of Inspector General, Office Of Investigations Data Use Agreement*

(Rev.144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

Release of _____ data.

I, _____, representing the Office of the Inspector General, will observe the following in the use of the Centers for Medicare & Medicaid Services (CMS) files released to me.

1. The files will be used only for purposes authorized by the Inspector General Act of 1978 or other applicable law.

2. *No information in the files released to the OIG will be used or disclosed except in strict accordance with all applicable confidentiality laws and regulations. Where practicable and consistent with OIG oversight responsibilities, the OIG will notify CMS of files extracted or derived from these files that are disclosed pursuant to Federal disclosure and confidentiality laws.*

3. *The information sought in this request is required to be produced to the Office of Investigations pursuant to the Inspector General Act of 1978, U.S.C. App. The information is also sought by the Office of the 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 C.F.R. 164.501(a); and 164.512(d).*

4. _____ will be designated as custodian of these files and will be responsible for establishment and maintenance of security arrangements to prevent unauthorized use. If the custodianship is transferred within the organization, CMS will be notified.

5. No listings or information from individual records, with identifiers will be published or otherwise released outside of those deemed appropriate by OIG to perform the legal scope of OIG duties and responsibilities.

6. The OIG needs to retain these files for up to 10 years. CMS will contact the OIG representative at the end of 5 years to confirm either that data will be destroyed or that OIG has a continuing need for the data. CMS will document its tracking system to indicate OIG's need for retention or destruction.

_____

(Representative of OIG--Typed and Signed) (Date)

(Custodian of Files, if different--Typed and Signed) (Date)

(CMS Representative--Typed and Signed) (Date)