### Table of Contents

<table>
<thead>
<tr>
<th>Chapters</th>
<th>Revised Sections</th>
<th>New Sections</th>
<th>Deleted Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Table of Contents</td>
<td></td>
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<tr>
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<td>3.2.5.2</td>
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<tr>
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<td>7.1</td>
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<td>2</td>
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<tr>
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<td>3</td>
<td>Table of Contents</td>
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<tr>
<td>3</td>
<td>8.3.3</td>
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<td>8.3.4</td>
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<td>8.4.1</td>
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<td>3</td>
<td>12.1.1 - 12.5.2</td>
<td></td>
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<tr>
<td>4</td>
<td>Table of Contents</td>
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<td>7</td>
<td>Table of Contents</td>
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<td>11</td>
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<tr>
<td>Exhibits</td>
<td>Table of Contents</td>
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<tr>
<td>Exhibits</td>
<td>Exhibit 1</td>
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<td>Exhibits</td>
<td>Exhibit 28</td>
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**NEW/REVISED MATERIAL--EFFECTIVE DATE:** November 28, 2001  
**IMPLEMENTATION DATE:** November 28, 2001

**Chapter 1, Table of Contents** -- adds, "Memorandum of Understanding (MOU) Regarding Requests from FBI/DOJ" and "Memorandum of Understanding (MOU) Between the Office of Inspector General and the Department of Justice - Sharing Fraud Referrals."
Chapter 1, Section 3.2, Medicare Benefit Integrity (BI) Unit -- adds the definition of proactive.

Chapter 1, Section 3.2.1, Organizational Requirements -- clarifies the contractor's organizational requirements.

Chapter 1, Section 3.2.3, Anti-Fraud Training -- adds the budget performance requirements (BPR) training requirements for the benefit integrity (BI) unit.

Chapter 1, Section 3.2.4, Procedural Requirements -- adds the bullets for a QI program; onsite visits to a provider; a contractor accompanying law enforcement on onsite visits to a provider; and clarifies referral to law enforcement.

Chapter 1, Section 3.2.5, Medicare Fraud Information Specialist (MFIS) -- adds the requirement for submittal of a work plan.

Chapter 1, Section 4, Coordination of MR and Benefit Integrity (BI) Units -- adds the paragraph on Activity Code 23007 requirements.

Chapter 1, Section 7.1, Request for Information from Outside Organizations -- adds the sections on "Memorandum of Understanding (MOU) Regarding Requests from FBI/DOJ."

Chapter 1, Section 7.1.1, Inter-Agency Agreement (IAA) -- adds Inter-Agency Agreement.

Chapter 1, Section 7.1.2, MOU Between the OIG and the DOJ - Sharing Fraud Referrals -- adds MOU between OIG and DOJ - Sharing Fraud Referrals.

Chapter 2, Section 3, Complaints -- is revised to clarify clearinghouse function.

Chapter 2, Section 3.4, Development of Complaints and Cases -- is revised to add cases to the title; add complaint to the prioritization requirement; and change the definition of case.

Chapter 2, Section 4, Fraud Alerts-- clarifies fraud alerts.

Chapter 2, Section 4.1, Types of Fraud Alerts -- clarifies types of fraud alerts.

Chapter 2, Section 4.2, Alert Specifications -- clarifies alert specifications for fraud alerts.

Chapter 2, Section 4.3, Editorial Requirements -- clarifies editorial requirements for fraud alerts.

Chapter 2, Section 4.4, Coordination -- Clarifies coordination of fraud alerts.

Chapter 2, Section 4.5, Distribution of Alerts -- clarifies distribution of fraud alerts.

Chapter 2, Section 6, OIG Referrals and Appropriate FID Entries -- clarifies FID information and the timeframe for entering the case into the FID.

Chapter 3, Table of Contents -- adds sections 8.4.1 and 12.1 - 12.5.2.

Chapter 3, Section 8.3.3, Consent Settlement Instructions -- clarifies Option 2 and Option 3.
Chapter 3, Section 8.3.4, Consent Settlement Budget and Performance Requirements (BPR) -- adds this section on the requirements for tracking consent settlements.

Chapter 3, Section 12.1.1, Basis of Authority -- adds this new section to clarify CMPs.

Chapter 3, Section 12.1.2, Purpose -- adds purpose of CMPs.

Chapter 3, Section 12.1.3, Enforcement -- adds enforcement of CMPs.

Chapter 3, Section 12.1.4, Administrative Actions -- clarifies administrative actions for CMPs.

Chapter 3, Section 12.1.5, Documents -- clarifies documentary evidence for CMPs.

Chapter 3, Section 12.2, CMP Authorities -- clarifies the authorities under which CMPs may be imposed.

Chapter 3, Section 12.2.1, CMPs Delegated to CMS -- clarifies CMPs delegated to CMS.

Chapter 3, Section 12.2.2, CMPs Delegated to OIG -- clarifies CMPs delegated to OIG.

Chapter 3, Section 12.3.1, Referral Process to CMS -- clarifies the CMP referral by contractors to CMS.

Chapter 3, Section 12.3.2, Referrals to OIG -- clarifies CMP referrals to OIG.

Chapter 3, Section 12.4, CMS Generic CMP Case Contents -- clarifies what should be included in the CMP case package.

Chapter 3, Section 12.5.1, Beneficiary Right to Itemized Statement -- clarifies the right to an itemized statement.

Chapter 3, Section 12.5.2, Medicare Limiting Charge Violations -- clarifies limiting charge violations.

Chapter 4, Table of Contents -- adds section 1.1.1.

Chapter 4, Section 1, Discounts, Rebates, and Other Reductions in Price -- clarifies what actions the contractor should take when the contractor learns of questionable discount programs.

Chapter 7, Table of Contents -- adds section 11 on the QI program, and section 12 on vulnerability reports.

Chapter 7, Section 11, Quality Improvement (QI) Program Reporting -- adds this section on QI program reporting.

Chapter 7, Section 12, Vulnerability Report -- adds this section on vulnerability reports.

Exhibits Table of Contents -- adds Exhibits 25, 26, 27, and 28; and deletes Exhibit 2, 2.1.1, and 2.1.2.

Exhibit 1, Definitions -- is revised to add the definition of closed case.
Exhibit 2, Request for Information from Outside Organizations -- deletes this Exhibit and moves the information to Chapter 1, §7.1.

Exhibit 2.1, Memorandum of Understanding Regarding Requests from FBI/DOJ -- deletes this Exhibit and moves the information to Chapter 1, §7.1

Exhibit 2.1.1, Reporting Requirements -- deletes this Exhibit and moves the information to Chapter 1, §7.1

Exhibit 2.1.2, Periodic Exchange of Information Among OIG, FBI, DOJ, Attorneys, and Medicare Contractors -- deletes this Exhibit and moves the information to Chapter 1, §7.1.

Exhibit 25, Form Letter for DOJ Requests -- adds Exhibit 25 to the Exhibits.

Exhibits 26, DOJ Report (Excel Spreadsheet) -- adds Exhibit 26 to the Exhibits.

Exhibits 27, National Medicare Fraud Alert -- adds Exhibit 27 to the Exhibits.

Exhibits 28, Restricted Medicare Fraud Alert -- adds Exhibit 28 to the Exhibits.

MANUALIZATIONS -- EFFECTIVE/IMPLEMENTATION DATE: Not Applicable

Chapter 1, Section 3.2.1, Organizational Requirements -- manualizes Program Memorandum Transmittal No. AB-00-23 on Medicare supplemental insurers.

Chapter 1, Section 7.1, Request for Information from Outside Organizations -- manualizes Program Memorandum Transmittal No. AB-00-54 on the MOU between the OIG and the Department of Justice - Sharing Fraud Referrals.

Chapter 3, Section 8.4.1, Procedures for the Benefit Integrity (BI) and Medical Review (MR) Units on Unsolicited Voluntary Refund Checks -- manualizes Program Memorandum Transmittal No. AB-00-41 on Procedures for Benefit Integrity (BI) and Medical Review (MR) Units on Unsolicited/Voluntary Refund Checks.

Chapter 4, Section 1.1.1, Anti-Kickback Statute Implications -- manualizes Program Memorandum Transmittal No. B-00-69 on Blood Glucose Strips - Marketing to Medicare Beneficiaries.
Medicare Program Integrity Manual

Chapter 1 - Overview of Medical Review (MR) and Benefit Integrity (BI) and Medicare Integrity Program-Provider Education and Training (MIP-PET) Programs

Table of Contents (Rev. 16, 11-28-01)

1 – Introduction
   1.1 – Definitions
   1.2 – Types of Claims for which Contractors are Responsible

2 – The Medicare MR Program
   2.1 - National Coverage Decisions (NCD), Coverage Provisions in Interpretive Manuals, Local Medical Review Policy (LMRP) and Individual Claim Determinations
   2.2 – Least Costly Alternative
   2.3 – LMRP Development Process
       2.3.1 – Identification of Services For Which a New or Revised LMRP is Needed
       2.3.2 – Techniques for Writing LMRPs
           2.3.2.1 – Evidence Supporting LMRPs
           2.3.2.2 – Use of Absolute Words in LMRPs
           2.3.2.3 – LMRP Requirements That Alternative Service Be Tried First
       2.3.3 – Coverage Rules in LMRPs
       2.3.4 – Coding Provisions in LMRPs
       2.3.5 – LMRP Comment Process
       2.3.6 – LMRP Notice Process
       2.3.7 – LMRP Format
       2.3.8 - Retired LMRP
       2.3.9 - AMA Current Procedural Terminology (CPT) Copyright Agreement
   2.4 – Application of LMRP
   2.5 – Utilization Guidelines and Edit Parameters
   2.6 – Manual Review Personnel and Levels of Review
   2.7 – The Carrier Advisory Committee (CAC)
       2.7.1 – The CAC
       2.7.2 – Purpose of the CAC
       2.7.3 – Membership on the CAC
       2.7.4 – Role of CAC Members
       2.7.5 – CAC Structure
       2.7.6 – CAC Process
3 – The Medicare Fraud Program
3.1 – Examples of Medicare Fraud

3.2 – Medicare Benefit Integrity Unit

3.2.1 – Organizational Requirements

3.2.2 – Liability of Benefit Integrity Employees

3.2.3 – Anti-Fraud Training

3.2.3.1 – Training for Law Enforcement Organizations

3.2.4 – Procedural Requirements

3.2.4.1 – Maintain Controlled Filing System and Documentation

3.2.5 – Medicare Fraud Information Specialist (MFIS)

3.2.5.1 – MFIS Position Description

3.2.5.2 – MFIS Budget Performance Requirements (BPR)

3.2.6 – Security Requirements

3.3 – DMERC Fraud Functions

4 – Coordination of Medical Review (MR) and Benefit Integrity (BI) Units

5 – MIP-PET Program

5.1 – MIP-PET Activities

6 – Contractor Medical Director (CMD)

7 – Other Program Integrity (PI) Requirements

7.1 – Request for Information from Outside Organizations

7.1.1 - Inter-Agency Agreement (IAA)

7.1.2 - Memorandum of Understanding (MOU) Between the Office of Inspector General and the Department of Justice - Sharing Fraud Referrals

7.2 – Contractor Coordination With Other Contractors and Peer Review Organizations (PROs)

7.2.1 – Contractor Coordination with Other Entities

7.3 – Beneficiary, Provider, Outreach Activities

7.4 - Maintaining the Confidentiality of MR Records

3.2 - Medicare Benefit Integrity (BI) Unit - (Rev. 16, 11-28-01)

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

- Prevents fraud by identifying program vulnerabilities;
• Proactively identifies incidents of fraud that exist within its service area and takes appropriate action on each case;

• Develops (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;

• Develops cases and refers them to the Office of Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions. (See PIM Chapter 3 §10ff, §11ff and §12ff.);

• Provides outreach to providers and beneficiaries; and

• Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups. (See Chapter 1, §3.2.5.1 and §§ 7.1, 7.2, 7.2.1)

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

Proactive (self-initiated) leads may be generated and/or identified by any internal contractor component, not just the BI unit (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment, etc.). However, the BI unit shall pursue leads through data analysis, the Internet, the Fraud Investigation Database (FID), news media, etc.

The BI unit 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. The BI unit should meet periodically with staff from other internal components 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, etc.) 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 contractor data is proactive.
3.2.1 – Organizational Requirements - (Rev. 16, 11-28-01)

Organizationally, each contractor shall have a component responsible for the detection, development, and initiating corrective action of fraud cases. Staff supervised by a full-time unit manager shall conduct required fraud activities. This group is referred to as the "benefit integrity unit." It may consist of employees who work full-time on Medicare fraud issues or employees who work part-time on Medicare and part-time on benefit integrity or fraud for the contractor's private line of business. If an employee works Medicare and private side cases, the contractor must take special care not to mix Medicare and private side data. Staff from the BI unit must identify themselves to providers as working in the benefit integrity unit when making contact with providers suspected of committing fraud. If workload supports a full-time unit, it must be a separate and distinct unit within the contractor organization and may not be combined with the MR and corporate-side PI units, i.e., it shall handle only Medicare cases. Contractors that are both intermediaries and carriers may combine the intermediary and carrier anti-fraud activities within a single unit. This includes providing electronic data processing and medical consultant support necessary for the unit to complete its mission. Multi-State contractors shall maintain at least one contact at each site. Separate time records shall be maintained on any part-time staff assigned to the BI unit. Large contractors shall, however, establish separate distinct BI units. Regardless of the number of personnel in the BI unit, all necessary action must be taken to ensure the integrity of Medicare payments. This means that an effective Medicare payment safeguard program must be in place.

The unit manager shall have sufficient authority to guide PI activities. The manager shall be able to establish, control, evaluate, and revise fraud detection procedures to ensure their compliance with Medicare requirements.

The unit manager shall prioritize work coming into the unit to ensure that the cases with the greatest program impact are given the highest priority. Allegations or cases having the greatest program impact would include cases involving:

- Multi-State fraud;
- Patient abuse;
- High dollar amounts of potential overpayment;
- Likelihood for an increase in the amount of fraud or enlargement of a pattern; or
- Fraud complaints made by Medicare supplemental insurers. Contractors shall give high priority to fraud complaints made by Medicare supplemental insurers. If the referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews and/or medical record reviews,
contractors shall (a) conduct an immediate data run to determine possible Medicare losses and (b) refer the case to the Office of Inspector General (OIG).

To ensure the integrity of the BI unit referrals to OIG/OI, referrals by the BI unit to OIG/OI are not subject to the approval of contractor management officials.

3.2.3 – Anti-Fraud Training - (Rev. 16, 11-28-01)

All levels of contractor employees shall know the goals and techniques of fraud detection and control in general and as they relate to their own areas of responsibility (i.e., general orientation for new employees and highly technical sessions for BI unit, claims processing, medical review, audit and appeals staff). All BI unit staff shall be adequately qualified for the work of detecting and investigating situations of potential fraud. CMS separates the requirements into two different levels in recognition that new and experienced staff has different needs. BI units shall consult the RO if they want to confirm that specific training sessions will meet CMS’s requirements.

A - Level I - One Time Completion

BI employees shall complete 36 hours of Level I training directly pertinent to fraud detection and investigation that is easily applied to the health care and Medicare environment within the first year of employment in the three categories below. This means that Level I training shall be completed one time only.

- Fraud detection - 16 hours
- Data analysis - 16 hours
- Interviewing techniques - 4 hours

B - Level II - Annual Completion

BI unit employees shall annually complete a total of six hours of advanced training to maintain skills and learn the most advanced techniques in two areas that can be easily applied to the health care and Medicare environment:

- Advanced fraud detection - 4 hours
- Advanced data analysis - 2 hours

C - CMS National Benefit Integrity Training

Each contractor shall send the appropriate representative(s) to CMS’s national benefit integrity training in each year it is provided.
3.2.4 – Procedural Requirements--(Rev. 16, 11-28-01)

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

- Refer potential fraud cases promptly to the BI unit;
- Forward complaints alleging fraud to the BI unit;
- Maintain confidentiality of referrals to the BI unit so that the civil rights of those involved are protected; and
- Forward to the BI unit documentation of the details of telephone or personal contacts involving fraud issues discussed with providers or provider staff, \textit{and retain in individual provider files for a minimum of five years or longer if required by State law.}

In addition, the BI unit \textit{shall} have written procedures for personnel to:

- Keep educational/warning correspondence with providers and other fraud documentation concerning specific issues in individual provider files for \textit{five years or longer if required by State law}, so that contractors are able to retrieve such documentation easily;
- Maintain communication and information flowing between the BI, MR, and as appropriate, intermediary audit staffs and program safeguard contractors (PSC);
- Take appropriate \textit{administrative} action on cases not accepted by OIG. Assure MR staff is immediately notified regarding OIG’s decision. At a minimum, provide for recovery of identified overpayments and other corrective actions discussed in PIM Chapter 3, §§8ff, §§9ff, §§10ff and §11ff;
- Properly prepare and document cases referred to OIG/OI; \textit{(See PIM Exhibits 16.1 and 16.2 for details.) A summary page shall be included with each fraud referral made to the OIG. The referral format listed in Exhibits 16.1 and 16.2 shall be followed, unless written guidance is provided by the applicable OIG/OI office and approved by the applicable CMS RO. Contractors shall maintain files on the written guidance provided by the OIG/OI;}
- Furnish all available information to OIG/OI with respect to providers
requesting reinstatement;

• Ensure no payments are made for services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (see PIM Chapter 3, §11 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. (see PIM Chapter 3, §11.);

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

• Ensure all cases where a provider consistently fails to comply with the provisions of the assignment agreement are reported to the RO;

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

Conduct reviews (including procedures for reviewing questionable billing codes), make beneficiary contacts, (see PIM Chapter 2 §3.4 for details concerning reviews) and referral of cases to and from the MR unit;

• Maintain procedures for a Quality Improvement (QI) program;

• Ensure that the contractor does not go onsite to a provider without obtaining the provider's permission before the arrival of the contractor. If the provider objects to the visit or objects to disclosing the information the contractor wants to review, the contractor shall contact the RO for advice where fraud is suspected. It may be warranted to make an onsite visit to a provider without prior notice; however, unannounced onsite visits shall be conducted with caution. The contractor shall contact the RO and applicable OI field office before making an unannounced visit and receive their approval. Contractor staff shall never engage in covert operations (e.g., undercover or surveillance activities); and

• Obtain written permission (e-mail or letter) from the RO if the contractor is requested to accompany OI or any other law enforcement agency when they are going onsite to a provider for the purpose of gathering evidence in a fraud case (e.g., executing a search warrant). However, should the RO grant permission, law enforcement must make clear the role of contractor personnel in the proposed onsite visit. The potential harm to the case and the safety of contractor personnel shall be thoroughly evaluated. Contractor personnel shall properly identify themselves as CMS contractor employees, and under no
circumstances represent themselves as law enforcement personnel or special agents. Lastly, under no circumstances shall contractor personnel accompany law enforcement in situations where their personal safety is in question.

3.2.5 – Medicare Fraud Information Specialist (MFIS) – (Rev. 16, 11-28-01)

The MFIS position is to be 100 percent dedicated to the MFIS activities described below, unless CO and the applicable RO approves otherwise. The MFISs' primary responsibility is to share information concerning fraud with ROs, contractors in their jurisdiction, other MFISs, law enforcement agencies, State agencies, and other interested organizations (e.g., Ombudsmen, Administration on Aging (AoA), Harkin Grantees and other grantee recipients) for both Part A and Part B of the Medicare program. The MFISs are not fraud investigators. Without RO and CO concurrence, the MFISs are not to perform functions such as complaint resolution, case development, clearinghouse functions, OIG hotline referrals, fraud investigation database (FID) entries, data analysis, incentive reward program (IRP) entries, and onsite audits.

The MFISs are Medicare contractor employees. As such, they report directly to the contractor's BI unit manager or BI unit director equivalent. The MFISs' jurisdiction will correspond to their RO's jurisdiction; it is not to cross over RO boundaries, other than when needed on an exception basis. The ROs in coordination with the CO will promptly determine the contractor that will employ each MFIS whenever an MFIS terminates their employment with the contractor or a contractor leaves the Medicare program. The jurisdictions break down according to the following ROs and the number of MFIS required for each region:

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<th>Regional Office</th>
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<tbody>
<tr>
<td>I Boston</td>
<td>1</td>
</tr>
<tr>
<td>II New York</td>
<td>1 1/2 (1/2 is Puerto Rico)</td>
</tr>
<tr>
<td>III Philadelphia</td>
<td>1</td>
</tr>
<tr>
<td>IV Atlanta</td>
<td>3 (1 solely dedicated to Florida)</td>
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<tr>
<td>IV RHHI</td>
<td>2</td>
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<tr>
<td>V Chicago</td>
<td>2</td>
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<tr>
<td>VI Dallas</td>
<td>1</td>
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<td>VII Kansas City</td>
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<td>X Seattle</td>
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The designated MFISs in each region will be responsible for both Part A and Part B of the Medicare program with the exception of the DMERC and RHHI MFISs.
The DMERC MFIS position will report to Region X, and is responsible for informing other ROs of schemes, cases and/or investigations affecting those regions.

There will be two RHHI MFIS who will report to Region IV, and they are currently located at United Government Services (UGS) in Wisconsin and Palmetto Government Benefits Administrators (PGBA) in South Carolina. The UGS RHHI MFIS will be responsible for the following: Alaska, Arizona, California, Colorado, Delaware, District of Columbia, Hawaii, Idaho, Iowa, Kansas, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Jersey, New York, North Dakota, Oregon, Pennsylvania, Puerto Rico, South Dakota, U.S. Virgin Islands, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The PGBA RHHI MFIS will be responsible for the following: Alabama, American Samoa, Arkansas, Connecticut, Florida, Georgia, Guam, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Mississippi, New Hampshire, New Mexico, North Carolina, Ohio, Oklahoma, Rhode Island, South Carolina, Tennessee, Texas, and Vermont. The RHHI MFIS is also responsible for informing other ROs of schemes, cases, and/or investigations affecting those regions.

All contractors regardless of where the MFIS is located must communicate with their assigned MFIS and utilize his/her services. The major duties and responsibilities listed below should be performed by the MFIS equally for all contractors within their jurisdiction.

For budget purposes, MFISs are required to submit a work plan and the level of activity for all training and outreach functions to their RO 30 days before the beginning of the fiscal year. MFISs are to submit monthly reports to the RO. These reports should quantify activities wherever possible. At a minimum, the reports should include the information listed below:

1. Networking activities such as meetings attended and conference calls with the following information:
   a) Identity of the meetings and the speakers;
   b) Dates of the meeting;
   c) Location of the meetings;
   d) How many meetings were attended;
   e) Number of attendees for each meeting; and
   f) The results of each meeting.

2. Outreach/training activities (e.g., CMS health care partner interaction) with the following information:
   a) Identity of the outreach/training;
   b) Dates of the outreach/training;
   c) Location of the outreach/training;
   d) The number of training/outreach sessions conducted; and
3. Planned events (e.g., calendar of upcoming months).

4. Alerts (CMS, OIG, MFIS) to include those authored by the MFIS in addition to those not authored by the MFIS but distributed by them.

5. Special projects (e.g., significant activities not included in the above).

3.2.5.2 - MFIS Budget Performance Requirements (BPR--(Rev. 16, 11-28-01))

MFISs are to report all costs associated with MFIS activity in Activity Code 23001. This activity code applies only to contractors at which the RO has indicated an MFIS will be located. The BPR states to report the number of fraud conferences/meetings coordinated by the MFIS in workload column 1; the number of fraud conferences/meetings attended by the MFIS in workload column 2; and the number of presentations performed for law enforcement, ombudsmen, Harkin Grantees and other grantees, and other CMS health care partners in workload column 3. To clarify workload column 1 and 2, the conferences and meetings include conference calls coordinated and attended by the MFIS in lieu of coordinating and attending in-person conferences and meetings.

4 – Coordination of MR and Benefit Integrity (BI) Units--(Rev. 16, 11-28-01)

The BI unit’s responsibilities include looking for potential fraud. The MR unit’s responsibilities include looking for potential errors. Contractor BI and medical review staff must work closely together, especially in the areas of:

- Data analysis; and
- Identification of potential errors or potential fraud which should be referred to the other component.

The BI and MR units must have ongoing discussions and close-working relationships regarding situations identified which may be signs of fraud. Intermediaries must also include the cost report audit unit in the ongoing discussions.

A – Referrals from the MR Unit to the Benefit Integrity (BI) 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 MR unit personnel
shall discuss the case with the BI unit. If the BI unit agrees that there is potential fraud, the MR unit shall then refer the case to the BI unit for further development. Cases involving providers who show 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 BI unit.

B – Referrals from the Benefit Integrity (BI) Unit to the MR Unit and Other Units

The BI unit often receives complaints alleging fraud that are determined to be errors rather than fraud. When this occurs, the BI unit shall refer the case to the MR unit.

Contractors are also responsible for preventing and minimizing the opportunity for fraud. The contractors shall identify contractor procedures that may make Medicare vulnerable to potential fraud and take appropriate action. For example, contractors may determine that there are problems in the provider enrollment process that make it possible for individuals excluded from the Medicare program to obtain a provider identification number. The BI unit shall bring these vulnerabilities to the attention of the provider enrollment unit and monitor the situation until action is taken to correct the problem.

There may be situations when the BI unit initiates the referral of potential fraud to the MR unit for a medical determination. For example, the BI unit may request the MR unit review a case along with the applicable claims to determine if the services were performed at the level billed. The MR unit would then return the case to the BI unit with their determination. Therefore, when the MR unit is requested by the BI unit to perform medical review as part of fraud case development, the MR costs shall be charged to the BI line (Activity Code 23007 in the BPR).

7 – Other Program Integrity (PI) Requirements

7.1 – Request for Information from Outside Organizations—(Rev. 16, 11-28-01) {tc "7.1 – Request for Information from Outside Organizations" \ 2}

Federal and State law enforcement agencies may seek information to further their investigation or prosecution of individuals or businesses alleged to have committed fraud. In deciding to share information voluntarily or in response to outside requests, the contractor 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).

The Privacy Act affords protection only to individuals. Therefore, there is a privacy issue only when the information pertains to specific persons, e.g., physicians or beneficiaries.
In all cases, the contractor is free to share with law enforcement the nature of the scams or fraudulent schemes active in the area.

Contractors may share certain information 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. When there is a question concerning whether information may be disclosed, the contractor shall request approval from the Privacy Act Coordinator in the RO.

Some information may be released under a "routine use." Routine uses specify who may be given the information and the basis or reason for access that must exist. Routine uses vary by a system of records and decisions concerning the applicability of a routine use lies solely in the purview of the system's manager for each system of records.

The Privacy Act protects information that is referred to as "records," maintained in what is referred to as "systems 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, his education, financial transactions, medical history, criminal or employment history that contains his name, or the identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voice print or a photograph. A "system of records" means a group of any 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. The Federal Register notice for the systems of records maintained by the agency may be found in the Privacy Act Issuances, 1991 Compilation, Volume 1.

A - Requests from Private, Non-Law Enforcement Agencies

Generally, contractors can furnish information on a scheme where it is operating, and specialties involved. The name of a suspect cannot be disclosed. Contractors shall refer these requests to the RO.

B - Requests from Medicare Contractors, Peer Review Organizations (PROs), State Survey and Certification Agencies, and State Attorney General Offices

Contractors may furnish requested specific information on ongoing fraud investigations to any of these agencies. If the request concerns cases already referred to the OIG/OI, contractors shall refer the requesting agency to the OIG/OI.

C - Requests from Medicaid Fraud Control Unit

Under current Privacy Act requirements applicable to program integrity investigations, contractors may respond to requests for information on current investigations.
D - Requests from OIG/OI and RO for Data and Other Records

Contractors shall provide the RO or OIG/OI with requested information, and maintain cost information related to fulfilling these requests. If major/costly systems enhancements are required to fulfill a request, the contractor 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 contractor's files. Examples include, but are not limited to, copies of claims, beneficiary and provider payment histories, utilization data, provider contact reports, and educational/warning letters.

Contractors shall respond to such requests within 30 calendar days whenever possible. If that timeframe cannot be met, the contractor shall notify the requesting office as soon as possible (but not later than 30 days) after receiving the request. Contractors shall include an estimate of when all requested data will be supplied.

**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. Examples include, but are not limited to, requests to conduct telephone surveys of a sample of beneficiaries, reviews of medical records for medical necessity by the medical review component and/or documentation of services, and educational contacts.

Contractors shall respond to such requests within 45 calendar days, when possible. If that time frame cannot be met, the contractor shall notify the requesting office within the 45 day timeframe, and include an estimate of when all requested data will be supplied.

E - Procedures for Sharing CMS Data with the Department of Justice (DOJ)

In April 1994, CMS entered into an interagency agreement with DHHS, Office of Inspector General (OIG), and DOJ that permitted CMS contractors to furnish information related to the investigation of health care fraud matters directly to DOJ that previously had to be routed through OIG. In light of the increasing number of requests for data and information attributable to a rise in law enforcement, CMS recently renegotiated the agreement with DOJ.

The new agreement takes the form of a short form letter (see Exhibit 25) which 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.
Data requests for the investigation of health care fraud matters will come directly from an FBI agent or an Assistant United States Attorney, and will identify the file name or type of data needed, the desired media format for receipt of the data, and full contact information to which to send the data. If necessary, the contractor may contact the requestor to clarify issues or resolve problems with the data request. This format of data request also applies to subcontractors, though CMS will try to ensure that requests intended for subcontractors are routed to the contractor.

CMS has established a cost limit for any individual data request of $200,000. 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's 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 contractors may not have sufficient money in their budgets to respond to DOJ requests, in which case contractors are advised to submit to CMS a Supplemental Budget Request (SBR).

To facilitate CMS's ability to track the frequency and burden of DOJ requests, CMS is requesting that the contractor 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 Exhibit 26) and should include, at a minimum, the following fields:

1. 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; and
5. Contractors' capacity to fill request, including date of SBR submission, if necessary.

The report should be submitted to CMS concurrent with the quarterly payment suspension tracking report, and should similarly be sent to the attention of the Program Integrity Group, Division of Benefit Integrity and Law Enforcement Liaison.

7.1.1 - Inter-Agency Agreement (IAA)- (Rev. 16, 11-28-01)

An inter-agency agreement exists between CMS, OIG and the FBI. The content of that agreement does not change nor conflict with how contractors refer cases. The contractor continues to refer all cases to the OIG. The OIG will refer cases to the FBI, as it deems appropriate. Contractors do not refer cases to the FBI or other law enforcement agencies, including the Medicaid Fraud Control Units (MFCU), without the prior approval of the OIG/OI.

A - Applicability Interagency Agreement (IAA) to Other Federal Agencies
The IAA applies only to the DOJ, including U.S. Attorneys, and the FBI. Requests from other agencies, such as Postal Inspection Service or Drug Enforcement Administration, should continue to be referred to the appropriate OIG/OI.

B - Focal Point for Processing Requests

The Medicare Benefit Integrity unit manager is the focal point for processing information requests received from law enforcement agencies. The BI unit Manager shall:

- Serve as the contact person for all information requests;
- Provide timely written acknowledgement of receipt of all information requests;
- Coordinate the efforts of all components within operations involved in compiling the requested information;
- Respond timely to all information requests by providing the requested information, or contact the requesting agency in writing and explaining the reasons why compliance cannot be made; and
- Request the intervention of the Regional Office (RO) when the contractor and the requesting official cannot reach an accommodation.

C - Duplicate Requests for Information

The DOJ and the OIG will exchange information on cases they are working on to prevent duplicate investigations. If the contractor receives duplicate requests for information, the contractor should notify the requestors. If the requestors are not willing to change their requests, the contractor should ask the RO for assistance.

D - Data Covered by the IAA

Contractors should comply with reasonable written requests from the FBI and DOJ, including Assistant U.S. Attorneys (AUSAs), for data and records related to a specific investigation of an individual or group of individuals, or entity or group of entities. In addition, while "fishing expeditions" are not permitted, requests for information on a reasonable number of providers whose identity is unknown may be appropriate when these requests target particular practices that DOJ/FBI believe may be fraudulent. If a DOJ attorney or FBI agent wishes to make such a request, the attorney or agent should first discuss it with contractor personnel to ascertain whether the contractor has information corroborating or negating the DOJ/FBI information. They also should determine whether the request presents an unreasonable burden on the contractor, or to determine whether the request can be met in a different manner.

Acceptable data requests include, but are not limited to:

- Information contained on claim forms and other records maintained on individual providers or suppliers;
• Billing procedure updates and other Medicare publications furnished to providers or suppliers;
• Contractor correspondence to and from providers/suppliers;
• Billing history of beneficiaries;
• Analysis performed by BI units; and
• Data analysis routinely done by Medicare contractors such as utilization reviews.

E - Requests Believed to be Excessive, or Otherwise Burdensome or Expensive

Requests may be received that are believed to be unreasonable because the data being requested:

• Is a "fishing expedition";
• Would be very expensive to generate;
• Appear to be beyond the scope of authority or jurisdiction; or
• Cannot be furnished in the time requested.

Contractors shall evaluate the ability to respond to the requests before deciding to commit the required resources. While the IAA assumes that law enforcement agencies and CMS contractors will cooperate with one another, it does not commit CMS to fund all requests.

Contractors shall try to resolve issues with the agent or attorney making the request if the contractor believes it cannot comply with a request. The contractor shall explain to the requestor why the request cannot be fulfilled. In many cases, the contractor and the requestor may be able to restructure the request to meet the requestor's needs.

If the contractor is unable to reach agreement, it shall refer the matter to the appropriate RO for Medicare. The RO reviews the request, obtains additional information as necessary, and makes a final decision on the request. The RO will promptly notify the contractor and the requestor of the decision. While most requests for data will be permitted under the Privacy Act, contractors may raise any concerns regarding filling requests with the RO.

Contractors shall consult with the RO if there is receipt of an otherwise reasonable request that would be very costly to fulfill or would affect its ability to perform other Medicare requirements. CMS will fund reasonable requests to the extent funds are available. If funds are not available, such requests may be denied. Contractors shall notify the RO, and obtain their approval before denying a request because of funding.

F - Privacy Act Responsibilities

The MOU is consistent with the Privacy Act. Therefore, requests that conform to the MOU 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.

First, 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 which 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 which 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 mentioned routine use, 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. Contractors shall refer requests that raise Privacy Act concerns and/or issues to the RO for further consideration.

**G - Reporting Requirements**

For each request received, including those from OIG, contractors 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 had to intervene and the outcome (request fulfilled or not fulfilled); and
- The cost of furnishing a response to each request.

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

**7.1.2 - Memorandum of Understanding (MOU) Between the Office of Inspector General and the Department of Justice - Sharing Fraud Referrals--(Rev. 16, 11-28-01)**

Under the MOU between the Office of Inspector General's Office of Investigations (OI) and the Department of Justice’s Federal Bureau of Investigation (FBI), October 18, 1999, the OI will provide a copy of the contractor fraud referral and all related information within five working days to the FBI Headquarters. The referral information received from the Medicare contractor includes all the relevant information to the potential fraud case. The OI will copy the contractor fraud referral to the FBI and will notify the FBI of any action they will take on the referral. The OI field offices will no longer forward health care fraud referrals directly to the local FBI field office. The OI will notify Medicare contractors of its decision on the contractor fraud referral, with specific instructions on all matters related to the referral, within 90 calendar days.

Upon receipt of fraud referrals, the OI regional field offices are required to perform one or more of the following:

- Open an investigation;
- Return the matter to the contractor for further development;
- Forward the referral to the local FBI office or other law enforcement agency for investigation; or
- Close the case with no action necessary and refer the case back to the contractor for
The contractor shall follow PIM instructions in Chapter 3, Section 10.1 of the PIM to follow-up with the OI to determine their decision after the 90 calendar day period. The contractor is encouraged to have dialogue with law enforcement during case development, and to discuss fraud referrals at periodic meetings. If the OI does not give the contractor a definite answer after the 90-day period, the contractor shall contact the RO to help obtain the needed information. The FBI will notify the contractor of their action on the contractor fraud referral within 45 calendar days from the day the FBI receives referral from the OI. However, if the contractor has not received feedback at the end of the 45 calendar day period, the contractor may contact the applicable local FBI field office for a status. The contractor shall not contact the FBI Headquarters for a status of the fraud referral. In the case of multiple providers or servicing contractors, the FBI will notify the Medicare contractor that initiated the referral as to the decision.

Chapter 2

3 - Complaints - (Rev. 16, 11-28-01)

Complaints may be presented to contractors by telephone, in writing, or in person. As recipients of Medicare covered services, beneficiaries are in a unique position to assist in detecting program fraud. Likewise, employees of providers are often good sources. Regardless of the complainant, it is essential that the contractor be perceived as being genuinely interested in learning of abusive and fraudulent practices and shall act promptly on such referrals. Telephone representatives shall be instructed not to advise beneficiaries to "work it out" with, or to re-contact, the provider. Also, telephone representatives shall not require that the complaint be put in writing. Contractors shall review complaints against specific criteria developed and documented jointly by the BI and MR units to determine whether a complaint alleges abuse and should be referred to the MR unit, or whether it alleges fraud and should be referred to the BI unit. If complaints reviewed by the BI unit turn out to be abuse, the BI unit shall complete development of the case and refer it to the MR unit for further action. The BI unit frequently refers complaints to the MR, correspondence unit, or other component/department/agency if the complaint may not be one of fraud. The BI unit shall retain a copy of the development for the files and shall follow up with the MR unit or other internal contractor department to ascertain and document any actual dollars saved as a result of referrals.

The BI unit should only receive and develop complaints that are likely to indicate fraud situations. The clearinghouse function (i.e., screening of incoming inquiries: written, telephone, or walk-in) shall not be performed by the BI unit, but costs may be allocated to
BI if they are fraud related. The BI unit shall return to the appropriate contractor unit (e.g., customer service unit) any complaints that are not fraud situations.

To the greatest extent possible, the BI unit should be able to confirm that complaints of fraud are being properly routed to the BI unit.

3.4 - Development of Complaints and Cases - (Rev. 16, 11-28-01)

When contractors receive an allegation of fraud, or identify a potentially fraudulent situation, they initiated action to determine the facts and the magnitude of the alleged fraud. They conduct a variety of reviews to determine the appropriateness of payments even when there is no evidence of fraud. Prioritization of the complaint and case workload is critical to ensure that the resources available are devoted primarily to high priority complaints and cases. (See PIM Chapter 1, §3.2.1.) (Consider complaints by current or former employees for early contact with OIG/OI. OIG/OI may request that contractors perform only limited internal development and then immediately refer the case to them.)

Development is establishing the factual basis for (i.e., substantiating) an allegation. A case exists when the contractor has substantiated an allegation that a provider, beneficiary, supplier, or other subject: (a) engaged in 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. While substantiation does not imply the proving of the information in a court of law, the definition of "contractor substantiation" does include any and all cases (regardless of dollar threshold or subject matter) where contractor staff verify to their own satisfaction that an allegation is likely to be true and a referral to law enforcement is required.

4 – Fraud Alerts--(Rev. 16, 11-28-01)

Fraud Alerts are issued when there is a need to advise the carriers, intermediaries, law enforcement, PROs, and beneficiary communities about an activity that resulted in the filing of inappropriate and potentially false Medicare claims.

The Alert describes the particular billing, merchandising practice or activity in enough detail to enable the contractor to determine whether the practice exists in their jurisdiction.

When one of these Alerts is received, the contractor shall determine whether the scheme exists within their jurisdiction. If it does, contractors shall take appropriate action to protect the Medicare trust funds. Action may include denials, suspensions, overpayment recovery, and/or development of the case for referral to OIG. In each case, whichever
action the contractor takes must be based on findings developed independently of the Alert. Once the Alert has been investigated, report the results of the investigation to the RO (i.e., whether the scheme exists in the contractor's jurisdiction) and necessary steps that were taken to safeguard the Medicare trust funds.

4.1 – Types of Fraud Alerts—(Rev. 16, 11-28-01)

There are two types of Fraud Alerts, National (nonrestricted) Medicare Fraud Alerts (NMFAs) and Restricted Medicare Fraud Alerts (RMFAs). These Alerts are produced and distributed to those listed on the audience line on the appropriate CMS letterhead. NMFAs are reproduced on blue border letterhead and RMFAs are reproduced on red border letterhead.

A – National Medicare Fraud Alerts (NMFA)

The most commonly issued Alert is the NMFA (refer to Exhibit 27 for the NMFA template). These Alerts do not identify specific providers or other entities suspected of committing fraud. They focus on a particular scheme or scam and are intended to serve as a fraud detection lead.

CMS CO issues a NMFA when the fraudulent or abusive activity is perceived to be, or has the potential for being, widespread, i.e., crossing contractor jurisdictions. These Alerts are numbered sequentially. Because CMS and OIG use a comparable numbering system, CMS Alerts are identified either as CMS NMFA, for nonrestricted Alerts, or for restricted Alerts, CMS RMFA, followed by the Alert number appearing in the bottom left hand corner. OIG Alerts are identified by OIG, followed by the Alert number appearing in parentheses at the bottom left hand corner. The National Medicare Fraud Alert is to be put on blue border paper. The MFISs distribute both OIG and CMS Alerts to all agencies in their jurisdiction within 15 working days of receipt by the contractor.

When sending a draft National Medicare Fraud Alert to CO, they should be mailed to:

Centers for Medicare & Medicaid Services
OFM/PIG/DBIL
Mail Stop C3-02-16
7500 Security Blvd.
Baltimore, MD 21244
Attention: Fraud Alert Lead

A NMFA contains the following two disclaimers, in bold print:

"Distribution of this Fraud Alert is Limited to the Following Audience:
CMS Regional Offices, All Medicare Carrier and Intermediary Benefit Integrity Units, Program Safeguard Contractors, Medicare Integrity Program (MIP) Units, Peer Review Organizations, Medicaid Fraud Control Units, the Office of Inspector General,"
the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney Offices, U.S. Postal Inspectors, Internal Revenue Service, State Surveyors, State Attorneys General, and the State Insurance Division.

It is not intended to be used as a basis for the denial of any claim or adverse action against any provider. Such decisions must be based on facts independent of this Alert."

"This Alert is provided for educational and informational purposes only. It is intended to assist interested parties in obtaining additional information concerning potential fraud and to alert affected parties to the nature of the suspected fraud. It is not intended to be used as a basis for denial of claims or any adverse action against any provider or supplier. Such decisions must be made based on facts developed independent of this Alert."

B – Restricted Medicare Fraud Alerts (RMFA)

CMS issues a Restricted Fraud Alert when specific providers are identified as being suspected of engaging in fraudulent or abusive practices or activities. Contractors prepare this type of Alert (refer to Exhibit 28 for the RMFA template) when advising other Medicare carriers, intermediaries, PROs, MFCUs, OIG, FBI, or DOJ of a particular provider or providers, suspected of fraud. Distribution is limited to Medicare contractors, CMS, PROs, OIG/OI, FBI, MFCUs, U.S. Postal Service, IRS, and the Offices of the U.S. Attorney. CMS CO will issue each MFIS one copy of a RMFA. Each MFIS will distribute said Alert to the contractor in their MFIS jurisdiction for reproduction on the red border letter provided to it. Contractors may issue local Restricted Alerts as they deem appropriate, subject to above distribution limits.

When sending a draft Restricted Fraud Alert to CO, they should be mailed to:

Centers for Medicare & Medicaid Services
OFM/PIG/DBIL
Mail Stop C3-02-16
7500 Security Blvd.
Baltimore, MD 21244
Attention: Fraud Alert Lead

The envelope should be marked, "personal and confidential", "do not open in mailroom". The content of this Alert is not disclosable to the public even under the Freedom of Information Act. Public disclosure of information protected by the Privacy Act has serious legal consequences for the disclosing individual. It is intended solely for the use of those parties appearing on the audience line. It contains the names and other identifying information of providers or suppliers who are suspected of fraud.

A Restricted Fraud Alert must contain the following disclaimer exactly as below:
C – Alerts to CO

Contractors prepare one of these Alerts when:

- Contractors need to notify CMS of a scheme that is about to be publicized on the national media;
- The case involves patient abuse or large dollar amount (approximately $1 million or more or potential for widespread abuse); or
- The issues involved are politically sensitive, e.g., congressional hearings are planned to accept testimony on a fraudulent or abusive practice.

The Alert is prepared and submitted in the same manner as a NMFA but the audience line reads, CO Only.

4.2 – Alert Specifications--(Rev. 16, 11-28-01)

Alerts drafted by the benefit integrity unit must meet the following criteria:

- The Alert is to be entitled, "National Medicare Fraud Alert," "Restricted Medicare Fraud Alert," or "CMS CO Alert";
- It includes an audience line that indicates the audience that needs to be made
It has a subject line that briefly describes the issue or subject of the Alert, including the provider’s UPIN, Tax ID, and FID case number (if applicable);

It includes the source of information which defines the alleged improper/suspect behavior (e.g., PIM, MCM, MIM section, NCD, LMRP, etc.);

The body of the Alert describes the matter in enough detail to enable readers to determine their susceptibility to the activity and what they need to do to protect themselves. It includes diagnosis, Current Procedural Terminology (CPT), and HCPCS codes, the dollar amount involved, the States affected, and applicable policy references, as appropriate;

It includes a discovery line that indicates how the contractor who initiated the Alert discovered the problem. (*See note below.) This should be a clear, detailed explanation that will enable others to determine what to look for in their systems. If a previous Fraud Alert was issued addressing a similar situation, include the Fraud Alert reference;

It includes a detection methodology detailing the steps or approaches other contractors would use to determine whether this practice is occurring in their jurisdiction (*see note below.), including the reports run, the edits used, and the timeframes followed;

It includes a status that details the current position of the case (e.g., with OIG, FBI, overpayment identified and amount, etc.);

It includes the name and telephone number of a person or organization to be contacted in the event of a complaint or question; and

It contains the appropriate disclaimer depending on the type of Alert. CO Alerts do not need a disclaimer.

*NOTE: DO NOT INCLUDE THE “DISCOVERY” AND “DETECTION METHODOLOGY” SECTIONS WHEN DISTRIBUTING AN ALERT TO A PROVIDER PROFESSIONAL ORGANIZATION OR OTHER OUTSIDE GROUP. THESE SECTIONS ARE DISCLOSABLE ONLY TO ROs, CONTRACTORS AND FEDERAL LAW ENFORCEMENT AGENCIES. RESTRICTED ALERTS SHOULD NOT BE DISTRIBUTED BEYOND THE APPROVED DISTRIBUTION LIST.

4.3 – Editorial Requirements—(Rev. 16, 11-28-01)
Contractors should adhere to the following requirements when drafting a Fraud Alert:

- Avoid an emotional writing style such as frequent exclamation points, underlining, and bold type. State the issue in as matter-of-fact way as possible;

- Avoid generalizing the problem to groups, specialties, or types of providers. Focus on the billing practice or issue;

- Do not state that performance of the activity is fraud even though the practice violates Medicare requirements. Couch the message in terms of "alleged," "suspected," "potential," "possible," "may be fraud";

- When stating applicable penalties, use "may" (e.g., "... may result in exclusion from the Medicare and Medicaid programs"). Do not state that certain penalties will be applied; and

- Avoid programmatic jargon or unnecessary terms of art. Use plain English, whenever possible, while remaining technically accurate. If technical terms are necessary, explain them.

Be certain the Alert is technically accurate. Have it reviewed by the MFIS serving your contractor jurisdiction and at least one other MFIS prior to submitting proposed Alerts to CMS CO for publication. Consult with RO and OIG, as necessary. Do not sacrifice technical accuracy in the interest of a speedy issuance or writing in plain English.

Issue portions of Alerts in Spanish or other appropriate foreign language if there is a non-English speaking population (see above) that is potentially affected by the scheme, and there are plans to distribute the Alert to such groups.

4.4 – Coordination--(Rev. 16, 11-28-01)

Before preparing an Alert, consult with the applicable CMS RO and/or MFIS and BI unit manager. The MFIS knows whether or not a similar Alert has been issued by contacting MFISs in contiguous jurisdictions. If so, use that Alert and add the name and address of your organization to the contact section. If there is no such Alert, forward the Alert in draft to the applicable MFIS. The MFIS forwards the draft to CMS Program Integrity Group for review and clearance. Following its review, PI acknowledges the Alert and notifies the contractor whether:

- A National Alert will be issued;

- A Restricted Alert will be issued; or

- The Alert should be issued as a local MFIS Alert.
CMS CO keeps the MFIS informed of the progress of the Alert throughout the clearance process.

4.5 – Distribution of Alerts--(Rev. 16, 11-28-01)

CMS issues the Alert to the MFISs for further distribution. Approved Alerts are sent to the MFIS through the electronic mail system. Upon receipt of an approved Alert, the MFIS will add their name and telephone number to the existing contact information on the Alert. They will then reproduce the Alert on their own stationary. MFISs are to distribute the Alert to the entities that appear on the audience line.

6 - OIG Referrals and Appropriate FID Entries--(Rev. 16, 11-28-01)

The FID is a comprehensive nationwide on-line mainframe board system directed to fraud and abuse data accumulation.

The following agencies/organizations currently have access to the FID:

- Medicare Intermediaries and Carriers, including RHHIs and DMERCs;
- CMS;
- FBI;
- DOJ;
- Office of United States Attorney Generals;
- HHS OIG;
- Department of Labor OIG;
- Defense Contractor Investigation Service;
- Postal Inspection Service;
- Tennessee Valley Authority Inspector General;
- Medicare Program Safeguard Contractors;
- Medicaid Fraud Control Units; and
• Other Federal and State partners seeking to address program integrity concerns in judicial or State health care programs.

**FID Background**

The FID captures information on cases that are under development by the Medicare contractor and/or have been referred to law enforcement for further investigation. A case exists when the contractor has substantiated an allegation that a provider, beneficiary, supplier, or other subject: (a) engaged in improper billing, (b) submitted improper claims with actual knowledge of their falsity; or (c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. While substantiation does not imply the proving of the information in a court of law, the definition of “contractor substantiation” does include any and all cases (regardless of dollar threshold or subject matter) where contractor staff verify to their own satisfaction that an allegation is likely to be true and a referral to law enforcement is required. Situations where numerous complaints are made, allegations forwarded by provider employees or ex-employees, and/or proactive data analysis producing clear evidence of wrongdoing are common examples of such situations.

**FID Operational Issues**

Individual complaints (statements alleging improper entitlement), simple overpayment recoveries (not including fraud), and medical review abuses are not commonly considered “cases” for purposes of FID entry and are more appropriately documented in complaint control systems.

Finally, the term “substantiated” does not imply the proving of the information in a court of law. Contractors do not prove fraud; such action is within the purview of the Department of Justice.

Immediate advisements are excepted from the requirement of substantiation for purposes of advising the OIG, and are not counted as referrals to the OIG until the issue is documented in the FID and formally referred.

The FID also reports other pertinent information. Some examples of the types of data included in the FID are:

• Subject of an investigation (i.e., physician, hospital, SNF, HHA, Comprehensive Outpatient Rehabilitation Facility (CORF), etc.);

• Allegation information/nature of the scheme;

• Status of the case;

• Disposition of a case (i.e., administrative action, prosecution, exclusion, settlement, etc.); and
• Contact information for contractor and/or law enforcement.

The FID also has monitoring/reporting capabilities, such as:

• The number of cases by subject, subject subtype, region, contractor, HCPCS, etc.;

• Length of time to close out a case;

• Number of cases referred to OIG/FBI;

• Number of cases accepted by OIG/FBI; and

• Dollar amount recovered through settlement, suspensions, and recoveries other than case settlements.

Initial Entry and Update Requirements

Once the contractor has substantiated that a case exists, it shall be entered into the FID within 30 days. After initial entry, cases shall be updated every 30 days while under development at the contractor, and every 90 days once the case has been referred to law enforcement.

Open or pending fraud cases with the OIG as of 1/1/93, which involve contractor-substantiated allegations of fraud, should be entered into the FID and referred to law enforcement within 30 days of identification. It is the contractors’ responsibility to follow up with the OIG and CMS RO on cases to assure that the referrals are not held for an extended time without action. If the OIG does not respond to the contractor within the 90-day time frame, the contractor should follow-up with OIG/OI to determine if they are going to accept the case. If the 90 days have been exceeded with no decision from the OIG, then the contractor should attempt one more contact with the OIG to render a decision.

If within a specified and reasonable time period (e.g., mutually agreed upon number of days) the OIG does not accept the case or is still unwilling to render a decision on the case, contractors should proceed with administrative action necessary to ensure the integrity of the Medicare Trust Funds. In all cases, contractors should institute all appropriate remedies available to them (e.g., overpayment recoupment, suspension, prepay review) and inform their respective regional office of their decision to proceed with administrative actions. Contractors should always develop and initiate appropriate administrative action prior to the elapsing of the 90 days and inform OIG of this proposed action prior to implementing the remedy.

Referrals accepted by OIG or FBI, are assigned an OIG/FBI case number. It is the responsibility of the contractor to obtain and enter the case number into the FID.
The contractor should revise information in the FID action field after the case is referred to the OIG/FBI. Any actions taken by law enforcement, (e.g., indictments, searches and seizures, warrants) as well as contractor corrective/administrative actions should all be entered into the FID. If the contractor is not able to obtain status on cases referred to law enforcement, this should be brought to the attention of the CMS RO and/or CMS CO.

To restate, Medicare benefit integrity unit managers need to ensure that their referrals are handled according to OIG procedures (i.e., the referral is reviewed, accepted or rejected, or referred to another law enforcement agency within 90 calendar days of the referral). It is the contractors' responsibility to follow up on cases to assure that the referrals are not held for an extended period without action.

The narrative section on the FID should clearly identify any case development being done by the contractor. Also, the sooner a comprehensive case is entered into FID, the more efficiently other contractors, CMS, and law enforcement agencies can react to the investigation and perform related trend data analysis.

The contractor should enter cases that are initiated and referred by law enforcement into the FID within 30 days of law enforcement approval. Absent their objections, and with their input, the case should go in the FID. However, it must be clear in the entry that the "case" came from law enforcement, not the contractor, and should not be counted as a contractor referral. Contractors should enter as much information as possible, and in their possession. This instruction is given with the understanding that the case did not result from contractor action and the realization that the contractor may not have information for some/many data fields. Should you become aware of any sensitive law enforcement information (e.g., on-going video surveillance, a planned raid by law enforcement, outstanding arrest warrants, etc.), this should not be entered in the FID, unless, after the fact and approved by the applicable OIG/FBI case agent. Also, do not enter the names of agents in the case description field. This information belongs in the "contact" portion of the case screens.

In addition to contacting OIG regarding the status of a case, there is a need for the contractor to actively keep track of his or her referral(s). This means that FID entries should address:

- Contacting the FBI or Assistant United States Attorney (AUSA) regarding their actions on case;
- Updating the action screen to capture subsequent law enforcement referrals (e.g., OIG declines case, contractor refers case to FBI, FBI accepts case);
- Keeping apprised of MR/Provider Audit and Reimbursement actions if they are taking actions on a case;
- Updating the amount being withheld, denied, or paid;
• Entering information on convictions /sentences in the action screen; and

• Revising the narrative screens to incorporate any updated information from the action screens.

If problems are encountered which undermine these activities, they should be discussed with BI staff from the CMS RO. The contractor should document all major actions taken in the Action-Disposition screen (e.g., overpayment calculated, payment suspension imposed, prepay initiated/removed, etc.). In addition, it is extremely important to document in the FID any consultations with law enforcement as well as administrative actions and associated monetary assessments by the contractor. Contractors are responsible for providing such documentation.

It is not appropriate for an OIG or FBI Agent, or an AUSA to request that a contractor not enter a contractor developed case, or update the FID on a related contractor developed case. Contractors should inform law enforcement agents making such requests that you are required by CMS to maintain the FID and that you do not have the discretion to do otherwise. Further, advise them to contact the CMS RO or their headquarters if the matter persists.

Cases not referred must be updated every 30 days and every 90 days once it has been referred.

Cases can be deleted from the FID only by users with the "File Manager" (system administrator) designation. As applicable and necessary, CMS CO and RO staff will contact and discuss with the contractor the need to correct and/or delete a case from the database. In the event that a contractor decides that a case should be deleted from the FID, this information should be forwarded to the CMS RO, CMS CO FID contacts, or BI Coordinator for approval.

**Duplicate FID Cases**

A duplicate case exists when any given contractor enters a provider, supplier, or beneficiary as the subject of an investigation more than once, absent different allegations or other differentiating criteria requiring a separate referral.

*It is not considered a duplicate case if multiple contractors enter cases for the same provider as the subject of an investigation. These cases, however, must reflect a coordinated effort by all contractors involved and investigating the provider. Case numbers must be referenced and the case description summaries must reflect this coordination. The FID now has the capability of cross-checking for related cases.*

*If a case is being developed on a provider that was already the subject of a closed case, a new case should be opened. The closed case, however, should be mentioned in the case narrative screen and cross-referenced to the old FID case number.*
The case target, whether entity or individual, should be entered as the subject of the FID case. Any and all related providers, suppliers, or beneficiaries, who are a subject of the case, should then be identified under AKAs, DBAs, and Affiliates. However, if the individuals are the primary subjects/targets of the investigation and independent cases are made against them, then individual cases should be established in the FID with corresponding individual referrals to OIG.

It is the contractor Benefit Integrity Unit’s responsibility to check for potential duplicate entries of FID cases.

**Documenting an Overpayment in the FID**

Under the redesigned FID, we expect a separate data field for "Estimated Overpayment." Redesigned action screens also record "Overpayment Assessed" and "Overpayment Recouped." However, until such time as the redesigned FID is released, the contractor should enter the best estimate of the overpayment figure. As the substantiated allegation progresses, the contractor will replace the estimated loss with the actual loss. If the overpayment is recovered before the case is closed, the amount recovered should be entered in the applicable field, and in addition, should be captured as a FID "action". If the recovery occurs after the case is closed, the contractor must still update the FID with the recovered amount, updating both the "estimated overpayment" and "action" fields. **These fields may continue to be updated even though the case is "closed." A case is closed when no further action is required by the contractor and law enforcement.**

**Administrative Action**

In addition to the referral of cases to the OIG, contractors should identify and take corrective action to prevent future improper payment (for example, by denying false claims, placing the provider or suppliers’ claims on pre-payment review, post-pay review, payment suspension, or CMPs). The contractor should take all appropriate action in order to prevent any further payment of inappropriate claims and to recover any overpayments that may have already been made, regardless of whether the OIG/FBI accepts or declines the case referral. **Contractor action may vary** from case to case. In one instance, it may be appropriate to suspend payment pending further development of the case and calculation of an overpayment. In another instance, suspending payment may alert the provider to detection of the fraudulent activity and undermine a covert operation already underway, or actively being planned, by Federal law enforcement.

To be certain that the contractor intervention matches the alleged situation, it is important to consult with the CMS RO, and as applicable (e.g., when law enforcement has an open investigation), the OIG, FBI, and both the civil and criminal divisions in the U.S. Attorney’s office, before implementing payment suspensions, overpayment recoveries, etc. Where there is reliable evidence of fraud and a law enforcement referral pending, or already made, the contractor must advise the CMS RO and the agency that has the lead for the investigation prior to initiating the administrative action.
All cases where the allegations of fraud have been substantiated should be referred to the OIG. The OIG has 90 calendar days to accept the referral, refer the case to the Department of Justice (e.g., FBI, AUSA, etc.), return the case for additional development, or decline the case. Acceptance or rejection of the referral, like all other significant contacts with the OIG, should be documented in the FID. The OIG has 90 calendar days to accept the referral, refer the case to the Department of Justice (e.g., FBI, AUSA, etc.), or reject the case.

Immediate Advisement to the OIG

The contractor must immediately "advise" OIG when allegations concerning one or more of the characteristics listed below are received:

- Indications of contractor employee fraud (e.g., altering claims data or manipulating it to create a payment preferential treatment to certain providers; improper preferential treatment in collection of overpayments; embezzlement);

- Current provider employee who personally calls or visits the contractor and has information or evidence fraud is currently ongoing. Notification to law enforcement should be at the time of the occurrence whenever possible;

- Allegations of kickbacks, bribes; and

- A crime by a Federal employee.

When an immediate "advisement" is required, all available information must be forwarded, unless otherwise directed by OIG. However, the initial forwarding of the applicable information does not equate to the contractor completing the full referral "package" as defined in the PIM (EXHIBIT 16.1), and does not equate to a case referral to law enforcement. Do not enter the information into the FID, unless directed to do so by the OIG.

The "case" information is to be entered into the FID concurrent with, or within 30 days after, the "advisement" if the contractor substantiates the allegation, or upon such time the OIG accepts the "advisement" and opens a case.

Contractors should not expend resources attempting to substantiate the allegation until so directed by CMS and/or the OIG. For example, if a contractor receives an allegation of kickbacks, the contractor should immediately advise the OIG of the allegation, but not initiate an independent contractor query until requested to do so by the OIG and guidance on the parameters of the query are provided by the OIG. In this example, CMS nor its contractors have the authority (jurisdiction) to investigate allegations of kickbacks, thus "immediate advisement" to OIG.
OIG Declination

When the OIG formally declines a referral and does not refer the case to the FBI, the contractor is free to refer the case to another law enforcement agency (e.g., FBI, Postal, IRS, etc.). However, when this occurs, it is considered an update reflecting a subsequent action, not a new referral to law enforcement. As a general rule, subsequent referrals to other law enforcement agencies do not count as new case entries in the FID, nor are they counted for workload purposes as new referrals to law enforcement.

MFIS and the FID

MFISs receive training on how to input and maintain cases in the FID. The intent is to use MFISs as "FID experts" and points of contact for questions and comments on the FID. The MFISs should be responsive to FID questions from carriers and intermediaries and law enforcement personnel within their jurisdiction.

MFISs should regularly share FID information and analysis (e.g., FID system reports) with the BI unit manager, or their designee, for their applicable jurisdiction. The MFIS serves as a resource to CMS on the FID including FID training. While the MFIS should not enter cases into the FID or monitor FID quality, if the MFIS detects any inaccuracies or discrepancies they should notify the respective contractor staff and/or management. Upon request, the MFIS will furnish FID reports to the BI unit manager within their jurisdiction.

FID Access

If you have never applied for access to the FID system and require authorization, an "Application for Access to CMS Computer Systems" must be completed, submitted and approved. This form may be acquired from the appropriate RACF Group Administrator for all CMS central and regional office and contract users, or in the CMS Division of Benefit Integrity and Law Enforcement Liaison for all law enforcement personnel or other users.

For those individuals who have received prior authorization, but are experiencing authorization lapses or password problems, the same contacts referenced above should be contacted. Internet access problems are appropriately directed to CMS's Division of Systems and Network Engineering at CMS Central Office while software or other connection problems are handled by the CMS Action Desk at (410) 786-2580.

Persistent problems or instances where corrective actions cannot be made, should be forwarded to the CMS Division of Program Integrity Operations. The Division of Benefit Integrity and Law Enforcement Liaison is also the direct point of contact for special extracts and reporting options as well as access submissions of “nonstandard” users.

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Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

Table of Contents - (Rev. 16, 11-28-01)

1 – Introduction
   1.1 – Provider Tracking System (PTS)
   1.2 – Evaluating Effectiveness of Corrective Actions

2 – Verifying Potential Error and Setting Priorities
   2.1 - Determining Whether the Problem is Widespread or Provider Specific

3 – Provider Education
   3.1 – Provider Contacts by the BI Unit

4 – Overview of Prepayment and Postpayment Review

5 – Prepayment Review of Selected Claims
   5.1 – Automated and Manual Prepayment Review
      5.1.1 – Prepayment Edits
      5.1.1.1 – Evaluation of Prepayment Edits
   5.2 – Categories of MR Edits
   5.3 – Documentation Specifications for Areas Selected for MR
      5.3.1 – Laboratory Claims
      5.3.2 – Documentation for Non-physician Claims
      5.3.3 – Development of Claims for Additional Documentation
   5.4 – CMS Mandated Edits

6 – Postpayment Review of Claims
   6.1 – Comprehensive Post-payment MR
      6.1.1 - Intermediary Selection of Providers for Comprehensive Medical Review (CMR)
   6.2 – Intermediary Procedures for Provider On-Site CMRs (Type 1)
   6.3 – Intermediary CMR Procedures Using Statistical Sampling for Overpayment Estimation (Type 2)
      6.3.1 - Select Period To Be Reviewed and Composition of Universe
      6.3.2 - Select Sample
      6.3.2.1 - Select Sample Design
6.3.2.2 - Select Sample Size and Claims to Include
6.3.2.3 - Document Universe and Frame
6.3.3 - Actions After Provider and Sample Have Been Selected
   6.3.3.1 - File Compilation and Provider Notification of the CMR
   6.3.3.2 - Onsite and In-House Reviews
   6.3.3.3 - Re-adjudication and Documentation of Claims
   6.3.3.4 - Effect of Sections 1879 and 1870 of the social Security Act
   6.3.3.5 - Estimate of the Correct Payment Amount and Subsequent Over/Underpayment
   6.3.3.6 - Final Notification of the CMR Results/Demand Letter
6.3.4 - Recovery of Overpayment and Corrective Actions
6.3.5 - Administrative and Judicial Appeal Rights
   6.3.5.1 - Effect of Pending Appeals on Recovery of Overpayments
   6.3.5.2 - Changes Resulting from Provider Appeals
6.3.6 - Cost Report Appeal Issues
6.3.7 - Projection Methodologies and Instructions for Reviews of Home Health Agencies
6.3.8 - Projection Methodologies and Instructions for Reviews of Skilled Nursing Facilities (SNFs)
6.3.9 - Projection Methodologies and Instructions for Reviews of Comprehensive Outpatient Rehabilitation Facilities (CORFs)
6.3.10 - Projection Methodologies and Instructions for Reviews of Community Mental Health Centers (CMHCs)

6.4 – Carrier CMR Procedures
   6.4.1 - CMR Case Selection
   6.4.2 - Conducting the CMR
   6.4.3 - CMR Corrective Actions

7 – Appeal of Denials
   7.1 – Reversed Denials Pending Further Action by Law Enforcement

8 – Overpayment Procedures
   8.1 – Overpayment Assessment Procedures
      8.1.1 – Definition of Overpayment Assessment Terms
   8.2 – Assessing Overpayment When Review Was Based on SVRS
   8.3 – Assessing Overpayment or Potential Overpayment When Review Was Based on Limited Sample or Limited SVRS Sub-sample
      8.3.1 – Contractor Activities to Support Assessing Overpayment
      8.3.2 – Conduct of Expanded Review Based on SVRS and Recoupment of Projected Overpayment by Contractors
      8.3.3 – Consent Settlement Instructions
      8.3.4 - Consent Settlement Budget and Performance Requirements (BPR)
   8.4 – Voluntary Repayment during an Active Fraud Investigation
      8.4.1 - Procedures for the Benefit Integrity (BI) and Medical Review (MR) Units on Unsolicited/Voluntary Refund Checks
   8.5 - Coordination with Audit and Reimbursement Staff
9 – Suspension of Payment

9.1 – When Suspension of Payment May Be Used

9.1.1 – Fraud or Willful Misrepresentation Exists - Fraud Suspensions
9.1.2 – Overpayment Exists But the Amount is Not Determined - General Suspensions
9.1.3 – Payments to be Made May Not be Correct - General Suspensions
9.1.4 – Provider Fails to Furnish Records and Other Requested Information - General Suspensions

9.2 – Procedures for Implementing Suspension of Payment

9.2.1 – CMS Approval
9.2.2 – The Notice of Intent to Suspend
9.2.2.1 – Prior Notice Versus Concurrent Notice
9.2.2.2 – Content of Notice
9.2.2.3 – Shortening the Notice Period for Cause
9.2.2.4 – Mailing the Notice to the Provider
9.2.2.5 – Opportunity for Rebuttal
9.2.3 – Claims Review and Case Development During the Suspension Period
9.2.3.1 – Claims Review
9.2.3.2 – Case Development
9.2.4 – Duration of Suspension of Payment
9.2.5 – Removing the Suspension
9.2.6 – Disposition of the Suspension
9.2.7 – Contractor Suspects Additional Improper Claims

9.3 – Suspension Process for Multi-Region Issues

9.3.1 – DMERCs
9.3.2 – Other Multi-Regional Contractors

10 – Referral of Cases to Other Entities for Action

10.1 – Referral of Cases to OIG/OI
10.1.1 – Referral of Potential Fraud Cases Involving Railroad Retirement Beneficiaries
10.1.2 – Cases Requiring Immediate Referral to OIG/OI
10.1.3 – Contractor Actions When Cases Are Referred to and Accepted by OIG/OI
10.1.3.1 – Suspension
10.1.3.2 – Denial of Payments for Cases Referred to and Accepted by OIG/OI
10.1.3.3 – Recoupment of Overpayments
10.1.4. – OIG/OI Case Summary and Referral
10.1.5 – Actions to be Taken When A Fraud Case is Refused by OIG/OI
10.1.5.1 – Continue to Monitor Provider and Document Case File
10.1.5.2 – Take Administrative Action on Cases Referred to and Refused by OIG/OI
10.1.5.3 – Refer to Other Law Enforcement Agencies

10.2 – Referral to State Agencies or Other Organizations
10.3 – Referral to PROs

11 – Administrative Sanctions
11.1 – The Contractor’s Role
11.2 – Authority to Exclude Practitioners, Providers, and Suppliers of Services
   11.2.1 – Basis for Exclusion Under §1128(b)(6) of the Act
   11.2.2 – Identification of Potential Exclusion Cases
   11.2.3 – Development of Potential Exclusion Cases
   11.2.4 – Contents of Sanction Recommendation
   11.2.5 – Notice of Administrative Sanction Action
      11.2.5.1 – Notification to Other Agencies
   11.2.6 – Denial of Payment to an Excluded Party
      11.2.6.1 – Denial of Payment to Employer of Excluded Physician
      11.2.6.2 – Denial of Payment to Beneficiaries and Others
11.3 – Appeals Process
11.4 – Reinstatements
   11.4.1 – Monthly Notification of Sanction Actions

12 – Civil Monetary Penalties (CMP)
12.1 - Background
   12.1.1 - Basis of Authority
   12.1.2 - Purpose
   12.1.3 - Enforcement
   12.1.4 - Administrative Actions
   12.1.5 - Documents
12.2 - CMP Authorities
   12.2.1 - Authorities Delegated to CMS
   12.2.2 - Authorities Delegated to OIG
12.3 - Referral Process
   12.3.1 - Referrals to CMS
   12.3.2 - Referrals to OIG
12.4 - CMS Generic CMP Case Contents
12.5 - Additional Guidance for Specific CMPs
   12.5.1 - Beneficiary Right to Itemized Statement
   12.5.2 - Medicare Limiting Charge Violation

13 – Monitor Compliance
13.1 – Resumption of Payment to A Provider - Continued Surveillance After Detection of Fraud
8.3.3 – Consent Settlement Instructions--(Rev. 16, 11-28-01)

The consent settlement process is an appropriate tool to modify a provider's billing practice while limiting contractor costs in monitoring provider practice patterns. Consent settlement documents carefully explain, in a neutral tone, what rights a provider waives by accepting a consent settlement. Also, the documents must explain in a neutral tone the consequences of not accepting a consent settlement. A key feature of a consent settlement is a binding statement that the provider agrees to waive any rights to appeal the decision regarding the potential overpayment. The consent settlement agreement must carefully explain this to ensure that the provider is knowingly and intentionally agreeing to a waiver of rights. A consent settlement correspondence must contain:

- A complete explanation of the review and the review findings;
- A thorough discussion of §§1879 and 1870 determinations where applicable; and
- The consequences of deciding to accept or decline a consent settlement.

When offering a provider a consent settlement, contractors may choose to present the consent settlement letter to the provider in a face-to-face meeting. The consent settlement correspondence describes the three options available to the provider.

A – Option 2 - Acceptance of Potential Projected Overpayment

Providers selecting Option 2 agree to refund the entire limited projected overpayment amount without submitting additional documentation. These providers forfeit their right to appeal the adjudication determinations made on the sampled cases and the potential projected overpayment that resulted from extrapolating to the universe. For providers who elect Option 1, do not audit any additional claims for the service under review within the time period audited. (If desired, waive Option 2.)

B – Option 1- Acceptance of Capped Potential Projected Overpayment

Providers selecting Option 1 agree to submit additional pre-existing documentation. Review this additional documentation and adjust the potential projected overpayment amount accordingly. Do not audit any additional claims for the service under review within the time period audited for providers who elect Option 1.

C – Option 3 - Election to Proceed to SVRS

If a provider fails to respond, this option is selected by default. For providers who select this option knowingly or by default, thereby rejecting the consent settlement offer and retaining their full appeal rights, contractors shall:
• Notify the provider of the actual overpayment and refer to overpayment recoupment staff. (See PIM Chapter 3 §8); and

• Initiate an expanded review of a SVRS of the provider's claims for the service under review. (See PIM Chapter 3 §8.3.2)

If the review results in a decision to recoup overpayment through the consent settlement process, the consent settlement must have been initiated within 12 months of the selection process.

A sample of Consent Settlement Documents can be found in Exhibit 15.

8.3.4 - Consent Settlement Budget and Performance Requirements (BPR)
(Rev. 16, 11-28-01)

In preparation for the BI BPR requirements, contractors shall keep a record of the number of consent settlements offered and accepted, and the number of SVRSs. These workload numbers are to be reported each fiscal year (e.g., BI develops a case and it is not accepted by law enforcement. BI should perform an overpayment estimation and offer the provider a consent settlement or SVRS. BI shall track this information and record the counts in the Miscellaneous field for Activity Code 23007).

8.4.1 - Procedures for the Benefit Integrity (BI) and Medical Review (MR) Units on Unsolicited/Voluntary Refund Checks (Rev. 16, 11-28-01)

This section provides program integrity guidance from a MR and BI perspective on unsolicited/voluntary refunds from providers/suppliers (including physicians and other practitioners).

All Medicare contractors receive voluntary refunds (amounts received for which there was no established accounts receivable). Providers may identify overpayments through internal compliance efforts or ad hoc internal investigations. Subsequently, providers should refund such identified overpayments. Fiscal intermediaries generally receive voluntary refunds in the form of an adjustment bill, but may receive some voluntary refunds as checks or reported as credit balances. Carriers generally receive unsolicited refund checks.

Voluntary refund checks payable to the Medicare program shall not be returned regardless of the amount of the refund. Refer to PIM, Chapter 3, Section 8.4, for the acknowledgement of voluntary refunds. The contractor shall ask the provider why the voluntary refund was made, how it was identified, what sampling techniques were
employed, what steps were taken to assure that the issue leading to the overpayment was corrected, the dates the corrective action was in place, claims and claims information involved in inappropriate payments, methodology used to arrive at the amount of the refund, and if a full assessment was performed to determine the entire timeframe and the total amount of refund for the period during which the problem existed that caused the refund.

When a provider returns an overpayment equal to or greater than 20 percent of the contractor's total annual Medicare payments for that provider (or in any other circumstances in which there are suspected patterns of inappropriate payment, the contractor shall perform data analysis for patterns of inappropriate program payment (e.g., payment for services not rendered, payment for medically unnecessary services, or payment for upcoded services). The data analysis shall be for the period that is the subject of the voluntary refund. Conduct further medical review if appropriate. In making that determination, consider whether the refund accurately reflects the full disclosure of the debt and that appropriate adjustments were made to the claims and the claims history files. Consider if the provider is currently the subject of a prepayment or postpayment review. Access the Fraud Investigation Database (FID) to determine if the provider is subject to any program safeguard activity. The BI and MR units should share their findings with each other. In cases where there are patterns of inappropriate payments, determine the appropriate corrective actions to take (e.g., provider education, prepayment and postpayment edits, creation of Local Medical Review Policies (LMRP), referral to law enforcement). Follow the guidelines in the Medicare Manuals to determine the appropriate corrective action(s). If fraud is suspected, refer the case to the BI unit expeditiously for appropriate action.

This section does not supersede PIM, Chapter 3, Section 8.4 above on "Voluntary Repayment During an Active Fraud Investigation."

12 – Civil Monetary Penalties (CMP)--(Rev. 16, 11-28-01)

12.1 – Background - (Rev. 16, 11-28-01)

Background includes Basis of Authority, Purpose, Administrative Actions, and Documents.

12.1.1 – Basis of Authority - (Rev. 16, 11-28-01)
In 1981, Congress added §1128A (42 U.S.C. 1320a-7a) to the Social Security Act to authorize the Secretary of Health and Human Services to impose civil money penalties (CMPs). Since the enactment of the first CMP authority in 1981, Congress has increased both the number and types of circumstances under which CMPs may be imposed. Most of the specific statutory provisions authorizing CMPs also permit the Secretary to impose an assessment in addition to the CMP. An assessment is an additional monetary payment in lieu of damages sustained by the government because of the improper claim. Also, for many statutory violations, the Secretary may exclude the individual or entity violating the statute from participating in Medicare and other Federal health care programs for specified periods of time.

In October 1994, the Secretary realigned the responsibility for enforcing these CMP authorities between the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG). CMS was delegated the responsibility for implementing CMPs which involve program compliance. The OIG was delegated the responsibility for implementing CMPs which involve threats to the integrity of the Medicare or Medicaid programs, i.e., those which involve fraud or false representations. On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) was enacted. This law provides for higher maximum CMPs ($10,000 per false item or service on a claim or instance of noncompliance instead of $2,000 per item or service), and higher assessments (three times the amount claimed instead of twice the amount) for some of the violations.

12.1.2 – Purpose--(Rev. 16, 11-28-01)

The central purpose of the CMP process is to promote compliance with the program rules and regulations. To achieve this, CMS and its contractors must enforce the regulatory standards and requirements.

Contractors must educate the industry and the public regarding compliance. Contractors have a statutory obligation to ensure compliance with regulations. Therefore, contractors’ efforts to achieve compliance should be directed toward promoting a clear awareness and understanding of the program through education. When these efforts for achieving voluntary compliance have failed, formal enforcement action should be referred to the appropriate agency.

12.1.3 – Enforcement--(Rev. 16, 11-28-01)

An essential part of enforcement is that potential violations be discovered at the earliest possible time. Every alleged violation should be identified, developed and processed in a timely manner. Delays in developing and/or processing the violations affect the program in several ways. Such delays may permit an unsafe medical condition to prevail if
prompt corrective action is not taken. Second, delays tend to improperly de-emphasize the seriousness of the violation. Lastly, delays diminish the deterrent effect.

12.1.4 – Administrative Actions--(Rev. 16, 11-28-01)

Contractors shall ensure that the program rules and regulations are being appropriately followed. If violations are noted (either through internal reviews or through a complaint process), the contractors are to take the appropriate steps to inform and educate the provider of the non-compliance and encourage future compliance.

If, after a period of time, there is no significant change by the provider (the non-compliance continues), then a final warning notice of plans to propose a corrective action (such as a CMP) is issued by the contractor. This notice should be sent by certified mail (return receipt required) to ensure its receipt by the provider. The notice should indicate that previous notifications sent to the provider failed to correct the problem, and that this is a final warning. Additionally, it should indicate that any further continuation of the non-compliance will result in the matter being forwarded to CMS or the OIG for administrative enforcement. While not specifically assessing a monetary penalty amount, the notice should indicate that this is one type of sanction that may be applied.

12.1.5 – Documents--(Rev. 16, 11-28-01)

Documentary evidence is extremely important in the CMP process. It is not only the evidence needed to support the administrative actions, but also a tool used for cross-referencing, verifying statements and/or providing backup or background information.

Documentary evidence should be identified, accounted for, and protected from loss, damage, or alteration. When copies of documents are made, care should be taken to ensure that all copies are legible and accurate. Wherever possible, documents or copies should be preserved in their original state; avoid making marks on the face of the documents. If marks or explanations were necessary for explanation or clarification, it would be better to include an additional copy of the document with marks on the copy.

12.2 – CMP Authorities--(Rev. 16, 11-28-01)

The following is a listing of those authorities under which CMS's Program Integrity Group and the OIG may impose civil money penalties, assessments, and/or exclusions for program non-compliance:
The following is a brief description of authorities from the Social Security Act:

- **Section 1806 (b)(2)(B)**--Any person or entity that fails to provide an itemized statement describing each item or service requested by a Medicare beneficiary.

- **Section 1833(h)(5)(D)**--Any person billing for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also cause an assessment and an exclusion.)

- **Section 1833(i)(6)**--Any person billing for an intraocular lens inserted during or after cataract surgery for which payment may be made for services in an ambulatory surgical center.

- **Section 1833(q)(2)(B)**--When seeking payment on an unassigned basis, any entity failing to provide information about a referring physician, including the referring physician's name and unique physician identification number. (This violation may also cause an exclusion.)

- **Sections 1834(a)(11)(A) and 1842(j)(2)**--Any supplier of durable medical equipment charging for covered items (furnished on a rental basis) after the rental payments may no longer be made (except for maintenance and servicing) as provided in §1834(a)(7)(A) of the Act. (This violation may also cause an assessment and an exclusion.)

- **Section 1834(a)(17)(C)**--Unsolicited telephone contacts by any supplier of durable medical equipment to Medicare beneficiaries regarding the furnishing of covered services. (This violation may also cause an exclusion.)

- **Sections 1834(a)(18)(B) and 1842(j)(2)**--Any durable medical equipment supplier that fails to make a refund to Medicare beneficiaries for a covered item for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also cause an assessment and an exclusion.)

- **Sections 1834(b)(5)(C) and 1842(j)(2)**--Any nonparticipating physician or supplier that charges a Medicare beneficiary more than the limiting charge as specified in §1834(b)(5)(B) of the Act for radiologist services. (This violation may also cause an assessment and an exclusion.)

- **Sections 1834(c)(4)(C) and 1842(j)(2)**--Any nonparticipating physician or supplier charging a Medicare beneficiary more than the limiting charge for mammography screening, as specified in §1834(c)(3) of the Act. (This violation may also cause an assessment and an exclusion.)
• Sections 1834(h)(3) and 1842(j)(2)--Any supplier of durable medical equipment, prosthetics, orthotics, and supplies charging for a covered prosthetic device, orthotic, or prosthetic (furnished on a rental basis) after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also cause an assessment and an exclusion.)

• Section 1834(h)(3)--Unsolicited telephone contacts by any supplier of durable medical equipment, prosthetics, orthotics to Medicare beneficiaries regarding the furnishing of prosthetic devices, orthotics, or prosthetics. (This violation may also cause an exclusion.)

• Section 1834(j)(2)(A)(iii)--Any durable medical equipment supplier that completes the medical necessity section on the certificate of medical necessity or fails to provide the fee schedule amount and the supplier's charge for the medical equipment or supply prior to distributing the certificate to the physician.

• Sections 1834(j)(4) and 1842(j)(2)--Any supplier of durable medical equipment, prosthetics, orthotics, and supplies that fails to make refunds in a timely manner to Medicare beneficiaries (for items or services billed on a nonassigned basis) if the supplier does not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined not to be medically necessary or reasonable. (This violation may also cause an assessment and an exclusion.)

• Sections 1834(k)(6) and 1842(j)(2)--Any practitioner or other person that bills or collects for outpatient therapy services or comprehensive outpatient rehabilitation services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

• Section 1842(b)(18)(B)--For practitioners specified in §1842(b)(18)(C) of the Act (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists), any practitioner billing (or collecting) for any services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

• Section 1842(k)--Any physician presenting a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987. (This violation may also cause an assessment and an exclusion.)

• Section 1842(l)(3)--Any non-participating physician who does not accept payment on an assigned basis and who fails to refund beneficiaries for services that are not reasonable or medically necessary or are of poor quality. (This violation may also cause an assessment and an exclusion.)

• Section 1842(m)(3)--Any nonparticipating physician billing for an elective surgical procedure on a non-assigned basis, charges at least $500, fails to disclose charge and coinsurance amounts to the Medicare beneficiary prior to rendering the service;
and fails to refund any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (This violation may cause an assessment and an exclusion.)

• Section 1842(n)(3)--Any physician billing diagnostic tests in excess of the scheduled fee amount. (This violation may cause an assessment and an exclusion.)

• Section 1842(p)(3)(A)--Any physician that fails to promptly provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill submitted on a non-assigned basis.

• Section 1842(p)(3)(B)--Any physician failing to provide the diagnosis code or codes after repeatedly being notified by CMS of the obligations on any request for payment or bill submitted on a non-assigned basis. (This violation is only subject to an exclusion.)

• Section 1848(g)(1)(B)-- Any nonparticipating physician, supplier, or other person who furnishes physicians' services and bills on a non-assigned basis; or collects in excess of the limiting charge; or fails to make an adjustment or refund to the Medicare beneficiary. (This violation may cause an assessment and an exclusion.)

• Section 1848(g)(3)--Any person billing for physicians' services on a non-assigned basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may cause an assessment and an exclusion.)

• Section 1848(g)(4)--Any physician, supplier, or other person (except one excluded from the Medicare program) that fails to submit a claim for a beneficiary within one year of providing the service; or imposes a charge for completing and submitting the standard claims form. (This violation may cause an exclusion.)

• Section 1862(b)(5)(C)--Any employer who (before October 1, 1998) fails to provide an employee's group health insurance coverage information to the Medicare contractor.

• Section 1862(b)(6)(B)--Any entity that fails to complete a claim form relating to the availability of other health benefit plans; or provides inaccurate information relating to the availability of other health benefit plans on the claim form.

• Section 1877(g)(5)--Any person failing to report information concerning ownership, investment, and compensation arrangements. (This violation may cause an assessment and an exclusion.)

• Section 1879(h)--Any durable medical equipment supplier (including a supplier of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies) failing to make refunds to Medicare beneficiaries for items or services billed on an
assigned basis if the supplier did not possess a Medicare supplier number; if the item or service is denied in advance; or the item or service is determined to be not medically necessary or reasonable. (This violation may cause an assessment and an exclusion.)

- **Section 1882(a)(2)**--Any person who issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards. (This violation may cause an assessment and an exclusion.)

- **Section 1882(p)(8)**--Any person who sells or issues nonstandard Medicare supplemental policies. (This violation may cause an assessment and an exclusion.)

- **Section 1882(p)(9)(C)**--Any person who sells a Medicare supplemental policy and fails to make available the core group of basic benefits as part of its product line; or fails to provide the individual (before the sale of the policy) an outline of coverage describing the benefits provided by the policy. (This violation may cause an assessment and an exclusion.)

- **Section 1882(q)(5)(C)**--Any person who fails to suspend a Medicare supplemental policy at the policyholder's request (if the policyholder applies for and is determined eligible for Medicaid); or automatically reinstate the policy as of the date the policyholder loses medical assistance eligibility (and the policy holder provides timely notice of losing his or her Medicaid eligibility). (This violation may cause an assessment and an exclusion.)

- **Section 1882(r)(6)(A)**--Any person that fails to refund or credit as required by the supplemental insurance policy loss ratio requirements. (This violation may cause an assessment and an exclusion.)

- **Section 1882(s)(4)**--Any issuer of a Medicare supplemental policy that does not waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare policy; or denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria. (This violation may cause an assessment and an exclusion.)

- **Section 1882(t)(2)**--Any issuer of a Medicare supplemental policy failing to provide medically necessary services to enrollees through the issuer's network of entities; imposes premiums on enrollees in excess of the premiums approved by the State; acts to expel an enrollee for reasons other than nonpayment of premiums; or does not provide each enrollee at the time of enrollment with specific information regarding policy restrictions; or fails to obtain a written acknowledgment from the enrollee of receipt of the information. (This violation may cause an assessment and an exclusion.)
The following is a brief description of authorities from the Social Security Act:

- **Section 1128(a)(1)(A), (B)** False or fraudulent claim for item or service including incorrect coding (upcoding) or medically unnecessary services.
- **Section 1128A(a)(1)(C)** Falsely certified specialty.
- **Section 1128A(a)(1)(D)** Claims presented by excluded party.
- **Section 1128A(a)(1)(E)** Pattern of claims for unnecessary services or supplies.
- **Section 1128A(a)(2)** Assignment agreement, PPS abuse violations.
- **Section 1128A(a)(3)** PPS false/misleading information influencing discharge decision.
- **Section 1128A(a)(4)** Excluded party retaining ownership or controlling interest in participating entity.
- **Section 1128A(a)(5)** Remuneration offered to induce program beneficiaries to use particular providers, practitioners or suppliers.
- **Section 1128A(a)(6)** Contracting with an excluded individual.
- **Section 1128A(a)(7)** Improper remuneration; i.e., kickbacks.
- **Section 1128A(b)** Hospital physician incentive plans.
- **Section 1128A(b)(3)** Physician falsely certifying medical necessity for home health benefits.
- **Section 1128E(b)** Failure to supply information on adverse action to the Health Integrity and Protection Data Bank (HIPDB).
- **Section 1140(b)(1)** Misuse of Departmental symbols/emblems.
- **Section 1819(b)(3)(B)** False statement in assessment of functional capacity of skilled nursing facility (SNF) resident.
- Section 1819(g)(2)(A) Notice to SNFs/nursing facility of standard scheduled survey.

- Section 1857(g)(1)(F) Managed care organization (MCO) fails to comply with requirements of §1852(j)(3) or §1852(k)(2)(A)(ii). (Prohibits MCO interference with the provider's advice to an enrollee; mandates that providers not affiliated with the MCO may not bill or collect in excess of the limiting charge.)

- Section 1862(b)(3)(c) Financial incentives not to enroll in a group health plan.

- Section 1866(g) Unbundling outpatient hospital costs.

- Section 1867 Dumping by hospital/responsible physician of patients needing emergency medical care.

- Section 1876(i)(6)(A)(i) Failure by HMOs/competitive medical plan/MCO to provide necessary care affecting beneficiaries.

- Section 1876(i)(6)(A)(ii) Premiums by HMOs/competitive medical plans/MCO in excess of permitted amounts.

- Section 1876(i)(6)(A)(iii) HMO/competitive medical plan/MCO expulsion/refusal to re-enroll individual per prescribed conditions.

- Section 1876(i)(6)(A)(iv) HMO/competitive medical plan/MCO practices to discourage enrollment of individuals.

- Section 1876(i)(6)(A)(v) False or misrepresenting HMO/competitive medical plan/MCO information to Secretary.

- Section 1876(i)(6)(A)(vi) Failure by HMO/competitive medical plan/MCO to assure prompt payment for Medicare risk-sharing contracts only or incentive plan provisions.

- Section 1876(i)(6)(A)(vii) HMO/competitive medical plan/MCO hiring/employing person excluded under §1128 or §1128A.
- **Section 1877(g)(3)** Ownership restrictions for billing clinical lab services.

- **Section 1877(g)(4)** Circumventing ownership restriction governing clinical labs and referring physicians.

- **Section 1882(d)(1)** Material misrepresentation referencing compliance of Medicare supplemental policies (including Medicare+Choice).

- **Section 1882(d)(2)** Selling Medicare supplemental policy (including Medicare+Choice) under false pretense.

- **Section 1882(d)(3)(A)** Selling health insurance that duplicates benefits.

- **Section 1882(d)(3)(B)** Selling or issuing Medicare supplemental policy (including Medicare+Choice) to a beneficiary without obtaining a written statement from beneficiary with regard to Medicaid status.

- **Section 1882(d)(4)(A)** Use of mailings in the sale on non-approved Medicare supplemental insurance (including Medicare+Choice).

- **Section 1891(c)(1)** Notifying home health agency of scheduled survey.

- **Section 1927(b)(3)(B)** False information on drug manufacturer survey from manufacturer/wholesaler/seller.

- **Section 1927(b)(3)(C)** Provision of untimely or false information by drug manufacturer with rebate agreement.

- **Section 1929(i)(3)** Notifying home and community-based care providers/settings of survey.

- **Section 421(c) of HCQIA** Failure to report medical malpractice liability to National Practitioner Data Bank.

- **Section 427(b) of HCQIA** Breaching confidentiality of information report to National Practitioner Data Bank.
12.3 – Referral Process—(Rev. 16, 11-28-01)

12.3.1 – Referral Process to CMS—(Rev. 16, 11-28-01)

Compliance is promoted through both administrative and formal legal actions. Administrative compliance action must first always be attempted by contractors through education and warning letters that request the provider to comply with Medicare’s rules and regulations. If the provider fails to take corrective action and continues to remain non-compliant, the contractor shall prepare a referral of a CMP case and forwarded it to its respective CMS RO component that has oversight of the Medicare Integrity Program.

It is important for contractors to promote program compliance in their respective jurisdictions. The contractors shall ensure that all materials presented to providers through education, published bulletins, or written communication are clear and concise and accurately represent the facts of compliance versus non-compliance. Providers must also be allowed the opportunity to present additional facts which may represent mitigating circumstances. Contractors shall consider this information in an objective manner before proceeding with a CMP referral to CMS.

When a contractor elects to make a CMP referral to CMS, the initial referral package should consist of a brief overview of the case; supportive documentation (as described in Chapter 3, Section 12.4 of the PIM) is not required at such time. The initial referral package shall consist of:

1. Identification of the provider including the provider’s name, address, date of birth, social security number, Medicare identification number(s), and the provider’s specialty. If the provider is an entity, include the names of its applicable owners, officers and directors;

2. Identification of the CMP authorities to be considered (use the authorities identified in Chapter 3, Section 12.2.1 of the PIM);

3. Identification of any applicable Medicare manual provisions;

4. A brief description of how the violations identified above were discovered, and the volume of violations identified;

5. Total overpayments due the program or due the beneficiary(ies), respectively;

6. A brief chronological listing of events depicting communication (oral and written) between the contractor and the provider;
7. A brief chronological listing of bulletins addressing the non-compliant area (starting with the bulletin released immediately prior to the first incident of non-compliance by the provider);

8. Any additional information that may be of value to support the referral; and

9. The name and phone number of contact(s) at the contractor.

Upon receipt of the above information, CMS staff will review the materials and conduct follow-up discussions with the contractor regarding the referral. Within 90 days of receipt of the referral, CMS will notify the contractor of its decision to accept or decline the referral.

If CMS declines the referral, the contractor shall continue in its efforts to educate and promote compliance by the provider. The contractor should also consider other (less severe) administrative remedies, which at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to State Licensing Boards or Medical/Professional Societies, where applicable. In all situations where inappropriate Medicare payments have been identified, contractors shall initiate the appropriate steps for recovery.

If CMS accepts the referral, the contractor shall provide any supportive documentation that may be requested, and be able to clarify any issues regarding the data in the case file or contractor processes.

12.3.2 – Referrals to OIG--(Rev. 16, 11-28-01)

Upon discovery of any case that may implicate any of the OIG's delegated CMP authority, regardless of whether there is any other pending activity, or whether the fraud case was closed, the contractor shall contact the OIG/OI Field Office to discuss the potential case. If this contact results in a referral, the contractor shall follow the same referral format as described in Chapter 3, Section 10.1.4 of the PIM. If a referral is not made or a referral is declined, the contractor shall consider other administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to State Licensing Boards or Medical/Professional Societies, where applicable. In all situations where inappropriate Medicare payments have been identified, contractors shall initiate the appropriate steps for recovery.

The contractor shall send to the OIG all cases, as appropriate, where an excluded provider or individual has billed or caused to be billed to the Medicare or Medicaid program for the furnishing of items or services after exclusion. Such misconduct is sanctionable under §1128A(a)(C)(I) of the Social Security Act.
12.4 – CMS Generic CMP Case Contents--(Rev. 16, 11-28-01)

The following information, if available, shall be included as part of the CMP case package and made available upon request by CMS:

1. Background information:
   a. All known identification numbers (i.e., PIN, UPIN, etc.);
   b. Provider's first and last name or entity name (if subject is an entity, also include the full name of the principal operator); and
   c. Provider's address (street, city, state and zip code). If violator is an entity, identify address where principal operator will personally receive his/her mail.

2. Copies of any interviews, reports or statements obtained regarding the violation.

3. Copies of documentation supporting a confirmation of the violation.

4. Copies of all applicable correspondence between beneficiary and provider.

5. Copies of all applicable correspondence (including telephone contacts) between contractor and provider.

6. Copies of provider's applicable bills to beneficiaries and/or Medicare contractors, and associated payment histories.

7. Copies of any complaints regarding provider and disposition of the complaint.

8. Copies of all publications (e.g., bulletins, and newsletters) sent to providers by the contractor, which discuss the type of violation being addressed in the CMP case.

9. Copies of any monitoring reports regarding the provider.

10. Name and telephone number of contractor contact.

12.5 – Additional Guidance for Specific CMPs--(Rev. 16, 11-28-01)

12.5.1 – Beneficiary Right to Itemized Statement--(Rev. 16, 11-28-01)
The following is background information for developing specific CMS CMP cases:

Effective for services or items provided on or after January 1, 1999, §4311 of the Balanced Budget Act (BBA) provides that Medicare beneficiaries have the right to request and receive an itemized statement from their health care provider of service (e.g., hospital, nursing facility, home health agency, physician, non-physician practitioner, DMEPOS supplier). Upon receipt of this request, providers have 30 days to furnish the itemized statement to the beneficiary. Health care providers who fail to provide an itemized statement may be subject to a CMP of not more than $100 for each failure to furnish the information (§1806(b)(2)(B) of the Social Security Act). An itemized statement is defined as a listing of each service(s) or item(s) provided to the beneficiary. Statements that reflect a grouping of services or items (such as a revenue code) are not considered an itemized statement.

A beneficiary who files a complaint with a contractor regarding a provider’s failure to provide an itemized statement must initially validate that his/her request was in writing (if available), and that the statutory 30-day time limit (calendar days) for receiving the information has expired. In most cases, an additional five calendar days should be allowed for the provider to receive the beneficiary’s written request. If the beneficiary did not make his/her request in writing, inform him/her that he/she must first initiate the request to the provider in writing. It is only after this condition and the time limit condition are met that the contractor may contact the provider.

Once the contractor confirms that the complaint is valid, the contractor should initiate steps to assist the beneficiary in getting the provider to furnish the itemized statement. Contractors are to initiate the same or similar procedures when receiving complaints regarding mandatory submission of claims (i.e., communicating with the provider about their non-compliance and the possibility of the imposition of a CMP).

If the contractor’s intervention results in the provider furnishing an itemized statement to the beneficiary, the conditions for the statute are considered met, and a CMP case should not be developed. Should the contractor’s intervention prove unsuccessful, the contractor shall consider referring the potential CMP case to CMS following the guidelines established in Chapter 3, Sections 12.3 and 12.4 of the PIM.

There may be instances where a beneficiary receives an itemized statement and the contractor receives the beneficiary’s request (written or oral) to review discrepancies on his/her itemized statement. Contractors are to follow their normal operating procedures in handling these complaints. Contractors are to determine whether itemized services or items were provided, or if any other irregularity (including duplicate billing) resulted in improper Medicare payments. If so, contractors shall recover the improper payments.
12.5.2 – Medicare Limiting Charge Violations--(Rev. 16, 11-28-01)

The Omnibus Budget Reconciliation Act (OBRA) of 1989 established a limitation on actual charges (balanced billing) by nonparticipating physicians. (Refer to §1848(g) of the Act, and MCM §§5000ff. and 7555, respectively for further information.)

As a result of the reduction in limiting charge monitoring activities (i.e., the discontinuance of the Limiting Charge Exception Report and Limiting Charge Monitoring Report, the discontinuance of sending compliance monitoring letters and Refund/Adjustment Verification Forms), developing a Limiting Charge CMP case will require the following additional information:

1) Contact with the provider: Based on CMS instructions, contractors are to assist beneficiaries in obtaining overcharge refunds from the providers. This assistance reinstates the activity of sending the refund verification forms and compliance monitoring letters respective to the beneficiary(ies) who request assistance. Copies of these communications will become part of the CMP case file. Ensure that the communication includes language which reminds the provider that the limiting charge amounts for most physician fee schedule services are listed on the disclosure reports they receive in their yearly participation enrollment packages. (This constitutes “notice” of the Medicare charge limits for those services.) Additionally, the provider’s letter should also include information which describes “what constitutes a violation of the charge limit,” and that providers are provided notification on their copy of the remittance statements when they exceed the limiting charge. Providers who elected not to receive remittance statements for non-assigned claims, should be reminded that they are still bound by the limiting charge rules, and that they are required to make refunds of overcharges. It may be appropriate at this time for providers to reconsider their decision not to receive remittance forms for non-assigned claims. Providers should also be informed of what action to take in order to receive these statements.

2) Limiting Charge Monitoring Reports (LCMR): Produce LCMRs for all limiting charge violations respective to the provider and which encompasses the last three years. Contractors shall also identify those beneficiaries appearing on the reports who have requested assistance in obtaining a refund from their provider.
1 – Discounts, Rebates, and Other Reductions in Price

1.1 – Anti-Kickback Statute Implications

1.1.1 - Blood Glucose Test Strips - Marketing to Medicare Beneficiaries

1.2 – Cost-Based Payment (Intermediary Processing of Part A Claims): Necessary Factors for Protected Discounts

1.3 – Charge-Based Payment (Intermediary Processing of Part B Claims): Necessary Factors for Protected Discounts

1.4 – Risk-Based Provider Payment: Necessary Factors for Protected Discounts

2 – Hospital Incentives

3 – Breaches of Assignment Agreement by Physician or Other Supplier

4 – Participation Agreement and Limiting Charge Violations

A contractor that learns of a questionable discount program shall contact OIG/OI to determine how to proceed. OIG/OI may ask for immediate referral of the matter for investigation.

1.1.1 - Blood Glucose Test Strips - Marketing to Medicare Beneficiaries - (Rev. 16, 11-28-01)

This section explains marketing practices that could be in violation of the Medicare anti-kickback statute, 42 United States Code (U.S.C.) 1320a-7b(b). There must be compliance with the Medicare anti-kickback statute and the Office of Inspector General’s...
Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.

Marketing practices may influence Medicare beneficiaries who utilize medical supplies, such as blood glucose strips, on a repeated basis. Beneficiaries are advised to report any instances of fraudulent or abusive practices, such as misleading advertising and excessive or non-requested deliveries of test strips, to their Durable Medical Equipment Regional Carriers. **Contractors shall periodically remind suppliers that beneficiaries must specifically request refills of supplies before they are dispensed.**

Advertising incentives that indicate or imply a routine waiver of coinsurance or deductibles could be in violation of 42 U.S.C. 1320a-7b(b). Routine waivers of coinsurance or deductibles are unlawful because they could result in (1) false claims, (2) violation of the anti-kickback statute, and/or (3) excessive utilization of items and services paid for by Medicare.

In addition, 42 U.S.C. 1320a-7a(a) (5) prohibits a person from offering or transferring remuneration. Remuneration is a waiver of coinsurance and deductible amounts with exceptions for certain financial hardship waivers that are not prohibited.

Suppliers should seek legal counsel if they have any questions or concerns regarding waivers of deductibles and/or coinsurance of the propriety of marketing or advertising material.

Any supplier who routinely waives co-payments or deductibles can be criminally prosecuted and excluded from participating in Federal health care programs.

Medicare Program Integrity Manual

Chapter 7 - MR and BI Reports

Table of Contents--(Rev. 16, 11-28-01)

1 - Medicare Focused Medical Review Status Report (MFSR)

2 -Program Integrity Management Reports (PIMR)

3 BMedicare Fraud Unit Quarterly Status Report
5 - Quarterly Carrier MR Savings Report
   5.1 - Purpose and Scope
   5.2 - Submission to CMS
   5.3 - Completing the Carrier MR Savings Report

6 - Quarterly Intermediary MR Savings Report
   6.1 - Submission
   6.2 - Completing the Quarterly Intermediary MR Activity Report
       6.2.1 - Screen 6
       6.2.2 - Screen 7
       6.2.3 - Other Review Data

7 - FMR Activity Report

8 - Report of Benefit Savings (RBS)
   8.1 - Types of Savings to Report- Denials
   8.2 - Completion of the RBS

9 - Retain Data to Support Savings Reported on the RBS

10 - List of MR Codes, Categories, and Conversion Factors for FY 2000

11 - Quality Improvement (QI) Program Report

12 - Vulnerabilities Report
BI units shall assist in protecting the Medicare Trust Fund from those entities that would seek payment for items and services under false or fraudulent circumstances. This includes effectively developing potential fraud cases and referral of them to the Office of Inspector General (OIG) for determining if criminal and/or civil statutes have been violated.

In order to accomplish their responsibilities, CMS requires the Medicare contractors to develop BI QI programs. The purpose of the QI program is to systematically improve the quality of the case referrals; enhance proactive approaches to identify potential fraud; and identify program vulnerabilities resulting from investigative activities. The QI plan shall be submitted each fiscal year to the RO 30 days before the beginning of the fiscal year. The content of the BI QI program shall:

1. Ensure decisions made are effective in preventing, detecting, and deterring potential fraud in the Medicare program;

2. Ensure standard operational procedures are in place and are adhered to and monitored;

3. Improve the case development actions and documentation standards;

4. Ensure the proper handling of complaints;

5. Increase the potential acceptance of OIG case referrals by submitting quality referrals;

6. Improve the working relationship with law enforcement through enhanced networking and training;

7. Improve proactive use of data analysis;

8. Improve the quality of cases referred to law enforcement through partnering. Partnering is an informal meeting with law enforcement to discuss case details prior to referral;

9. Improve communication and coordination efforts with partners (OIG, FBI, other carriers, intermediaries, PSCs, etc.);

10. Implement and maintain a cross-functional data analysis team in each site. It will consist of representation from each functional unit and meet monthly to share data, observations of questionable billing practice patterns, voluntary refund information,
and other concerns;

11. Improve and increase program safeguard actions including payment suspensions, prepayment review and referral to medical review, as appropriate;

12. Ensure proper maintenance and updating of the FID;

13. Ensure the accuracy of medical review decisions made in support of BI. The accuracy of these medical review determinations in support of BI whether made by BI or MR staff shall be a component of the BI QI program.

(Utilizing this tool will increase the number of cases accepted by law enforcement and ensure the efficiency and effectiveness of the program.)

The contractor shall submit the results of the QI program to the RO on a quarterly basis. This report shall include the following information:

- The date QI was performed and by whom;
- The program weakness or vulnerability;
- Source of the program weakness/vulnerability;
- How the program weakness/vulnerability was detected;
- The PIM chapter(s) and section(s) or Program Memorandum (PM) supporting the identification of the program weakness/vulnerability;
- Actions taken to correct the program weakness/vulnerability;
- Actions to avoid the same program weakness/vulnerability from recurring;
- How the weakness/vulnerability is being monitored for compliance;
- The results of individual and unit error rate percentages of quality reviews; and
- A synopsis of management practices within the context of the QI program.

12 - Vulnerability Report--(Rev. 16, 11-28-01)

Program vulnerabilities can be identified through a variety of sources such as the Chief Financial Officer's (CFO) Audit, Fraud Alerts, the General Accounting Office (GAO), the Office of Inspector General (OIG), and contractor operations, as examples. Contractors shall submit any identified program vulnerabilities to CMS RO and CO on a quarterly basis. The identified vulnerabilities shall also include recommendations for resolving the vulnerability and describe the detection methodology.

The contractor shall send the CMS CO a copy of the identified vulnerabilities to the following address:

Centers for Medicare and Medicaid Services (CMS)
Division of Benefit Integrity and Law Enforcement Liaison (DBILEL)
Re: Program Vulnerabilities
Medicare Program Integrity Manual

Exhibits

Table of Contents--(Rev. 16, 11-28-01)

1 - Definitions

3 - Description of CAC Members
   3.1 - Physicians
   3.2 - Clinical Laboratory Representative
   3.3 - Beneficiaries
   3.4 - Other Organizations

4 - Reliable Information

5 - Background Information for Contractor Staff When IRP is Questioned
   5.1 - Reward Eligibility Notification Letter
   5.2 - Reward Claim Form
   5.3 - How to Use the IRP Tracking System
   5.4 - Section I: Pending Case List Screen
   5.5 - Section II: Pending Case List by Contractor Screen
   5.6 - Section III: New Case
   5.7 - Section IV: Closed Case List
   5.8 - Section V: Closed Case List by Contractor
   5.9 - Section VI: Report Menu

6 - LMRP Format
   6.1 - LMRP Submission/Requirements

7 - Sample Letter for On-Site SVRS Reviews
   7.1 - Attachment to Letter for Provider Site SVRS Reviews
   7.2 - Intermediary SVRS Review Procedures Using Statistical Sampling for Overpayment Estimation (Type 2)
   7.3 - Select SVRS Period To Be Reviewed and Composition of Universe
7.4 - Select Sample
    7.4.1 - Select Sample Design
    7.4.2 - Select Sample Size and Claims to Include
    7.4.3 - Document Universe and Frame
    7.4.4 - Actions After Provider and Sample Have Been Selected
        7.4.4.1 - File Compilation and Provider Notification of the Review
7.5 - Exhibit-Sample Letter--Request For Medical Records
7.6 - Exhibit: Part A Sample Letter Notifying the Provider of the SVRS Results, and
    Request Repayment of Overpayments
        7.6.1 - Exhibit: Attachment to the Part A Letter Notifying the Provider of the
                SVRS Results, and Request Repayment of Overpayments
7.7 - Exhibit: Part B Sample Letter Notifying the Provider of the SVRS Results, and
    Request Repayment of Overpayments
        7.7.1 - Exhibit: Attachment to the Part B Letter Notifying the Provider of the
                SVRS Results, and Request Repayment of Overpayments

8 - Recovery of Overpayment and Corrective Actions

9 - Projection Methodologies and Instructions for Reviews of Home Health Agencies

10 - Projection Methodologies and Instructions for Reviews of Skilled Nursing Facilities
     (SNFs)

11 - Projection Methodologies and Instructions for Reviews of Comprehensive
     Outpatient Rehabilitation Facilities (CORFS)

12 - Projection Methodologies and Instructions for Reviews of Community Mental
     Health Centers (CMHCs)

13 - Postpayment CMR Summary Report Format Example

14 - Contractor Denials 1862(a)(1) of the Act
    14.1 - Section 1879 of the Act Determination - Limitation of Liability
    14.2 - Section 1870 of the Act Determination - Waiver of Recovery of an
           Overpayment
    14.3 - Section 1842(l) of the Act Determination - Refunds to Beneficiary

15 - Consent Settlement Documents

16 - Model Suspension of Payment Letters
    16.1 - OIG/OI Case Referral Fact Sheet Format
    16.2 - OIG/OI Case Summary Format

17 - Medicare Fraud Unit Managers

18 - Medicare Fraud Information Specialist (MFIS)
Exhibit 1 - Definitions
(Rev. 16, 11-28-01)

A

Abuse

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

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 claims.
**Contractor**

Contractor includes all intermediaries, carriers, Durable Medical Equipment Regional Carriers (DMERCs), RHHIs, and PSCs.

**Closed Case**

A FID case shall be closed when all fraud development activities are concluded by the contractor and law enforcement. Cases shall be closed even if the contractor is aware that the provider is actively making payments, or is in offset, or if a settlement decision has been reached and the contractor is unaware of the monetary amount being recouped.

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**Exhibit 25 - Form Letter for DOJ Requests**--(Rev. 16, 11-28-01)

**Date**

If request made to CMS:

Centers for Medicaid and Medicare Services
Office of Information Services
Director, Enterprise Databases Group
N2-04-27
Baltimore, Maryland 21244

cc: Regional Office of the Inspector General

If request made to Peer Review Organization (PRO), Fiscal Intermediary (FI), or Carrier:

Name of contact
PRO, FI, or Carrier

Address

cc: Regional Office of the Inspector General
Director, Enterprise Databases Group, CMS

Re: Request for disclosure of data in CMS Systems of Records
Dear (insert):

This letter is to request your assistance in obtaining data from the (insert file name) on (insert type of data needed and providers for which data is needed) for claims during the following time period: (insert time period). Please provide this data in (specify format, i.e., tape, disk, paper, etc.) directly to (insert name, address, telephone number, and role of the person in connection with the case).

Instructions to DOJ attorney or FBI agent filling out form letter: Use alternative paragraph number one, below, if the data is being sought in connection with an investigation of specific allegations of fraud. Use alternative paragraph number two, below, if the data is being sought to detect aberrant billing patterns or other indicia of possible fraud.

Alternative paragraph number one: The Department of Justice, through the undersigned representative of the Federal Bureau of Investigation, an office of the United States Attorney, or an office of the Department of Justice in Washington, D.C., seeks this data to investigate a violation or potential violation of law in CMS-administered health benefits programs (insert industry, entities, or persons). The Department of Justice file number for this matter is: (insert). CMS has issued and published routine uses authorizing disclosure of data in CMS Systems of Records for such purposes. (See 63 Federal Register 38414, July 16, 1998.)

Alternative paragraph number two: The Department of Justice, through the undersigned representative of the Federal Bureau of Investigation, an office of the United States Attorney, or an office of the Department of Justice in Washington, D.C., seeks this data for the purpose of discovering, detecting, and investigating violations or potential violations of law in CMS-administered health benefits programs. The focus of our examination is the following: (insert description of provider type(s) and/or transaction type(s) being examined for potential fraud). CMS has issued and published routine uses authorizing disclosure of data in CMS Systems of Records for such purposes. (See 63 Federal Register 38414, July 16, 1998.)

You can be assured that the DOJ will take all appropriate measures to ensure that this data will be maintained and used in compliance with Section VI (Confidentiality Procedures) of the Health Care Fraud and Abuse Control Program Guidelines agreed to by the Attorney General, the Secretary of the Department of Health and Human Services, and the Health Insurance Portability and Accountability Act of 1996.

I understand that CMS does not commit to processing my request if the estimated cost of doing so exceeds $200,000, and that a CMS representative will contact me if the estimated cost exceeds $200,000. Furthermore, I understand that CMS officials may intercede should a DOJ request for CMS data create a substantial resource impact on the data processing capabilities of the CMS Data Center, a Medicare Fiscal Intermediary,
Carrier, PRO, or other contractor. For requests initiated by the FBI or United States Attorney's offices, discussions to resolve such resource issues will be conducted between the CMS Assistant Regional Administrator for the Division of Financial Management and the appropriate FBI or Assistant United States Attorney (AUSA) supervisor. For requests initiated by DOJ headquarters, or where regional resolution has been unsuccessful, CMS officials may refer such resource issues to the appropriate DOJ headquarters official.

Thank you for your assistance with this matter. Please call me on (insert telephone) if you have any questions about this request.

Sincerely,

(provide name, title, and office)

EXHIBIT 26 - DOJ Report (Excel Spreadsheet)--(Rev. 16, 11-28-01)

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Identification Number</th>
<th>Date of DOJ Request</th>
<th>Nature of Request</th>
<th>DOJ Tracking # (if provided)</th>
<th>Cost to Fill</th>
<th>SBR Y or N</th>
<th>Date of SBR Submission</th>
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</table>

Exhibit 27 - National Medicare Fraud Alert--(Rev. 16, 11-28-01)

National Medicare Fraud Alert Template

NMFA 2001-xx

Date
Distribution of this Fraud Alert is Limited to the Following Audience:
CMS Regional Offices, All Medicare Carrier and Intermediary benefit integrity units, Program Safeguard Contractors, Medicare Integrity Program (MIP) Units, Peer Review Organizations, Medicaid Fraud Control Units, the Office of Inspector General, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney Offices, U.S. Postal Inspectors, Internal Revenue Service, State Surveyors, State Attorneys General, and the State Insurance Division.

**THIS ALERT IS PROVIDED FOR EDUCATIONAL AND INFORMATIONAL PURPOSES ONLY. IT IS INTENDED TO ASSIST PARTIES IN OBTAINING ADDITIONAL INFORMATION CONCERNING POTENTIAL FRAUD AND ABUSE AND TO ALERT AFFECTED PARTIES TO THE NATURE OF THE SUSPECTED FRAUD. IT IS NOT INTENDED TO BE USED AS A BASIS FOR DENIAL OF CLAIMS OR ANY ADVERSE ACTION AGAINST ANY PROVIDER OR SUPPLIER. SUCH DECISIONS MUST BE BASED ON FACTS DEVELOPED INDEPENDENT OF THIS ALERT.**

Exhibit 28 - Restricted Medicare Fraud Alert--(Rev. 16, 11-28-01)

RESTRICTED MEDICARE FRAUD ALERT TEMPLATE
THIS ALERT IS CONFIDENTIAL. It is not intended to be used as a basis for the denial of any claim or adverse action against any provider. Such decisions must be based on facts independent of this alert.

Distribution is Limited to the Following Audience:
CMS Regional Offices, Medicare Carrier and Intermediary benefit integrity units, Program Safeguard Contractors and Medicare Integrity Program Units, Peer Review Organizations, Medicaid Fraud Control Units, the Office of Inspector General, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney Offices, U.S. Postal Inspector Offices, and the Internal Revenue Service.

SUBJECT:

ACTIVITY:

SOURCE:

DISCOVERY:

DETECTION:

FID CASE (S):

STATUS:

CONTACT:

NOTICE: THIS FRAUD ALERT CONTAINS CONFIDENTIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT PURSUANT TO EXEMPTION (b) (2), (b)(5) AND (b)(7)(E) OF THE FOIA. ITS CONTENTS SHOULD NOT BE REPRODUCED OR RELEASED TO ANY OTHER PARTY WITHOUT WRITTEN APPROVAL OF THE BENEFITS INTEGRITY STAFF. DISCLOSURE TO UNAUTHORIZED PERSONS IS PROHIBITED AND MAY BE IN VIOLATION OF THE CRIMINAL PROVISIONS OF THE PRIVACY ACT.
THIS ALERT IS PROVIDED FOR EDUCATIONAL AND INFORMATIONAL PURPOSES ONLY. IT IS INTENDED TO ASSIST PARTIES IN OBTAINING ADDITIONAL INFORMATION CONCERNING POTENTIAL FRAUD AND ABUSE AND TO ALERT AFFECTED PARTIES TO THE NATURE OF THE SUSPECTED FRAUD. IT IS NOT INTENDED TO BE USED AS A BASIS FOR DENIAL OF CLAIMS OR ANY ADVERSE ACTION AGAINST ANY PROVIDER OR SUPPLIER. SUCH DECISIONS MUST BE BASED ON FACTS DEVELOPED INDEPENDENT OF THIS ALERT.