

Medicare Program Integrity Manual

Chapter 4 - Program Integrity

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4.1 - Introduction

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

CMS Pub. 100-08, Program Integrity Manual (PIM), reflects the principles, values, and priorities of the Medicare Integrity Program (MIP). The primary principle of program integrity (PI) is to pay claims correctly. To meet this goal, Zone Program Integrity Contractors (ZPICs) and Medicare Administrative Contractors (MACs) must ensure that Medicare pays the right amount for covered and correctly coded services rendered to eligible beneficiaries by legitimate providers. The Centers for Medicare & Medicaid Services (CMS) follows four parallel strategies in meeting this goal:

1. Prevent fraud through effective enrollment and education of providers/suppliers and beneficiaries;
2. Encourage early detection (through, for example, the Fraud Prevention System (FPS), medical review (MR) and data analysis);
3. Coordinate closely with partners, including other ZPICs, MACs, law enforcement (LE) agencies, and State Program Integrity units; and
4. Enact fair and firm enforcement policies.

The ZPICs shall follow the PIM to the extent outlined in their respective task orders' Statement of Work (SOW). The ZPICs shall only perform the functions outlined in the PIM as they pertain to their own operation. The ZPICs, in partnership with CMS, shall be proactive and innovative in finding ways to enhance the performance of PIM guidelines.

For this entire chapter, and until such time as all ZPICs are awarded, any reference to ZPICs shall also apply to Program Safeguard Contractors (PSCs), unless otherwise noted. All references to ZPICs shall also apply to Unified Program Integrity Contractor (UPIC) unless otherwise specified in the UPIC SOW. MACs shall follow the PIM in accordance with their SOW.

4.1.1 - Definitions

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

To facilitate understanding, the terms used in the PIM are defined in PIM Exhibit 1. The acronyms used in the PIM are listed in PIM Exhibit 23.

4.2 - The Medicare Fraud Program

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs, as indicated.

The primary goal of the ZPIC is to identify cases of suspected fraud, waste and abuse, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid. Payment suspension and

denial of payments and the recoupment of overpayments are examples of the actions that may be taken. Once such actions are taken, cases where there is potential fraud are referred to the OIG/Office of Investigations (OI) field office for consideration and initiation of criminal or civil prosecution, civil monetary penalties, or administrative sanction actions.

Preventing and detecting fraud, waste, and abuse involves a cooperative effort among beneficiaries; ZPICs; MACs; providers/suppliers; quality improvement organizations (QIOs); state Medicaid fraud control units (MFCUs); state Medicaid Program Integrity units; and federal agencies such as CMS; the Department of Health and Human Services (HHS); the OIG; the Federal Bureau of Investigation (FBI); and the Department of Justice (DOJ).

Each investigation is unique and shall be tailored to the specific circumstances. These guidelines are not to be interpreted as requiring the ZPIC to follow a specific course of action or establish any specific requirements on the part of the government or its agents with respect to any investigation. Similarly, these guidelines shall not be interpreted as creating any rights in favor of any person, including the subject of an investigation. When the ZPIC makes the determination of potential fraud, waste, or abuse, the ZPIC shall effectuate all appropriate administrative actions and refer the case to the OIG, if appropriate. When the ZPIC makes the determination that a situation is not potential fraud, the ZPIC shall close the matter, or refer the situation to the appropriate unit at the MAC, QIO, Recovery Auditor (RA), or other entity, when appropriate.

4.2.1 - Examples of Medicare Fraud (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs.

The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program. The violator may be a provider/supplier, a beneficiary, an employee of a provider/supplier, or some other person or business entity, including a billing service or a contractor employee.

Providers/suppliers have an obligation, under law, to conform to the requirements of the Medicare program. Fraud committed against the program may be prosecuted under various provisions of the United States Code and could result in the imposition of restitution, fines, and, in some instances, imprisonment. In addition, a range of administrative sanctions (such as exclusion from participation in the program) and civil monetary penalties may be imposed when facts and circumstances warrant such action.

Fraud may take such forms as (this is not an exhaustive list):

- Incorrect reporting of diagnoses or procedures to maximize payments;

- Billing for services not furnished and/or supplies not provided. This includes billing Medicare for appointments that the patient failed to keep;
- Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both Medicare and the beneficiary for the same service, or billing both Medicare and another insurer in an attempt to get paid twice;
- Altering claim forms, electronic claim records, medical documentation, etc., to obtain a higher payment amount;
- Soliciting, offering, or receiving a kickback, bribe, or rebate (e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment);
- Unbundling or “exploding” charges;
- Completing Certificates of Medical Necessity for patients not personally and professionally known by the provider;
- Participating in schemes that involve collusion between a provider and a beneficiary, or between a supplier a
- Participating in schemes that involve collusion between a provider and a MAC employee where the claim is assigned (e.g., the provider deliberately overbills for services, and the MAC employee then generates adjustments with little or no awareness on the part of the beneficiary);
- Billing based on “gang visits,” (e.g., a physician visits a nursing home and bills for 20 nursing home visits without furnishing any specific service to individual patients);
- Misrepresenting dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services;
- Billing non-covered or non-chargeable services as covered items;
- Repeatedly violating the participation agreement, assignment agreement, or the limitation amount;
- Using another person's Medicare card to obtain medical care;
- Giving false information about provider ownership; or
- Using the adjustment payment process to generate fraudulent payments.

Examples of cost report fraud include (this is not an exhaustive list):

- Incorrectly apportioning costs on cost reports;
- Including costs of non-covered services, supplies, or equipment in allowable costs;
- Providers making arrangements with employees, independent contractors, suppliers, and others that appear to be designed primarily to overcharge the program through various devices (commissions, fee splitting) to siphon off or conceal illegal profits;
- Billing Medicare for costs that were not incurred or were attributable to non-program activities, other enterprises, or personal expenses;
- Repeatedly including unallowable cost items on a provider's cost report for purposes of establishing a basis for appeal;
- Manipulating statistics to obtain additional payment, such as increasing the square footage in the outpatient areas to maximize payment;
- Claiming bad debts without first genuinely attempting to collect payment;
- Making improper payments to physicians for certain hospital-based physician arrangements;
- Paying amounts to owners or administrators that have been determined to be excessive in prior cost report settlements;
- Reporting days improperly that result in an overpayment if not adjusted;
- Depreciating assets that have been fully depreciated or sold;
- Using depreciation methods not approved by Medicare;
- Repaying interest expense for loans that were for an offset of interest income against the interest expense;
- Reporting program data where provider program amounts cannot be supported;
- Allocating costs improperly related to organizations that have been determined to be improper; or
- Manipulating accounting.

4.2.2 - Zone Program Integrity Contractor

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

The ZPIC is responsible for preventing, detecting, and deterring fraud, waste, and abuse in both the Medicare program and the Medicaid program through the collaboration of the Medicare-Medicaid Data Match Program (Medi-Medi). The ZPIC:

- Prevents fraud by identifying program vulnerabilities;
- Proactively identifies incidents of potential fraud, waste, and abuse that exist within its service area and takes appropriate action on each case;
- Investigates (determines the factual basis of) allegations of fraud made by beneficiaries, providers/suppliers, CMS, OIG, and other sources;.
- Explores all available sources of fraud leads in its zone, including the state Medicaid agency and the Medicaid Fraud Control Unit (MFCU);
- Initiates appropriate administrative actions where there is reliable evidence of fraud, including, but not limited to, payment suspensions and revocations;
- Refers cases to the OIG/ OI for consideration of civil and criminal prosecution and/or application of administrative sanctions (see section 4.18 of this chapter, as well as PIM, chapter 8);
- Refers any necessary provider/supplier and beneficiary outreach to the provider outreach and education (POE) staff at the MAC;
- Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups;
- Partners with state Medicaid Program Integrity units to perform the above activities for the Medi-Medi program; or
- Works closely with CMS on joint projects, investigations and other proactive, anti-fraud activities.

The ZPIC is required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent, wasteful, or abusive billing practices based on the various leads they receive.

Proactive leads are leads identified or *self-initiated by the ZPIC*. Examples of proactive leads include, but are not limited to: (1) ZPIC data analysis that uncovers inexplicable aberrancies that indicate potentially fraudulent, wasteful, or abusive billing for specific providers/suppliers; (2) the discovery of a new lead by a ZPIC during a provider/supplier or beneficiary interview; and (3) the combining of information from a variety of sources to create a new lead. The ZPIC shall pursue leads identified through data analysis (ZPICs

shall follow PIM chapter 2, section 2.3 for sources of data), the Internet, the Fraud Investigation Database (FID), news media, industry workgroups, conferences, etc. For workload reporting purposes, the ZPIC shall only identify as proactive those investigations and cases that the ZPIC self-initiated.

The ZPIC shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, (i.e., reviewing data for inexplicable aberrancies and relating the aberrancies to specific providers/suppliers, identifying “hit and run” providers/suppliers, etc.).

Fraud leads from any external source (e.g., LE, CMS referrals, beneficiary complaints, and the FPS) are considered to be reactive and not proactive. However, taking ideas from external sources, such as Fraud Alerts, and using them to look for unidentified aberrancies within ZPIC data is proactive.

4.2.2.1 - Organizational Requirements

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs, as indicated.

ZPIC program integrity (PI) managers shall have sufficient authority to guide PI activities and establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

ZPIC PI managers shall prioritize work coming into the ZPIC to ensure that investigations with the greatest program impact and/or urgency are given the highest priority. The ZPIC shall prioritize all work on an ongoing basis as new work is received. The ZPIC shall follow PIM, chapter 16 for FPS requirements and prioritization. The ZPIC shall prioritize the top 100 Alert Summary Records (ASRs) in the FPS along with other investigation work based on the PIM prioritization requirements in section 4.2.2.1 of this chapter. The ZPIC shall contact its Contracting Officer’s Representative (COR) and Investigations and Audits Group (IAG) Business Function Lead (BFL) if it has any questions or concerns about prioritization of workload.

The UPIC shall follow the FPS requirements in its UPIC SOW for prioritizing leads provided by CMS, including FPS.

Allegations having the greatest program impact would include investigations cases involving:

- Patient abuse or harm
- Multi-state fraud
- High dollar amounts of potential overpayment

- Likelihood of an increase in the amount of fraud or enlargement of a pattern
- LE requests for assistance that involve responding to court-imposed deadlines
- LE requests for assistance in ongoing investigations that involve national interagency (HHS-DOJ) initiatives or projects.
- **Note:** The ZPIC and MAC shall give high priority to fraud, waste, or abuse complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews, and/or medical record reviews, the ZPIC shall 1) conduct an immediate data run to determine possible Medicare losses, and 2) refer the case to the OIG.

4.2.2.2 - Liability of Zone Program Integrity Contractor Employees (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

Under the terms of their contracts (refer to 42 CFR §421.316(a)), ZPICs, their employees, and professional consultants are protected from criminal or civil liability as a result of the activities they perform under their contracts as long as they use due care. If a ZPIC or any of its employees or consultants is named as defendants in a lawsuit, CMS will determine, on a case-by-case basis, whether to request that the U.S. Attorney's office offer legal representation. If the U.S. Attorney's office does not provide legal representation, the ZPIC will be reimbursed for the reasonable cost of legal expenses it incurs in connection with defense of the lawsuit, as long as funds are available and the expenses are otherwise allowable under the terms of the contract.

If a ZPIC is served with a complaint, the ZPIC shall immediately contact its chief legal counsel and the COR. The ZPIC shall forward the complaint to the HHS Office of the Regional Chief Counsel (the CMS regional attorney) who, in turn, will notify the U.S. Attorney's office. The HHS Office of the Regional Chief Counsel and/or the COR will notify the ZPIC whether legal representation will be sought from the U.S. Attorney's office prior to the deadline for filing an answer to the complaint.

4.2.2.3 – Anti-Fraud Training (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

All levels of ZPIC employees shall know the goals and techniques of fraud detection and control in general, and as they relate to their own areas of responsibility and the level of knowledge required (i.e., general orientation for new employees and highly technical sessions for existing staff). All ZPIC staff shall be adequately qualified for the work of detecting and investigating situations of potential fraud, waste, and abuse.

4.2.2.3.1 - Training for Law Enforcement Organizations

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

The FBI agents, OIG, and DOJ attorneys need to understand Medicare. The ZPIC shall conduct special training programs for them upon request. The ZPIC should also consider inviting appropriate DOJ, OIG, and FBI personnel to existing programs for orienting employees about ZPIC operations or provide the aforementioned personnel with briefings on specific cases or Medicare issues.

4.2.2.4 - Procedural Requirements

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs, as indicated.

The MAC personnel conducting each segment of claims adjudication, MR, and professional relations functions shall be aware of their responsibility for identifying potential fraud, waste, or abuse and be familiar with internal procedures for forwarding potential fraud, waste, or abuse instances to the ZPIC. Any area within the MAC (e.g., MR, enrollment, second-level screening staff) that refers potential fraud, waste, and abuse to the ZPIC shall maintain a log of all these referrals. At a minimum, the log shall include the following information: provider/physician/supplier name, beneficiary name, Health Insurance Claim Number (HICN), nature of the referral, date the referral is forwarded to the ZPIC, name and contact information of the individual who made the referral, and the name of the ZPIC to whom the referral was made.

The MAC shall provide written procedures for personnel in various contractor functions (claims processing, MR, beneficiary services, provider/supplier outreach and education (POE), cost report audit, etc.) to help identify potential fraud situations. The MAC shall include provisions to ensure that personnel shall:

- Refer potential fraud, waste, or abuse situations promptly to the ZPIC;
- Forward complaints alleging fraud through the second-level screening staff to the ZPIC;
- Maintain confidentiality of referrals to the ZPIC;
- Forward to the ZPIC detailed documentation of telephone or personal contacts involving fraud issues discussed with providers/suppliers or provider/supplier staff, and retain such information in individual provider/supplier files; and

The ZPIC shall ensure the performance of the functions below and have written procedures for implementing these functions:

Investigations

- Keep educational/warning correspondence with providers/suppliers and other fraud documentation concerning specific issues in individual provider/supplier files so that ZPICs are able to easily retrieve such documentation.
- Maintain documentation on the number of investigations alleging fraud, waste or abuse, the number of cases referred to the OIG/OI (and the disposition of those cases), processing time of investigations, and types of violations referred to the OIG (e.g., item or service not received, unbundling, waiver of co-payment).
- Conduct investigations (following a plan of action) and make the appropriate beneficiary and provider contacts.

Communications/Coordination

- Maintain communication and information flowing between the ZPIC and the MAC MR staff, and as appropriate, MAC audit staff.
- Communicate with the MAC MR staff on all findings of overutilization and coordinate with the MAC POE staff to determine what, if any, education has been provided before any PI investigation is pursued.
- Obtain and share information on health care fraud issues/fraud investigations among MACs, ZPICs, CMS, and LE.
- Coordinate, attend, and actively participate in fraud-related meetings/conferences and inform, as well as include all appropriate parties in these meetings/conferences. These meetings/conferences include, but are not limited to, health care fraud task force meetings, conference calls, and industry-specific events.
- Distribute Fraud Alerts released by CMS to their staff.
- Serve as a resource to CMS, as necessary; for example, serve as a resource to CMS on the FID, provide ideas and feedback on Fraud Alerts and/or vulnerabilities within the Medicare or Medicaid programs.
- Report to the COR and IAG BFL all situations that have been identified where a provider consistently fails to comply with the provisions of the assignment agreement.
- Coordinate and communicate with the MR units within the MACs to avoid duplication of work.

Law Enforcement

- Serve as a reference point for LE and other organizations and agencies to contact when they need help or information on Medicare fraud issues and do not know whom to contact.
- Hire and retain employees who are qualified to testify in a criminal and civil trial when requested by LE.
- Provide support to LE agencies for investigation of potential fraud, including those for which an initial referral to LE did not originate from the ZPIC.
- Meet (in person or via telephone call) with the OIG agents to discuss pending or potential cases, as necessary.
- Meet (in person or via telephone) when needed with the DOJ to enhance coordination on current or pending cases.
- Furnish all available information upon request to the OIG/OI with respect to excluded providers/suppliers requesting reinstatement.
- Notify via e-mail the COR and IAG BFL who will obtain approval or disapproval when the ZPIC is asked to accompany the OIG/OI or any other LE agency onsite to a provider/supplier for the purpose of gathering evidence in a potential fraud case (e.g., executing a search warrant). However, LE must make clear the role of ZPIC personnel in the proposed onsite visit. The potential harm to the case and the safety of ZPIC personnel shall be thoroughly evaluated. The ZPIC personnel shall properly identify themselves as ZPIC employees and under no circumstances shall they represent themselves as LE personnel or special agents. Lastly, under no circumstances shall ZPIC personnel accompany LE in situations where their personal safety is in question.
- Maintain independence from LE and do not collect evidence, i.e., request medical records or conduct interviews, at their request.

Training

- Work with the COR and IAG BFL to develop and organize external programs and perform training, as appropriate, for LE, ombudsmen, grantees (e.g., Senior Medicare Patrols), and other CMS health care partners (e.g., Administration on Aging (AoA), state MFCUs).
- Help to develop fraud-related outreach materials (e.g., pamphlets, brochures, videos) in cooperation with beneficiary services and/or provider relations departments of the MACs for use in their training. Submit written outreach material to the COR and IAG BFL for clearance.

- Assist in preparing and developing fraud-related articles for MAC newsletters/bulletins. Once completed, the ZPIC shall submit such materials to the following email address: CPIFraudRelatedLeads@cms.hhs.gov, with a copy to the CORs and IAG BFLs.
- Provide resources and training for the development of existing employees and new hires.

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

- Ensure no payments are made for items or services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (refer to § 4.19, for exceptions).
- Ensure all instances where an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported to the OIG (refer to PIM, chapter 8,).
- Ensure no payments are made to a Medicare provider/supplier that employs an excluded individual or entity.

4.2.2.4.1 - Maintain Controlled Filing System and Documentation (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

The ZPIC shall maintain files on providers/suppliers who have been the subject of complaints, prepayment edits, ZPIC investigations, OIG/OI and/or DOJ investigations, U.S. Attorney prosecution, and any other civil, criminal, or administrative action for violations of the Medicare or Medicaid programs. The files shall contain documented warnings and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations.

The ZPIC shall set up a system for assigning and controlling numbers at the initiation of investigations, and shall ensure that:

- All incoming correspondence or other documentation associated with an investigation contains the same file number and is placed in a folder containing the original investigation material.
- Investigation files are adequately documented to provide an accurate and complete picture of the investigative effort.
- All contacts are clearly and appropriately documented.
- Each file contains the initial prioritization assigned and all updates.

It is important to establish and maintain histories and documentation on all fraud, waste, and abuse investigations and cases. The ZPIC shall conduct periodic reviews of data over the past several months to identify any patterns of potential fraud, waste, or abusive billings for particular providers. The ZPIC shall ensure that all evidentiary documents are kept free of annotations, underlining, bracketing, or other emphasizing pencil, pen, or similar marks.

The ZPIC shall establish an internal monitoring and investigation review system to ensure the adequacy and timeliness of fraud, waste, and abuse activities.

4.2.2.4.2 - File/Document Retention (Rev. 71, 04-09-04)

Files/documents shall be retained for 10 years. However, files/documents shall be retained indefinitely and shall not be destroyed if they relate to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements, or documents which prompt suspicions of fraud and abuse of overutilization of services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

4.2.2.5 – Reserved for Future Use (Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.5.1 – Reserved for Future Use (Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.5.2 – Reserved for Future Use (Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.6 – Program Integrity Security Requirements (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

To ensure a high level of security for the ZPIC functions, the ZPIC shall develop, implement, operate, and maintain security policies and procedures that meet and conform to the requirements of the Business Partners System Security Manual (BPSSM) and the CMS Informational Security Acceptable Risk Safeguards (ISARS). Further, the ZPIC shall adequately inform and train all ZPIC employees to follow ZPIC security policies and procedures so that the information the ZPIC obtain is confidential.

Note: The data ZPICs collect in administering ZPIC contracts belong to CMS. Thus, the ZPICs collect and use individually identifiable information on behalf of the Medicare program to routinely perform the business functions necessary for administering the Medicare program, such as MR and program integrity activities to prevent fraud, waste,

and abuse. Consequently, any disclosure of individually identifiable information without prior consent from the individual to whom the information pertains, or without statutory or contract authority, requires CMS' prior approval.

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

A. Zone Program Integrity Contractor Operations

- The ZPIC shall conduct their activities in areas not accessible to the general public.
- The ZPIC shall completely segregate itself from all other operations. Segregation shall include floor-to-ceiling walls and/or other measures described in ARS Appendix B PE-3 and CMS-2 that prevent unauthorized persons access to or inadvertent observation of sensitive and investigative information.
- Other requirements regarding ZPIC operations shall include sections 3.1, 3.1.2, 4.2, 4.2.5, and 4.2.6 of the BPSSM.

B. Handling and Physical Security of Sensitive and Investigative Material

Refer to ARS Appendix B PE-3 and CMS-1 for definitions of sensitive and investigative material.

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

- Establish a policy that employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need to know, which includes (this is not an exhaustive list):
 - Appropriate CMS personnel
 - ZPIC staff
 - MAC MR staff
 - ZPIC or MAC audit staff
 - ZPIC or MAC data analysis staff
 - ZPIC or MAC senior management
 - ZPIC or MAC corporate counsel
- The ARSs require that:

- The following workstation security requirements are specified and implemented: (1) what workstation functions can be performed, (2) the manner in which those functions are to be performed, and (3) the physical attributes of the surroundings of a specific workstation or class of workstation that can access sensitive CMS information. CMS requires that for ZPICs all local workstations as well as workstations used at home by ZPICs comply with these requirements.
- If ZPIC employees are authorized to work at home on sensitive data, they shall observe the same security practices that they observe at the office. These shall address such items as viruses, virtual private networks, and protection of sensitive data, including printed documents.
- Users are prohibited from installing desktop modems.
- The connection of portable computing or portable network devices on the CMS claims processing network is restricted to approved devices only. Removable hard drives and/or a Federal Information Processing Standards (FIPS)-approved method of cryptography shall be employed to protect information residing on portable and mobile information systems.
- Alternate work sites are those areas where employees, subcontractors, consultants, auditors, etc. perform work associated duties. The most common alternate work site is an employee's home. However, there may be other alternate work sites such as training centers, specialized work areas, processing centers, etc. For alternate work site equipment controls, (1) only CMS Business Partner-owned computers and software are used to process, access, and store sensitive information; (2) a specific room or area that has the appropriate space and facilities is used; (3) means are available to facilitate communication with the managers or other members of the Business Partner Security staff in case of security problems; (4) locking file cabinets or desk drawers; (5) "locking hardware" to secure IT equipment to larger objects such as desks or tables; and (6) smaller Business Partner-owned equipment is locked in a storage cabinet or desk when not in use. If wireless networks are used at alternate work sites, wireless base stations are placed away from outside walls to minimize transmission of data outside of the building.

The ZPIC shall also adhere to the following:

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

- Direct mailroom staff not to open ZPIC mail in the mailroom unless the ZPIC has requested the mailroom do so for safety and health precautions. Alternately, if mailroom staff opens ZPIC mail, mailroom staff shall not read the contents.
- For mail processing sites separate from the ZPIC, the ZPIC shall minimize the handling of ZPIC mail by multiple parties before delivery to the ZPIC.
- The ZPIC shall mark mail to CMS Central Office or to another ZPIC “personal and confidential” and address it to a specific person.
- Where more specialized instructions do not prohibit ZPIC employees, they may retain sensitive and investigative materials at their desks, in office work baskets, and at other points in the office during the course of the normal work day. Regardless of other requirements, the employees shall restrict access to sensitive and investigative materials, and ZPIC staff shall not leave such material unattended.
- The ZPIC staff shall safeguard all sensitive or investigative material when the materials are being transported or sent by ZPIC staff.
- The ZPIC shall maintain a controlled filing system (refer to section 4.2.2.4.1).

C. Designation of a Security Officer

The security officer shall take such action as is necessary to correct breaches of the security standards and to prevent recurrence of the breaches. In addition, the security officer shall document the action taken and maintain that documentation for at least seven (7) years. Actions shall include:

- Within one (1) hour of discovering a security incident, clearly and accurately report the incident following BPSSM requirements for reporting of security incidents. For purposes of this requirement, a security incident is the same as the definition in section 3.6 of the BPSSM, Incident Reporting and Response.
- Specifically, the report shall address the following where appropriate:
 - Types of information about beneficiaries shall at a minimum address whether the compromised information includes name, address, HICNs, and date of birth;
 - Types of information about providers/suppliers shall at a minimum address if the compromised information includes name, address, and provider/supplier ID;
 - Whether LE is investigating any of the providers/suppliers with compromised information; and
 - Police reports.

- Provide additional information that CMS requests within 72 hours of the request.
- If CMS requests, issue a Fraud Alert to all CMS Medicare contractors within 72 hours of the discovery that the data was compromised, listing the HICNs and provider/supplier IDs that were compromised.
- Within 72 hours of discovery of a security incident, when feasible, review all security measures and revise them if necessary so they are adequate to protect data against physical or electronic theft.

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

D. Staffing of the Zone Program Integrity Contractor and Security Training

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

At the point the ZPIC makes a hiring decision for a ZPIC position, and prior to the selected person's starting work, the ZPIC shall require the proposed candidate to fill out a conflict of interest declaration, as well as a confidentiality statement.

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

The ZPICs shall not employ temporary employees, such as those from temporary agencies, or students (nonpaid or interns).

At least once a year, the ZPICs shall thoroughly explain to and discuss with employees the special security considerations under which the ZPIC operates. Further, this training shall emphasize that in no instance shall employees disclose sensitive or investigative information, even in casual conversation. The ZPIC shall ensure that employees understand the training provided.

Refer to section 2.0 of the BPSSM and ARS Appendix B AT-2, AT-3, AT-4, SA-6, MA-5.0, PE-5.CMS.1, IR2-2.2, CP 3.1, CP 3.2, CP 3.3, and SA 3.CMS.1 for additional training requirements.

E. Access to Zone Program Integrity Contractor Information

Refer to section 2.3.4 of the BPSSM for requirements regarding access to ZPIC information.

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

F. Computer Security

Refer to section 4.1.1 of the BPSSM for the computer security requirements.

G. Telephone and Fax Security

The ZPICs shall implement phone security practices. The ZPICs shall discuss investigations only with those individuals who need to know the information and shall not divulge information to individuals not known to the ZPIC involved in the investigation of the related issue.

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

Employees shall be polite and brief in responding to phone calls but shall not volunteer any information or confirm or deny that an investigation is in process. However, ZPICs shall not respond to questions concerning any case the OIG, the FBI, or any other LE agency is investigating. The ZPICs shall refer such questions to the OIG, the FBI, etc., as appropriate.

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

4.2.3 - Durable Medical Equipment Medicare Administrative Contractor Fraud Functions

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The DME PSCs and the ZPICs shall process all complaints alleging DMEPOS fraud that are filed in their regions/zones in accordance with requirements of PIM Chapter 4, §4.6ff.

The BI unit manager has responsibility for all BI unit activity, including the coordination with outside organizations as specified in the PIM, chapter 4, §4.4.2.1.

A. General Requirements

Since the Medicare program has become particularly vulnerable to fraudulent activity in the DMEPOS area, each DME PSC shall:

- Routinely communicate with and exchange information with its DME PSC MR unit and ensure that referrals for prepayment MR review or other actions are made.
- Consult with the DME PSC medical directors workgroup in cases involving medical policy or coding issues.

Since the Medicare program has become particularly vulnerable to fraudulent activity in the DMEPOS area, each DME PSC and ZPIC shall:

- Fully utilize data available from the MAC with the pricing, data analysis and coding function (PDAC) to identify items susceptible to fraud.

Keep the PDAC contractor, other PSCs and ZPICs, GTLs, Associate GTLs, and SMEs informed of its ongoing activities and share information concerning aberrancies identified using data analysis, ongoing and emerging fraud schemes identified, and any other information that may be used to prevent similar activity from spreading to other jurisdictions.

4.3 – Medical Review for Program Integrity Purposes

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

Medical Review (MR) for Program Integrity (PI) is one of the parallel strategies of the Medicare Integrity Program (MIP) to encourage the early detection of fraud, waste, and abuse. The primary task of the ZPIC is to identify suspected fraud, develop investigations and cases thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any improper payments are identified. For this reason, it is recommended that MR is integrated early into the development of the investigative process. The focus of PI MR includes, but is not limited to:

- Possible falsification or other evidence of alterations of medical record documentation including, but not limited to: obliterated sections; missing pages, inserted pages, white out; and excessive late entries;
- Evidence that the service billed for was actually provided and/or provided as billed; or,
- Patterns and trends that may indicate potential fraud, waste, and abuse.

The statutory authority for the MR program includes the following sections of the Social Security Act (the Act):

- Section 1833(e), which states in part "...no payment shall be made to any provider... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider ...;"
- Section 1842(a)(2)(B), which requires MACs to "assist in the application of safeguards against unnecessary utilization of services furnished by providers ...; "
- Section 1862(a)(1), which states no Medicare payment shall be made for expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member;"

The remainder of Section 1862(a), which describes all statutory exclusions from coverage;

- Section 1893(b)(1) establishes the Medicare Integrity Program, which allows contractors to review activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies. . .")
- Sections 1812, 1861, and 1832, which describe the Medicare benefit categories; and
- Sections 1874, 1816, and 1842, which provide further authority.

The regulatory authority for the MR program rests in:

- 42 CFR §421.100 for intermediaries.
- 42 CFR §421.200 for carriers.
- 42 CFR §421.400 for MACs.

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

purposes. Refer to PIM chapter 2 in its entirety for MR and PI data analysis requirements.

The ZPIC and the MAC MR units shall have ongoing discussions and close working relationships regarding situations identified that may be signs of potential fraud, waste, or abuse. MACs shall also include the cost report audit unit in the on-going discussions. MAC MR staff shall coordinate and communicate with their associated ZPICs to ensure coordination of efforts, to prevent inappropriate duplication of review activities, and to assure contacts made by the MAC are not in conflict with program integrity related activities, as defined by the Joint Operating Agreement (JOA).

It is essential that MR is integrated early in the investigative plan of action to facilitate the timeliness of the investigative process. Before deploying significant MR resources to examine claims identified as potentially fraudulent, the ZPIC may perform a limited prepayment MR to help identify signs of potential fraud, waste, or abuse. The general recommendation for a provider/supplier specific edit would be to limit the prepayment MR to specific procedure codes, a specific number of claims, or based on a particular subset of beneficiaries identified through the ZPIC's analysis. Another option may be for the ZPIC to perform a MR probe to validate the data analysis or allegation by selecting a small representative sample of claims. The general recommendation for a provider/supplier-specific probe sample is 20-40 claims. This sample size should be sufficient to determine the need for additional prepayment or post-payment MR actions. MR resources shall be used efficiently and not cause a delay in the investigative process. In addition, development of an investigation shall continue while the contractor is awaiting the results of the MR.

A. Referrals from the Medicare Administrative Contractor to the Zone Program Integrity Contractor

If a provider/supplier 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 MAC MR unit personnel shall discuss this matter with the ZPIC. If the ZPIC agrees that there is potential fraud, the MAC MR unit shall then make a referral to the ZPIC for investigation.

Provider/supplier documentation that shows a pattern of repeated misconduct or conduct that is clearly abusive or potentially fraudulent, despite provider/supplier education and direct contact with the provider/supplier to explain identified errors, shall be referred to the ZPIC.

The focus of MAC MR is to reduce the error rate through MR and provider/supplier notification and feedback, whereas ZPIC MR for PI focuses on addressing situations of potential fraud, waste, and abuse.

B. Referrals from the Zone Program Integrity Contractor to the Medical Review Unit and Other Units

The ZPICs are also responsible for preventing and minimizing the opportunity for fraud. The ZPICs shall identify procedures that may make Medicare vulnerable to questionable billing or improper practices and take appropriate action.

CMS has implemented recurring edit modules in all claims processing systems to allow ZPICs and/or CMS to monitor specific beneficiary and/or provider/supplier numbers and other claims criteria. When appropriate, the ZPIC may request the MAC to install a prepayment or auto-denial edit. The MACs shall comply with requests from ZPICs and/or CMS to implement those edits. The MACs shall implement parameters for those edits/audits within the timeframe established in the MAC and ZPIC JOA, which shall not exceed more than 15 business days.

C. Program Integrity/Medical Review Determinations

When MAC MR staff is reviewing a medical record for MR purposes, its focus is on making a coverage and/or coding determination. However, when ZPIC staff is performing MR for PI purposes, its focus may be different (e.g., looking for possible falsification). The ZPIC shall follow all chapters of the PIM as applicable unless otherwise instructed in this chapter and/or in its Umbrella Statement of Work (USOW). Chapter 3 of the PIM outlines the procedures to be followed to make coverage and coding determinations.

1. The ZPIC shall maintain current references to support MR determinations. The review staff shall be familiar with the below references and be able to track requirements in the internal review guidelines back to the statute or manual. References include, but are not limited to:
 - CFRs;
 - CMS Internet Only Manuals (IOMs);
 - Local coverage determinations (LCDs);
 - National coverage determinations (NCDs); and
 - Internal review guidelines (sometimes defined as desktop procedures).
2. The ZPIC shall have specific review parameters and guidelines established for the identified claims. Each claim shall be evaluated using the same review guidelines. The claim and the medical record shall be linked by patient name, HICN, diagnosis, Internal Control Number (ICN), and procedure. The ZPIC shall have access to provider/supplier tracking systems from MR. The information on the tracking systems shall be used for comparison to ZPIC findings. The ZPIC shall also consider that the MR department may have established internal guidelines (see PIM, chapter 3).
3. The ZPIC shall evaluate if the provider specialty is reasonable for the procedure(s) being reviewed. As examples, one would not expect to see chiropractors billing for

cardiac care, podiatrists for dermatological procedures, and ophthalmologists for foot care.

4. The ZPIC shall evaluate and determine if there is evidence in the medical record that the service submitted was actually provided, and if so, if the service was medically reasonable and necessary. The ZPIC shall also verify diagnosis and match to age, gender, and procedure.
5. The ZPIC shall determine if patterns and/or trends exist in the medical record that may indicate potential fraud, waste, or abuse or demonstrate potential patient harm. Examples include, but are not limited to:
 - The medical records tend to have obvious or nearly identical documentation.
 - In reviews that cover a sequence of codes (e.g., evaluation and management codes, therapies, radiology), evidence may exist of a trend to use with greater frequency than would be expected the high-end billing codes representing higher level services.
 - In a provider/supplier review, a pattern may be identified of billing more hours of care than would normally be expected on a given workday.
 - The medical records indicate a procedure is being done more frequently than prescribed per suggested CMS guidance or industry standards of care, resulting in potential situations of patient harm.
6. The ZPIC shall evaluate the medical record for evidence of alterations including, but not limited to, obliterated sections, missing pages, inserted pages, white out, and excessive late entries. The ZPIC shall not consider undated or unsigned entries handwritten in the margin of a document. These entries shall be excluded from consideration when performing medical review. See chapter 3 for recordkeeping principles.
7. The ZPIC shall document errors found and communicate these to the provider/supplier in writing when the ZPIC's review does not find evidence of questionable billing or improper practices. A referral may be made to the POE staff at the MAC for additional provider/supplier education and follow up, if appropriate (see PIM, chapter 3).
8. The ZPIC shall adjust the service, in part or in whole, depending upon the service under review, when medical records/documentation do not support services billed by the provider/supplier.
9. The ZPIC shall thoroughly document the rationale utilized to make the MR decision.

D. Quality Assurance

Quality assurance activities shall ensure that each element is being performed consistently and accurately throughout the ZPIC's MR for PI program. In addition, the ZPIC shall have in place procedures for continuous quality improvement in order to continually improve the effectiveness of their processes.

1. The ZPIC shall assess the need for internal training on changes or new instructions (e.g., through minutes, agendas, sign-in sheets) and confirm with staff that they have participated in training as appropriate. The ZPIC staff shall be able to request training on specific issues.
2. The ZPIC shall evaluate internal mechanisms to determine whether staff members have correctly interpreted the training (training evaluation forms, staff assessments) and demonstrated the ability to implement the instruction (internal quality assessment processes).
3. The ZPIC shall have an objective process to assign staff to review projects, ensuring that the correct level of expertise is available. For example, situations dealing with therapy issues may include review by an appropriate therapist or use of a therapist as a consultant to develop internal guidelines. Situations with complicated or questionable medical issues, or where no policy exists, may require a physician consultant (medical director or outside consultant).
4. The ZPIC shall develop a system to address how it will monitor and maintain accuracy in decision making (inter-reviewer reliability) as referenced in chapter 3 of the PIM. The ZPIC shall establish a Quality Improvement (QI) process that verifies the accuracy of MR decisions made by licensed health care professionals. ZPICs shall include inter-rater reliability and/or peer-review assessments in their QI process and shall report these results as directed by CMS.
5. When the ZPIC evaluation results identify the need for prepayment edit placement at the MAC, the ZPIC shall have a system in place to evaluate the effectiveness of those edits on an ongoing basis as development continues. The MAC may provide the claims data necessary to the ZPIC to evaluate edits submitted at the request of the ZPIC. The evaluation of edits shall consider the timing and staffing needs for reviews. The ZPIC may submit an inquiry to the MAC to verify that a new edit is accomplishing its objective of selecting claims for MR 30 business days after an edit has been implemented or placed into production. The ZPIC shall use data analysis of the selected provider's claims history to verify possible changes in billing patterns.

Automated edits shall be evaluated annually.

Prepayment edits shall be evaluated on a quarterly basis. They shall be analyzed in conjunction with data analysis to confirm or re-establish priorities. For example, a prepayment edit is implemented to stop all claims with a specific diagnostic/procedure code and the provider stops submitting claims with that code to circumvent the edit. Data

analysis shall be used to identify if the provider's general billing pattern has changed in volume and/or to another/similar code that may need to be considered/evaluated to revise the current edit in question and/or expansion of the current investigation.

4.4 - Other Program Integrity Requirements

(Rev. 71, 04-09-04)

4.4.1 - Requests for Information From Outside Organizations

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

Federal, state, and local LE agencies may seek beneficiary and provider/supplier information to further their investigations or prosecutions of individuals or businesses alleged to have committed health care fraud and other crimes for which medical records may be sought as evidence. When these agencies request that a ZPIC disclose beneficiary records or provider/supplier information, the responsive disclosure shall comply with applicable federal law as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Business Associate provision of the ZPIC's contract. Federal law will dictate whether, and how much, requested information can be disclosed. The determination regarding disclosure will be contingent on the purpose for which it is sought and whether information is sought about beneficiaries or providers/suppliers. For example, certain general information that does not include specific beneficiary identifiers may be shared with a broader community, including private insurers. The information may include that of a general nature of how fraudulent practices were detected, the actions being taken, and aggregated data showing trends and/or patterns.

The ZPIC may release information, in accordance with the requirements specified in Sections A – G below, to the following organizations:

- Other ZPICs
- Qualified Independent Contractors (QICs)
- Quality Improvement Organizations (QIOs)
- State Attorneys General and State Agencies
- Medicaid Fraud Control Units (MFCUs)
- OIG
- DOJ
- FBI

Requests for information from entities not listed above shall be submitted to the COR for approval, with a copy to the IAG BFL.

In deciding to share information voluntarily or in response to outside requests, the ZPIC shall carefully review each request to ensure that disclosure would not violate the requirements of the Privacy Act of 1974 (5 U.S.C. §552a) and/or the Privacy Rule (45

CFR, Parts 160 and 164) implemented under the HIPAA. Both the Privacy Act and the Privacy Rule seek to strike a balance that allows the flow of health information needed to provide and promote high-quality health care while protecting the privacy of people who seek this care. In addition, both statutes provide individuals with the right to know with whom their personal information has been shared, necessitating the tracking of any disclosures of information by the ZPIC. The ZPIC shall direct questions concerning what information may be disclosed under the Privacy Act or Privacy Rule to the CMS Regional Office Freedom of Information Act (FOIA)/privacy coordinator. Ultimately, the authority to release information from a Privacy Act System of Records to a third-party rests with the system manager/business owner of the system of records.

The HIPAA Privacy Rule establishes national standards for the use and disclosure of individuals' health information (also called protected health information [PHI]) by organizations subject to the Privacy Rule (which are called "covered entities"). As "business associates" of CMS, ZPICs are contractually required to comply with the HIPAA Privacy Rule. The Privacy Rule restricts the disclosure of any information, in any form, that can identify the recipient of medical services; unless that disclosure is expressly permitted under the Privacy Rule. Two of the circumstances in which the Privacy Rule allows disclosure are for "health oversight activities" (45 CFR §164.512(d)) and for "law enforcement purposes" (45 CFR §164.512 (f)), provided the disclosure meets all the relevant prerequisite procedural requirements in those subsections. Generally, PHI may be disclosed to a health oversight agency (as defined in 45 CFR §164.501) for purposes of health oversight activities authorized by law, including administrative, civil, and criminal investigations necessary for appropriate oversight of the health care system (45 CFR §164.512(d)). The DOJ, through its United States Attorneys' Offices and its headquarters-level litigating divisions; the FBI; the HHS OIG; and other federal, state, or local enforcement agencies, are acting in the capacity of health oversight agencies when they investigate fraud against Medicare, Medicaid, or other health care insurers or programs.

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

The Privacy Act of 1974 protects information about an individual that is collected and maintained by a federal agency in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency. This includes, but is not limited to, information about educational background, financial transactions, medical history, criminal history, or employment history that

contains a name or an identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voiceprint or a photograph. A “system of records” is any group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identification assigned to the individual. For example, Medicare beneficiary data used by ZPICs are maintained in a CMS “system of records” covered by the Privacy Act.

Information from some systems of records may be released only if the disclosure would be consistent with “routine uses” that CMS has issued and published. Routine uses specify who may be given the information and the basis or reason for access that must exist. Routine uses vary by the specified system of records, and a decision concerning the applicability of a routine use lies solely in the purview of the system’s manager for each system of records. In instances where information is released as a routine use, the Privacy Act and Privacy Rule remain applicable. For example, the HHS has published a routine use that permits the disclosure of personal information concerning individuals to the DOJ, as needed for the evaluation of potential violations of civil or criminal law and for detecting, discovering, investigating, litigating, addressing, or prosecuting a violation or potential violation of law, in health benefits programs administered by CMS. Refer to 63 Fed. Reg. 38414 (July 16, 1998).

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

The Privacy Act permits disclosure of a record without the prior written consent of an individual if at least one (1) of 12 disclosure provisions apply. Two of these provisions, the “routine use” provision and/or another “law enforcement” provision, may apply to requests from the DOJ and/or the FBI.

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

Both the Fiscal Intermediary Shared System (FISS) #8 and #10, the Multi-Carrier System (MCS), and the VIPS Medicare System (VMS) contain a routine use that permits disclosure to:

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

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

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

In most cases, such 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 (1) of the 11 other exceptions to the Privacy Act applies.

The LE provision may apply to requests from the DOJ and/or the 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 LE 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 that maintains the record specifying the particular portion desired and the LE activity for which the record is sought.”

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

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

A. Requests from Private, Non-Law Enforcement Agencies

Generally, ZPICs may furnish information on a scheme (e.g., where it is operating, specialties involved). Neither the name of a beneficiary or suspect can be disclosed. If it is not possible to determine whether or not information may be released to an outside entity, the ZPIC shall contact its COR and IAG BFL for further guidance.

B. Requests from Other Zone Program Integrity Contractors

The ZPICs may furnish requested specific information concerning ongoing fraud investigations and individually identifiable PHI to any ZPIC or MAC. ZPICs and MACs are “business associates” of CMS under the Privacy Rule and thus are permitted to exchange information necessary to conduct health care operations. If the request

concerns investigations already referred to the OIG/OI, the ZPIC shall notify the OIG/OI of the request for information received from another ZPIC and notify the requesting ZPIC that the case has been referred to the OIG/OI.

C. Requests for Information from Qualified Independent Contractors

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

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

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

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

D. Requests from Quality Improvement Organizations and State Survey and Certification Agencies

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

E. Requests from State Attorneys General and State Agencies

The ZPIC may furnish requested specific information on ongoing fraud investigations to state Attorneys General and to state agencies. Releases of information to these entities in connection with their responsibility to investigate, prosecute, enforce, or implement a

state statute, rule, or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. (Refer to subsection H below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule.) The ZPIC may, at its discretion, share PIM Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, the ZPIC shall refer the requestor to the OIG/OI.

F. Requests from Medicaid Fraud Control Units

Under current Privacy Act requirements applicable to program integrity investigations, the ZPIC may respond to requests from MFCUs for information on current investigations. Releases of information to MFCUs in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). Refer to subsection H below for further information regarding the Privacy Act requirements. If individually identifiable PHI is requested, the disclosure shall comply with the Privacy Rule. Refer to subsection H below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule.

The ZPIC may, at its discretion, share PIM Exhibit 25 with the requestors as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, the ZPIC shall refer the requestor to the OIG/OI.

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

The ZPIC shall provide the OIG/OI with requested information and shall maintain cost information related to fulfilling these requests. A request for information shall consist of requests to run data for the OIG, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Such requested information may include LE requests for voluntary refund data (see section 4.16 of this chapter). The ZPIC shall not fulfill a request if there is a substantial impact (i.e., 40 hours or more) on the budget without prior COR approval. The ZPIC shall copy the IAG BFL on these requests for approval from the COR. 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/supplier. The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) calendar days when the information or material is contained in the ZPIC's files unless an exception exists as described below.

The ZPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested within 30 calendar days or sooner, when possible. The MAC

shall furnish requested information to the ZPIC within 20 calendar days of receipt of the request from the ZPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the ZPIC and the MAC COR as soon as they become known. The ZPIC shall communicate these extenuating circumstances to its COR. The ZPIC shall follow up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the ZPIC from meeting the thirty (30) day timeframe, the ZPIC shall inform the requestor what, if any, portion of the request can be provided within thirty (30) days. The ZPIC shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The ZPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

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

Priority II – This type of request is less critical than a Priority I request. A request for information shall consist of requests to run data for the OIG, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Based on the review of its available resources, the ZPIC shall inform the requestor what, if any, portion of the request can be provided. The ZPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The ZPICs shall respond to such requests within 45 calendar days or sooner, when possible. The MAC shall furnish requested information to the ZPIC within 30 calendar days of receipt of the request from the ZPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the ZPIC and the MAC COR as soon as they become known. The ZPIC shall communicate these extenuating circumstances to its COR. The ZPIC shall follow up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the ZPIC from meeting the 45-day timeframe, the ZPIC shall inform the requestor what, if any, portion of the request can be provided within 45 calendar days. The ZPIC shall notify the requesting office as soon as possible (but not later than 45 calendar days) after receiving the request. The ZPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

Request for Assistance – A LE request for assistance (RFA) is a type of request for information and shall consist of any LE requests that do not include running data and reports, but include requests such as the review and interpretation of medical records/medical documentation, interpretation of policies, and reviewing cost reports. The timeframes for RFIs specified in Priority I and II do not apply to RFAs. Due dates shall be negotiated with the requesting entity and documented appropriately along with the reasons for not meeting the agreed upon timeframes. The ZPIC shall contact the COR if an agreement cannot be reached on the timeframe for completion. Disclosures of

information to the OIG shall comply with the Privacy Rule and Privacy Act. When the OIG makes a data request, the ZPIC shall track these requests and document the following: (1) nature/purpose of the disclosure (cite a specific investigation and have a general description); (2) what information was disclosed; and (3) name of the individual and the agency. The aforementioned information shall be maintained in a secure file and made available to CMS upon request through a secure means.

CMS has established a level of effort limit of 40 hours for any individual request for support (Requests for Information and Requests for Assistance). If the estimated level of effort to fulfill any one request is likely to meet or exceed this figure, the ZPIC shall contact its COR for approval to proceed. A CMS representative will contact the OIG to explore the feasibility of other data search and/or production options.

The ZPIC shall obtain approval from the COR regarding requests started by the ZPIC that they subsequently anticipate will exceed that 40-hour level of effort. The ZPIC shall not exceed the 40-hour level of effort until it receives COR approval.

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

In April 1994, CMS entered into an interagency agreement with the OIG and the DOJ that permitted ZPICs to furnish information that previously had to be routed through OIG (refer to PIM Exhibit 16) including data related to the investigation of health care fraud matters directly to the DOJ that previously had to be routed through OIG (refer to PIM Exhibit 35). This agreement was supplemented on April 11, 2003, when in order to comply with the HIPAA Privacy Rule, the DOJ issued procedures, guidance, and a form letter for obtaining information (refer to PIM Exhibit 25). CMS and the DOJ have agreed that the DOJ's requests for individually identifiable health information will follow the procedures that appear on the form letter (refer to PIM Exhibit 25). The 2003 form letter must be customized to each request. The form letter mechanism is not applicable to requests regarding Medicare Secondary Payer (MSP) information, unless the DOJ requestor indicates he or she is pursuing an MSP fraud matter.

The PIM Exhibit 25 contains the entire document issued by the DOJ on April 11, 2003. The ZPIC shall familiarize itself with the instructions contained in this document. Data requests for individually identifiable PHI related to the investigation of health care fraud matters will come directly from those individuals at the FBI or the DOJ who are involved in the work of the health care oversight agency (including, for example, FBI agents, Assistant United States Attorneys (AUSAs), or designees such as analysts, auditors, investigators, or paralegals). For example, data may be sought to assess allegations of fraud; examine billing patterns; ascertain dollar losses to the Medicare program for a procedure, service, or time period; determine the nature and extent of a provider's/supplier's voluntary refund(s); or conduct a random sample of claims for MR. The LE agency should begin by consulting with the appropriate Medicare contractor (usually the ZPIC, but possibly also the MAC) or CMS to discuss the purpose or goal of the data request. Requests for cost report audits and/or associated documents shall be referred directly to the appropriate MAC.

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

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

If the DOJ confirms that claims data are necessary, the DOJ will prepare a formal request letter to the ZPIC with existing DOJ guidance (Exhibit 15).

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

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

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider/supplier. A request for information shall consist of requests to run data for the DOJ, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). The request shall be completed with the utmost urgency. Priority I requests shall be fulfilled within thirty (30) calendar days when the information or material is contained in the ZPIC's files unless an exception exists as described below.

The ZPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested within 30 calendar days or sooner, when possible. The MAC shall furnish requested information to the ZPIC within 20 calendar days of receipt of the request from the ZPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the ZPIC and the MAC COR as soon as they become known. The ZPIC shall communicate these extenuating circumstances to its COR. The ZPIC shall follow up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the ZPIC from meeting the thirty (30) day timeframe, the ZPIC shall inform the requestor what, if any, portion of the request can be provided within thirty (30) days. The ZPIC shall notify the requesting office as soon as possible (but not later than thirty (30) days) after receiving the request. The ZPIC shall also

document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

If the request requires that the ZPIC access NCH using DESY, the thirty (30) day timeframe for Priority I requests does not apply.

Priority II Requests – This type of request is less critical than a Priority I request. A request for information shall consist of requests to run data for the DOJ, extract of records, or a request to furnish any documentation or reports (see below for requests for assistance). Based on the review of its available resources, the ZPIC shall inform the requestor what, if any, portion of the request can be provided. The ZPIC shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The ZPIC shall respond to such requests within 45 calendar days or sooner, when possible. The MAC shall furnish requested information to the ZPIC within 30 calendar days of receipt of the request from the ZPIC unless there are extenuating circumstances. The MAC shall communicate any extenuating circumstances to the ZPIC and the MAC COR as soon as they become known. The ZPIC shall communicate these extenuating circumstances to their COR. The ZPIC shall follow up with other contractors, and document all communication with contractors to ensure the request is not delayed unnecessarily. If extenuating circumstances exist that prevent the ZPIC from meeting the 45-day timeframe, the ZPIC shall inform the requestor what, if any, portion of the request can be provided within 45 calendar days. The ZPIC shall notify the requesting office as soon as possible (but not later than 45 calendar days) after receiving the request. The ZPIC shall also document all communication with the requesting office regarding the delay, and shall include an estimate of when all requested information will be supplied.

Request for Assistance – A LE request for assistance (RFA) is a type of request for information and shall consist of any LE requests that do not include running data and reports, but include requests such as the review and interpretation of medical records/medical documentation, interpretation of policies, and reviewing cost reports. The timeframes for RFIs specified in Priority I and II do not apply to RFAs. Due dates shall be negotiated with the requesting entity and documented appropriately along with the reasons for not meeting the agreed upon timeframes. The ZPIC shall contact the COR if an agreement cannot be reached on the timeframe for completion.

Disclosures of information to the DOJ shall comply with the Privacy Rule and Privacy Act. When DOJ makes a data request, the ZPIC shall track these requests and document the following: (1) nature/purpose of the disclosure (cite a specific investigation and have a general description); (2) what information was disclosed; and (3) name of the individual and the agency. The aforementioned information shall be maintained in a secure file and made available to CMS upon request through a secure means.

CMS has established a level of effort limit of 40 hours for any individual request for support (RFIs and RFAs). If the estimated level of effort to fulfill any one request is

likely to meet or exceed this figure, the program integrity contractor shall contact its COR for approval to proceed. A CMS representative will contact the OIG to explore the feasibility of other data search and/or production options.

The ZPIC shall obtain approval from the COR regarding requests started by the ZPIC that they subsequently anticipate will exceed that 40-hour level of effort. The ZPIC shall not exceed the 40-hour level of effort until it receives COR approval.

I. Duplicate/Similar Requests for Information

If the ZPIC receives duplicate or similar requests for information from OIG and DOJ, the ZPIC shall notify the requestors. If the requestors are not willing to share the information, the ZPIC shall ask the COR and IAG BFL for assistance.

J. Reporting Requirements for the DOJ and OIG

For each data request received from the DOJ and the OIG, the ZPIC 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
- The cost of furnishing a response to each request
- The date completed

K. Law Enforcement Requests for Medical Review

The ZPIC shall not send document request letters or go onsite to providers/suppliers to obtain medical records solely at the direction of LE. However, if LE furnishes the medical records and requests the ZPIC to review and interpret medical records for them, the ZPIC shall require LE to put this request in writing. At a minimum, this request shall include the following information:

- The nature of the request (e.g., what type of service is in question, what is the allegation, and what should the reviewer be looking for in the medical record);
- The volume of records furnished;
- The due date; and
- The format required for response.

The ZPIC shall present the written request to the COR, and copy its IAG BFL prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the ZPIC has resources to fulfill the request. If so, the request may be approved.

If LE requests the ZPIC to perform MR on all investigations the ZPIC initiates, the ZPIC shall perform MR if it deems it necessary, on a case-by-case basis. The ZPIC shall inform the COR and copy its IAG BFL of such requests by LE.

It is recommended that the MR Manager be included in the evaluation of the Request for MR to provide input as to:

- The resources required;
- The resources available; and,
- Recommended revisions to the volume of records to be reviewed that will still provide a statistically and clinically significant sample to support the purpose or allegation in the request and provide for the best use of MR resources.

L. Law Enforcement Requests for ZPIC Audits of Medicare Provider Cost Reports Relating to Fraud

If LE requests the ZPIC to perform an audit of a Medicare provider's cost report for fraud, the ZPIC shall consult with the MAC to inquire if an audit of the cost report has already been performed. The ZPIC shall also consult with the COR and IAG BFL. The ZPIC shall provide its COR and copy its IAG BFL with the basis for the LE request and a detailed cost estimate to complete the audit. If the COR approves the audit, the ZPIC shall perform the audit within the time frame and cost agreed upon with LE.

M. Requests from Law Enforcement for Information Crossing Several ZPIC Zones

If a ZPIC receives a request from LE for information that crosses several ZPIC zones, the ZPIC shall contact its COR and IAG BFL. In the event that multiple zones are providing information in connection with the request, each ZPIC shall enter a separate entry into the FID as described in section 4.11.2.8 of this chapter. The COR and IAG BFL may assign a lead ZPIC to process these requests.

4.4.1.1 - Reserved for Future Use

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

4.4.2 - Zone Program Integrity Contractor Coordination with Other Zone Program Integrity Contractors

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

The ZPIC shall coordinate with ZPICs in other zones, as directed in the USOW and Task Order Statement of Works (SOWs).

4.4.2.1 - Zone Program Integrity Contractor Coordination with Other Entities

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

The ZPIC shall establish and maintain formal and informal communication with state survey agencies, the OIG, the DOJ, state Medicaid agency, other Medicare contractors, other ZPICs, and other organizations as applicable to determine information that is available and that should be exchanged to enhance program integrity activities.

If the ZPIC identifies a potential quality problem with a provider or practitioner in its area, it shall refer such cases to the appropriate entity, be it the QIO, state medical board, state licensing agency, etc. Any provider-specific information shall be handled as confidential information.

4.4.3 - Reserved for Future Use

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

4.5 - Reserved for Future Use

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

4.6 - Complaints

(Rev. 71, 04-09-04)

4.6.1 - Definition of a Complaint

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs.

A complaint is a statement, oral or written, alleging that a provider, supplier, or beneficiary received a Medicare reimbursement or benefit to which he or she is not entitled under current Medicare law, regulations, or policy. Included are allegations of misrepresentation and violations of Medicare requirements applicable to persons or entities that bill for covered items and services. Examples of complaints include (this is not an exhaustive list):

- Allegations that items or services were not received;
- Allegations that items or services were not furnished as shown on the Explanation of Medicare Benefits (EOMB), Notice of Utilization (NOU), or Medicare Summary Notice (MSN), or that the services were not performed by the provider/supplier shown;
- Allegations that a provider/supplier is billing Medicare for a different item or service than was furnished;

- Allegations that a provider or supplier has billed both the beneficiary and Medicare for the same item or service;
- Allegations regarding waiver of co-payments or deductibles;
- Allegations that a supplier or provider has misrepresented itself as having an affiliation with an agency or department of the state, local, or federal government, whether expressed or implied; and
- Allegations or inquiries from a beneficiary concerning payment for an item or service-that, in his/her opinion far exceeds reasonable payment for the item or service that the beneficiary received (e.g., the supplier or physician has “upcoded” to receive higher payment).

The following are not examples of a fraud complaint (this is not an exhaustive list):

- Complaints or inquiries regarding Medicare coverage policy;
- Complaints regarding the appeals process;
- Complaints over the status of a claim;
- Requests for an appeal or reconsideration; or
- Complaints concerning providers or suppliers (other than those complaints meeting the criteria established above) that are general in nature and are policy- or program-oriented.

Complaints alleging malpractice or poor quality of care may or may not involve a fraudulent situation. These complaints shall be reviewed and determined on a case-by-case basis. The ZPIC shall refer complaints alleging poor quality of care to the Medicare/Medicaid survey and certification agencies and the QIOs within two (2) business days. The ZPIC shall forward any medical records to the QIO upon receipt from the provider, when appropriate. Any complaints involving allegations of fraud shall be screened to determine if further investigation by the ZPIC is necessary.

4.6.2 - Complaint Screening

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs, Beneficiary Contact Center (BCC), and MACs, as indicated.

The BCC and MAC shall be responsible for screening all complaints of potential fraud, waste, and abuse. This screening shall occur in the two phases described below.

A. Initial Screening – Beneficiary Contact Center

The Customer Service Representatives (CSRs) at the BCC shall try to resolve as many complaints or inquiries as possible in the initial screening with data available in their desktop systems. The following are some scenarios that a CSR may receive and resolve in the initial phone call rather than refer to second-level screening (this is not an all-inclusive list):

- Lab Tests - CSRs shall ask callers if they recognize the referring physician. If they do, remind callers that the referring physician may have ordered some lab work for them. The beneficiaries usually do not have contact with the lab because specimens are sent to the lab by the referring physician office. (Tip: ask if they remember the doctor withdrawing blood or obtaining a tissue sample on their last visit).
- Anesthesia Services - CSRs shall check the beneficiary claims history for existing surgery or assistant surgeon services on the same date. If a surgery charge is on file, explain to the caller that anesthesia service is part of the surgery rendered on that day.
- Injections - CSRs shall check the beneficiary claim history for the injectable (name of medication) and the administration. Most of the time, the administration of the injection is not payable, as it is a bundled service under Part B only. There are very few exceptions to pay for the administration.
- Services for Spouse - If the beneficiaries state that services were rendered to their spouse and the HICNs are the same, with a different suffix, the CSR shall initiate the adjustment and the overpayment processes.
- Billing Errors - If the beneficiaries state that they already contacted their provider/supplier and the provider/supplier admitted there was a billing error but a check is still outstanding, the CSR shall follow the normal procedures for resolving this type of billing error.
- Services Performed on a Different Date - The beneficiaries state that a service was rendered, but on a different date. The CSR shall review the beneficiary claim history to determine if there are multiple dates billed for this service. If not, an adjustment to the claim may be required to record the proper date on the beneficiaries' file.
- Incident to Services - Services may be performed by a nurse in a doctor's office as "incident to." These services are usually billed under the physician's provider/supplier transaction access number (PTAN) (e.g., blood pressure check, injections). These services may be billed under the minimal evaluation and management codes.
- Billing Address vs. Practice Location Address - The CSR shall check the practice location address where services were rendered. Many times the Medicare

Summary Notice will show the billing address, causing the beneficiaries to think the billing might be fraud.

The CSRs shall use proper probing questions and shall use claim history files to determine if the complaint or inquiry needs to be referred for second-level screening.

Any provider/supplier inquiries regarding potential fraud, waste, and abuse shall be forwarded immediately to the second-level screening staff at the MAC for handling.

Immediate advisements shall be forwarded immediately to the second-level screening staff at the MAC for handling. These advisements include inquiries or allegations by beneficiaries or providers/suppliers concerning kickbacks, bribes, or a crime by a federal employee (e.g., altering claims data or manipulating them to create preferential treatment to certain providers/suppliers; improper preferential treatment collecting overpayments; or embezzlement). Indicators of contractor employee fraud shall be forwarded to the CMS Compliance Group.

The OIG Hotline is an OIG managed system that accepts tips and complaints from all sources about potential fraud, waste, abuse in the Medicare, Medicaid and CHIP programs. Complaints and any relevant documents originating from the OIG Hotline will be sent to the responsible MAC by the OIG via e-mail. Each MAC shall establish a resource mailbox to receive complaints from the OIG. The MAC shall review these complaints and process them in accordance with all other applicable complaint screening processes unless otherwise noted. Complaints originating from the OIG Hotline that the MAC receives must include a Medicare number and/or complainant contact information. Upon receipt of an OIG Hotline complaint, the complaint shall be forwarded immediately to the second-level screening staff at the MAC for review and processing. If the complaint does not include a Medicare number and/or complainant contact information, the complaint shall be closed with no further action necessary.

B. Second-Level Screening – MAC

When the complaint or inquiry cannot be resolved by the CSR at the BCC, the issue shall be referred for more detailed screening, resolution, or referral, as appropriate, to the MAC. The second-level screening staff at the MAC shall only screen potential fraud, waste, and abuse complaints or inquiries with a paid amount of \$100 or greater (including the deductible as payment) or three (3) or more beneficiary complaints or inquiries, regardless of dollar amount, about the same provider/supplier. Each complaint or inquiries shall be tracked and retained for one (1) year. Beneficiaries inquiring about complaints should be advised that they are being tracked and reviewed. The MAC shall perform a more in-depth review if additional complaints or inquiries are received. Complaints or inquiries that do not meet the threshold for second-level screening shall be closed. The second-level screening staff at the MAC shall maintain a log of all potential fraud, waste, and abuse complaints or inquiries received from the initial screening staff. At a minimum, the log shall include the following information:

- Beneficiary name;
- Provider/supplier name;
- Beneficiary HICN;
- Nature of the inquiry;
- Date received from the initial screening staff;
- Date referral was sent to the ZPIC;
- Destination of the referral (i.e., name of the ZPIC);
- Documentation that a complaint or inquiry received from the initial screening staff was not forwarded to the ZPIC and an explanation why (e.g., inquiry was misrouted or inquiry was a billing error that should not have been referred to the second-level screening staff); and
- Date complaint or inquiry was closed.

The MAC staff shall call the beneficiary or the provider/supplier, check claims history, and check provider/supplier correspondence files for educational or warning letters or contact reports that relate to similar complaints or inquiries, to help determine whether or not there is a pattern of potential fraud, waste, and abuse. The MAC shall request and review certain documents, such as itemized billing statements and other pertinent information, as appropriate, from the provider/supplier. If the MAC is unable to make a determination on the nature of the complaint or inquiry (e.g., fraud, waste, and abuse, billing errors) based on the aforementioned contacts and documents, the MAC shall order medical records and limit the number of medical records ordered to only those required to make a determination.

If the medical records are not received within 45 business days, the claim(s) shall be denied. If fraud is suspected when medical records are not received, these situations shall be referred to the ZPIC. The second-level screening staff shall only perform a billing and document review on medical records to verify that services were rendered. If fraud, waste, and abuse are suspected after performing the billing and document review, the medical record shall be forwarded to the ZPIC-for clinician review. If the MAC staff determines that the complaint or inquiry is not a fraud and/or abuse issue, and if the staff discovers that the complaint or inquiry has other issues (e.g., MR, enrollment, claims processing), it shall be referred to the appropriate department and then closed.

If the MAC second-level screening staff determines that the complaint or inquiry is a potential fraud, waste, and abuse situation, the second-level screening staff shall forward it to the ZPIC for further development within 45 business days of the date of receipt from the initial screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later. The MAC shall refer immediate advisements received by beneficiaries or providers/suppliers and potential fraud, waste, or abuse complaints received by current or former provider/supplier employees immediately to the ZPIC for further development.

All OIG Hotline complaints sent to the MAC by the OIG shall be reviewed, determinations shall be made, and final action shall be taken within 45-business days after the complaints have been received, even if additional documents have been requested but not yet received. The MAC shall use the date contained in the e-mail from the OIG at the start of the 45-business day timeframe.

If the MAC requests additional documentation that is received after the 45-business day timeframe and the complaint is closed, the complaint shall be reopened but only if the additional information warrants further action or if the additional information would change the initial determination. The MAC has 30 business days from the date the complaint was reopened to take final action on the reopened complaint. If the MAC is the second contractor assigned to a complaint, the second contractor has 45 business days from the date the complaint is received to take final action on a complaint.

MACs that refer a complaint to the ZPIC shall notify the ZPIC via e-mail that a complaint is being referred as potentially fraudulent. The MAC shall develop a referral package (see below for what should be included in the referral package) for all complaints being referred to the ZPIC and shall send the complaint via a secure method such as e-mail or mail directly to the ZPIC.

Once the complaint has been referred to the ZPIC, the MAC shall close the complaint in its internal tracking system. These referrals shall be done in accordance with the timeframes established above.

If the MAC receives a complaint from the OIG that has been erroneously assigned to the MAC, the contractor shall transfer the erroneously assigned complaint to the appropriate MAC within 10 business days from the date it determined that the complaint was erroneously assigned.

To refer an erroneously assigned complaint to a MAC, the referring contractor shall send an e-mail containing all relevant complaint information and documents to the correct contractor notifying it that a complaint is being reassigned. Within 10 business days of receiving the e-mail, the receiving contractor shall review the complaint. Final action shall be taken in accordance with the timeframes established above.

The MAC shall refer complaints alleging fraud, waste, or abuse in the Medicaid program to the appropriate Program Integrity Unit (PIU) within the State Medicaid Agency (SMA) noted in Exhibit 47. Entities committing such fraud, waste, or abuse include but are not limited to: Medicaid providers; Medicaid recipients; Medicaid managed care organizations or waiver program contractors, their employees, agents or subcontractors. The MAC shall send the complaint information with any supporting documents to the appropriate PIU.

The MAC shall identify and refer complaints alleging fraud, waste, or abuse in the Medicare Part C or Part D programs to the MEDIC. This includes complaints that do not have a credible allegation of fraud.

The MAC shall identify and refer complaints alleging fraud, waste, or abuse involving the Federal Marketplace and State-Based Exchanges, insurance agents/brokers marketing Marketplace plans, and Marketplace consumers to the following email address: marketplaceintegrity@cms.hhs.gov, with a copy to the CORs. The MAC shall close the complaint in its internal tracking system. These referrals shall be done in accordance with the timeframes established above.

The MAC shall identify and refer complaints that do not allege fraud, waste, or abuse involving CMS programs (e.g., Social Security Administration, Health Resources and Services Administration, U.S. Department of Labor, and U.S. Department of Veterans Affairs) back to the OIG with a copy to the CORs. The MAC shall close the complaint in its internal tracking system. These referrals shall be done in accordance with the timeframes established above.

If the MAC receives duplicate complaints, they should be kept open and cross-reference the other complaint number(s). When the complaint is closed, monetary actions (if involved) shall only be claimed on the primary complaint, and the information updated on the duplicate complaint(s) should reference the same resolution of the primary complaint.

Complaints shall be forwarded to the ZPIC for further review under the circumstances listed below (this is not an exhaustive list):

- Claim forms may have been altered or up-coded to obtain a higher reimbursement amount;
- Documentation appears to indicate that the provider/supplier has attempted to obtain duplicate reimbursement (e.g., billing both Medicare and the beneficiary for the same service or billing both Medicare and another insurer in an attempt to be paid twice). This apparent double-billing does not include routine assignment violations. An example for referral might be that a provider/supplier has submitted a claim to Medicare, and then in two (2) business days resubmits the same claim in an attempt to bypass the duplicate edits and gain double payment. A referral shall be made in instances where the provider/supplier has done the above repeatedly, indicating a potential pattern;
- Potential misrepresentation with respect to the nature of the services rendered, charges for the services rendered, identity of the person receiving the services, identity of persons or doctor providing the services, dates of the services, etc;
- Alleged submissions of claims for non-covered services are misrepresented as covered services, excluding demand bills and those with Advanced Beneficiary Notices (ABNs);
- Claims involving potential collusion between a provider/supplier and a beneficiary resulting in higher costs or charges to the Medicare program;

- Alleged use of another person's Medicare number to obtain medical care;
- Alleged alteration of claim history records to generate inappropriate payments;
- Alleged use of the adjustment payment process to generate inappropriate payments; or
- Any other instance that is likely to indicate a potential fraud, waste, and abuse situation.

Note: Since this is not an all-inclusive list, the ZPIC has the right to request additional information in the resolution of the complaint referral or the subsequent development of a related case (e.g., provider/supplier enrollment information).

When the above situations occur requiring that the complaint be referred to the ZPIC for review, the MAC shall prepare a referral package that includes, at a minimum, the following:

- Provider/supplier name, provider/supplier number, and address.
- Type of provider/supplier involved in the allegation and the perpetrator, if an employee of the provider/supplier.
- Type of service involved in the allegation.
- Place of service.
- Nature of the allegation(s).
- Timeframe of the allegation(s).
- Narration of the steps taken and results found during the MAC's screening process (discussion of beneficiary contact, if applicable, information determined from reviewing internal data, etc.).
- Date of service, procedure code(s).
- Beneficiary name, beneficiary HICN, telephone number.
- Name and telephone number of the MAC employee who received the complaint.

NOTE: Since this is not an all-inclusive list, the ZPIC has the right to request additional information in the resolution of the complaint referral or the subsequent development of a related case (e.g., provider/supplier enrollment information).

When a provider/supplier inquiry or complaint of potential fraud or IA is received, the second-level screening staff shall not perform any screening but shall prepare a referral

package within two business days of when this inquiry or IA was received, and send it to the ZPIC during the same timeframe. The referral package shall consist of the following information:

- Provider/supplier name and address.
- Type of provider/supplier involved in the allegation and the perpetrator, if an employee of a provider/supplier.
- Type of service involved in the allegation.
- Relationship to the provider/supplier (e.g., employee or another provider/supplier).
- Place of service.
- Nature of the allegation(s).
- Timeframe of the allegation(s).
- Date of service, procedure code(s).
- Name and telephone number of the MAC employee who received the complaint.

The MAC shall maintain a copy of all referral packages.

4.6.2.1 – Zone Program Integrity Contractor Responsibilities (Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs and MACs, as indicated.

When the complaint is received from the MAC screening staff, the ZPIC shall further screen the complaint, resolve the complaint, or make referrals as needed to the appropriate entity.

The MAC shall screen and forward the complaints within 45 business days from the date of receipt by the second-level screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later, to the ZPIC. The ZPIC shall send the acknowledgement letter within 15 calendar days of receipt of the complaint referral from the MAC second-level screening staff, unless it can be resolved sooner. The letter shall be sent on ZPIC letterhead and shall contain the telephone number of the ZPIC analyst handling the case.

If the ZPIC staff determines, after screening the complaint, that it is not a potential fraud, waste, and/or abuse issue, but involves other issues (e.g., MR, enrollment, claims processing), the complaint shall be referred to the MAC area responsible for second-level

screening. The MAC second-level screening staff shall track the complaints returned by the ZPIC. However, the ZPIC shall send an acknowledgement to the complainant, indicating that a referral is being made, if applicable, to the appropriate MAC unit for further action.

The ZPIC shall track complaints referred by the MAC second-level screening area in the ZPIC's internal tracking system.

The ZPIC shall send the complainant a resolution letter within seven (7) calendar days of resolving the complaint investigation.

4.6.3 - Screening Leads

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

Screening is the initial step in the review of a lead (described in section 4.2.2 of this chapter) to determine the need to perform further investigation based on the potential for fraud, waste, or abuse. Screening shall be completed within 21 calendar days after receipt of the lead.

The receipt date of the lead is generally determined by the date the ZPIC receives a complaint. If the lead resulted from data analysis conducted by the ZPIC, the receipt of the lead shall be the date the lead was referred from the ZPIC data analysis department to its investigation or screening unit. For a new lead that is identified from an active or current ZPIC investigation, the receipt of the lead shall be the date the new lead was identified by the ZPIC investigator.

Note: If criteria for an IA are met during evaluation of the lead, the ZPIC shall forward the IA to LE and continue to screen the lead, if deemed appropriate.

Activities that the ZPIC may perform in relation to the screening process include, but are not limited to:

- Verification of provider's enrollment status;
- Data analysis;
- Contact with the complainant, when the lead source is a complaint;
- Beneficiary interviews;
- Referring/ordering physician interviews if there is no indication that the physician(s) are involved in the scheme related to the lead; and
- Site verification to validate the provider's/supplier's practice location.

Any screening activities shall not involve contact with the subject provider/supplier or implementation of any administrative actions (i.e., post-payment reviews, prepayment reviews/edits, payment suspension, and revocation). However, if the lead is based solely on a potential assignment violation issue, the ZPIC may contact the provider directly to

resolve only the assignment violation issue. If there are circumstances noted in FID that would raise additional concerns, the ZPIC shall contact its COR and IAG BFL for further guidance. If the lead involves potential patient harm, the ZPIC shall immediately notify CMS within two (2) business days.

After completing its screening, the ZPIC shall close the lead if it does not appear to be related to fraud, waste, or abuse. Prior to closing the lead, the ZPIC shall take any appropriate actions (i.e., referrals to the MAC, RA, state, or QIO). For example, if a lead does not appear to be related to potential fraud, waste, or abuse but the lead needs to be referred to the MAC, the date that the ZPIC refers the information to the MAC is the last day of the screening.

At a minimum, the ZPIC shall document the following information in its case file:

- The date the lead was received and closed;
- Lead source (e.g., beneficiary, MAC, provider/supplier);
- Record the name and telephone number of the individual (or organization), if applicable, that provided the information concerning the alleged fraud or abuse;
- Indicate the provider's/supplier's name, address, and ID number;
- Start and end date of the screening;
- Description of the actions/activities performed;
- Start and end date of each action/activity;
- A brief description of the action taken to close the lead (e.g., reviewed records and substantiated amounts billed). Ensure that sufficient information is provided to understand the reason for the closeout;
- The number of leads received to date regarding this provider/supplier, including the present lead. This information is useful in identifying providers/suppliers that are involved in an undue number of complaints; and
- Any documentation associated with the ZPIC's activities (i.e., referrals to other entities).

Additionally, if the screening process exceeds 21 calendar days, the ZPIC shall document the reasons, circumstances, dates, and actions associated with the delay to its COR and IAG BFL within its monthly reporting in CMS ARTS.

4.6.4 - Vetting Leads with CMS

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

All leads and any new subjects that the ZPIC determines warrant further investigation shall be vetted through CMS for approval before transitioning to an investigation. The ZPIC shall submit the lead to CMS within two (2) business days of the ZPIC determining that the lead should be transitioned into an investigation. For the submission to CMS, the ZPIC shall use the designated CMS Vetting Form, which shall include, at a minimum, NPI, name, and practice location.

The ZPIC shall only open investigations on leads that are approved by CMS. If the ZPIC is instructed by CMS to close the lead without further action, the ZPIC shall do so within two (2) business days. If the screening results in a new investigation or becomes part of an existing investigation, the aforementioned screening information shall become part of the investigation file. If, during the course of a ZPIC investigation, it is determined that additional NPIs should be incorporated into the ongoing investigation, the ZPIC shall vet each additional NPI with CMS utilizing the approved CMS process described above before implementing any investigative actions (noted in section 4.7 of this chapter) on the additional NPIs. For any new investigations, the ZPIC shall complete the appropriate updates in the FID within seven (7) calendar days.

4.7 - Investigations

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

This section applies to ZPICs.

An investigation is the expanded analysis performed on leads once such lead is vetted and approved by CMS to be opened as an investigation. The ZPIC shall focus its investigation in an effort to establish the facts and the magnitude of the alleged fraud, waste, or abuse and take any appropriate action to protect Medicare Trust Fund dollars.

Activities that the ZPIC may perform in relation to the investigative process include, but are not limited to:

- Screening activities noted in section 4.6.3 of this chapter;
- Contact with the provider via telephone or on-site visit;
- Medical record requests and reviews (as defined in PIM, chapter 3);
- Implementation of auto-denial edits; and
- Administrative actions (as defined in PIM chapters 3, 8, and 15).

For any investigative activities that require preapproval by CMS (i.e., payment suspensions, and revocations), the ZPIC shall submit those requests to CMS for approval with a copy to its COR and BFLs for approval when initiating those actions.

Prioritization of the investigation workload is critical to ensure that the resources available are devoted primarily to high-priority investigations.

The ZPIC shall maintain files on all investigations. The files shall be organized by provider or supplier and shall contain all pertinent documents including, but not limited to, the original referral or complaint, investigative findings, reports of telephone contacts, warning letters, documented discussions, documented results of any investigative activities, any data analysis or analytical work involving the potential subject or target of the investigation, and decision memoranda regarding final disposition of the investigation (refer to section 4.2.2.4.2 of this chapter for information concerning the retention of these documents).

Under the terms of their contract, the ZPICs shall investigate potential fraud, waste, or abuse on the part of providers, suppliers, and other entities that receive reimbursement under the Medicare program for services rendered to beneficiaries. The ZPICs shall refer potential fraud cases to LE, as appropriate, and provide support for these cases. In addition, the ZPICs may provide data and other information related to potential fraud cases initiated by LE when the cases involve entities or individuals that receive reimbursement under the Medicare program for services rendered to beneficiaries.

For those investigations that are national in scope, CMS will designate a lead ZPIC, if appropriate, to facilitate activities across the zones.

4.7.1 – Conducting Investigations

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

The ZPIC shall, unless otherwise advised by CMS, use one or more of the following investigative methods (this is not an exhaustive list.):

- Perform validation checks of physician licensure;
- Perform data analysis (ZPICs shall follow PIM, chapter 2);
- Initiate other analysis enhancements to authenticate proper payments;
- Interview a small number of beneficiaries. Do not alarm the beneficiaries or imply that the provider did anything wrong. The purpose is to determine whether there appear to be other false potentially inappropriate claims or if this was a one-time occurrence;
- Look for past contacts by the ZPIC or the MAC MR unit concerning comparable violations. Also, check provider correspondence files for educational/warning letters or for contact reports that relate to similar complaints. Review the complaint file. Discuss suspicions. Coordinate with MR and audit staff, as appropriate;
- Review telephone calls or mail written questionnaires to physicians, confirming the need for home health services or DMEPOS;

- Perform provider/supplier onsite visits and/or provider/supplier interviews;
- Review a small sample of claims submitted within recent months. Depending on the nature of the problem, the ZPIC may need to request medical documentation or other evidence that would validate or cast doubt on the validity of the claims; and
- Analyze and compile relevant documentation (e.g., medical records or cost reports).

After reviewing the provider's/supplier's background, specialty, and profile, the ZPIC decides whether the situation involves potential fraud, waste, or abuse, or may be more accurately categorized as a billing error. For example, records might indicate that a physician has billed, in some instances, both Medicare and the beneficiary for the same service. Upon review, the ZPIC may determine that, rather than attempting to be paid twice for the same service, the physician made an error in his/her billing methodology. Therefore, this error would be considered a determination of incorrect billing, rather than potential fraud, waste, or abuse involving intentional duplicate billing. If the ZPIC determines that an overpayment exists solely on data analysis, the ZPIC shall obtain COR and IAG BFL approval prior to initiating the overpayment.

4.7.2 – Closing Investigations

(Rev. 675, Issued: 09-09-16, Effective: 12-12-16, Implementation: 12-12-16)

An investigation shall be closed if it is referred to LE (i.e., it is referred to OIG, DOJ, FBI, or AUSA) and there are no pending administrative actions. In addition, an investigation may be closed due to the following circumstances:

- When no further action is warranted by the ZPIC and the matter is referred back to the MAC or to another CMS contractor for further review;,
- If it is closed with administrative action(s);
- If the potential fraud is not substantiated; and/or
- If CMS declined a requested administrative action.

4.8 - Disposition of Cases Referred to Law Enforcement

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16, Implementation: 11-08-16)

The ZPIC shall refer investigations to law enforcement when it has substantiated allegations of fraud including, but not limited to, documented allegations that a provider, beneficiary, supplier, or other subject: (a) engaged in a pattern of improper billing, (b) submitted improper claims with suspected knowledge of their falsity, or (c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. Prior to making such referrals, the ZPIC shall, unless otherwise instructed by CMS, effectuate all appropriate administrative actions, except for requesting the collection of an overpayment from the MAC that is directly related to the underlying reason for the referral. This definition of a case includes any and all allegations (regardless of dollar

threshold or subject matter) where ZPIC staff verifies that there is potential Medicare fraud (the allegation is likely to be true) and a referral to federal law enforcement (OIG, FBI, DOJ) has been performed. ZPICs do not prove fraud; such action is within the purview of the DOJ.

4.8.1 – Reversed Denials by Administrative Law Judges on Open Cases (Rev. 667, Issued: 08-08-16, Effective: 11-08-16, Implementation: 11-08-16)

If a case is still pending at the OIG, FBI, or AUSA, and denials are reversed by an Administrative Law Judge (ALJ), the ZPIC should recommend to CMS that it consider protesting the ALJ's decision to the DHHS Appeals Council, which has the authority to remand or reverse the ALJ's decision. ZPICs should be aware, however, that ALJs are bound only by statutory and administrative law (federal regulations), CMS rulings, and National Coverage Determinations.

The ZPIC shall consult with its COR and IAG BFL before initiating a protest of an ALJ's decision. They should be aware that the Appeals Council has only 60 days in which to decide whether to review an ALJ's decisions. Thus, CMS needs to protest the ALJ decision within 30 days of the decision, to allow the Appeals Council to review within the 60-day limit. The ZPIC shall notify all involved parties immediately if it learns that claims/claim denials have been reversed by an ALJ in a case pending prosecution.

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

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

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

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

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

4.9 - Incentive Reward Program

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

Section 203(b)(1) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) instructs the Secretary to establish a program to encourage individuals to report information on individuals and entities that are engaged in or have engaged in acts or omissions that constitute grounds for the imposition of a sanction under sections 1128, 1128A, or 1128B of the Social Security Act (the Act), or who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act.

The Incentive Reward Program (IRP) was established to pay an incentive reward to individuals who provide information on Medicare fraud and abuse or other sanctionable activities. The applicable regulations are in 42 CFR § 420.405.

4.9.1 - ZPIC Responsibilities for the Incentive Reward Program

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs and MACs, as indicated.

For ZPICs and MACs, the IRP responsibilities explained below shall be worked out in the ZPIC and MAC Joint Operating Agreement (JOA).

4.9.2 - Guidelines for Processing Incoming Complaints

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs and MACs, as indicated.

On or after July 8, 1998, any complaints received that pertain to a potentially sanctionable offense as defined by sections 1128, 1128A, or 1128B of the Act, or that pertain to those who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act, are eligible for consideration for reward under the IRP. The ZPIC should consider the complainant for the reward program. Complaints may originate from a variety of sources such as the OIG Hotline, the ZPIC, customer service representatives, etc. The ZPIC and MAC shall inform their staff of this

program to ensure that the staff will respond to or refer questions correctly. PIM, Exhibit 5 provides IRP background information to assist staff who handle inquiries.

The ZPIC and MAC shall treat all complaints as legitimate until proven otherwise. The MAC shall refer potential fraud, waste, and abuse incoming complaints to the ZPIC for investigation. Complaints shall either be resolved by the ZPIC or, if determined to be a sanctionable offense, referred to the OIG for investigation. Complaints that belong in another ZPIC's zone shall be recorded and forwarded to the appropriate ZPIC. All information shall be forwarded according to existing procedures.

If an individual registers a complaint about a Medicare managed care provider/supplier, ZPICs and MACs shall record and forward all information to:

Centers for Medicare & Medicaid Services
Centers for Medicare Management
Performance Review Division
Mail Stop C4-23-07
7500 Security Blvd.
Baltimore, MD 21244

4.9.3 - Guidelines for Incentive Reward Program Complaint Tracking (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

If the ZPIC receives a related complaint and the complainant is eligible for an IRP, the ZPIC shall notate the IRPs in the FID and coordinate with its COR and IAG BFL when issuance of the award is identified.

4.9.4 - Excluded Individuals (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The following individuals are not eligible to receive a reward under the IRP:

- An individual who was, or is, an immediate family member of an officer or employee of the Department of Health and Human Services, its PSCs, its ZPICs, ACs, MACs, or subcontractors, the Social Security Administration (SSA), the OIG, a state Medicaid agency, the DOJ, the FBI, or any other federal, state, or local law enforcement agency at the time he or she came into possession, or divulged information leading to a recovery of Medicare funds. Immediate family is as defined in 42 CFR 411.12(b), which includes any of the following:

- Husband or wife
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law

- Grandparent or grandchild.
- Any other federal or state employee, PSC, ZPIC, AC, MAC, or subcontractor, or DHHS grantee, if the information submitted came to his/her knowledge during the course of his/her official duties.
- An individual who received a reward under another government program for the same information furnished.
- An individual who illegally obtained the information he/she submitted.
- An individual who participated in the sanctionable offense with respect to which payment would be made.

4.9.5 - Amount and Payment of Reward (Rev. 71, 04-09-04)

The amount of the reward shall not exceed 10 percent of the overpayments recovered in the case, or \$1,000, whichever is less. Collected fines and penalties are not included as part of the recovered money for purposes of calculating the reward amount. If multiple complainants are involved in the same case, the reward will be shared equally among each complainant but not to exceed the maximum amount of the reward.

4.9.6 - Program Safeguard Contractor and Zone Program Integrity Contractor Responsibilities (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

For PSCs or ZPICs and ACs or PSCs or ZPICs and MACs, the IRP responsibilities explained below shall be worked out in the Joint Operating Agreement.

4.9.6.1 - Guidelines for Processing Incoming Complaints (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

On or after July 8, 1998, any complaints received that pertain to a potentially sanctionable offense as defined by §§1128, 1128A, or 1128B of the Act, or that pertain to those who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act, are eligible for consideration for reward under the IRP. While the complainant may not specifically request to be included in the IRP, the PSC or the ZPIC BI unit should consider the complainant for the reward program.

Complaints may originate from a variety of sources such as the OIG Hotline, the PSC BI unit, the ZPIC BI unit, customer service representatives, etc. PSCs, ZPICs, ACs, and MACs shall inform their staff of this program so they will respond to or refer questions correctly. PIM Exhibit 5 provides IRP background information to assist staff who handle inquiries. PSCs, ZPICs, ACs, and MACs, shall treat all complaints as legitimate until proven otherwise. They shall refer incoming complaints to the PSC or the ZPIC BI unit for investigation. Complaints shall either be resolved by the PSC or the ZPIC BI unit or, if determined to be a sanctionable offense, referred to the OIG for investigation.

Complaints that belong in another PSC's jurisdiction or another ZPIC's zone shall be recorded and forwarded to the appropriate PSC or the ZPIC. All information shall be forwarded to them according to existing procedures.

If an individual registers a complaint about a Medicare Managed Care provider, PSCs, ZPICs, ACs, and MACs shall record and forward all information to:

Centers for Medicare & Medicaid Services
Centers for Medicare Management
Performance Review Division
Mail Stop C4-23-07
7500 Security Blvd.
Baltimore, MD 21244

4.9.6.2 - Guidelines for Incentive Reward Program Complaint Tracking (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSCs and the ZPICs shall continue to track all incoming complaints potentially eligible for reward in their existing internal tracking system. The following complainant information shall be included:

- Name;
- Health insurance claim number or Social Security number (for non-beneficiary complaints);
- Address;
- Telephone number; or

Any other requested identifying information needed to contact the individual.

The PSC and the ZPIC BI units shall refer cases to the OIG for investigation if referral criteria are met according to PIM Chapter 4, §4.18.1 - Referral of Cases to the Office of the Inspector General (OIG). The case report shall also be forwarded to the OIG.

The PSC and the ZPIC BI unit shall enter all available information into the IRP tracking database. Information that shall be maintained on the IRP tracking database includes:

- Date the case is referred to the OIG.
- OIG determination of acceptance.
- If accepted by OIG, the date and final disposition of the case by the OIG (e.g., civil monetary penalty (CMP), exclusion, referral to DOJ).

- Any provider identifying information required in the FID, e.g., the Unique Physician Identification Number (UPIN).

The OIG has 90 calendar days from the referral date to make a determination for disposition of the case. If no action is taken by the OIG within the 90 calendar days, the PSC and the ZPIC BI unit should begin the process for recovering the overpayment and issuance of the reward, if appropriate.

4.9.6.3 - Overpayment Recovery

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units shall initiate overpayment recovery actions according to PIM Chapter 3, §3.8ff, if it is determined an overpayment exist. Only ACs or MACs shall issue demand letters and recoup the overpayment.

4.9.6.4 - Eligibility Notification

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

After all fraudulently obtained Medicare funds have been recovered and all fines and penalties collected, if appropriate, the PSC and the ZPIC BI unit will send a reward eligibility notification letter and a reward claim form to the complainant by mail at the most recent address supplied by the individual. PIM Exhibit 5.1 provides a sample eligibility notification letter and Exhibit 5.2 provides a sample reward claim form that may be used as guides.

4.9.6.5 - Incentive Reward Payment

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

After the complainant has returned the reward claim form with appropriate attachments, the PSC and the ZPIC BI unit shall determine the amount of the reward and initiate payment. The reward payment should be disbursed to the complainant from the overpayment money recovered. Payments made under this system are considered income and subject to reporting under Internal Revenue Service tax law. No systems changes to implement these procedures are to be made.

For PSCs and ZPICs, only the AC or MAC shall make IRP payments. The PSC and the ZPIC shall provide the necessary documentation to the AC or MAC to initiate the IRP payment.

4.9.6.6 - Reward Payment Audit Trail

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI unit shall maintain an audit trail of the disbursed check. The following data shall be included:

- Amount of the disbursed check

- Date issued
- Check number
- Overpayment amount identified
- Overpayment amount recovered
- Social Security number of complainant
- Party the complaint is against

The PSC and the ZPIC BI unit shall update the IRP tracking database to reflect disbursement of the reward check to the complainant, and the PSC and the ZPIC shall work with the AC or MAC via the JOA to disburse the reward check.

4.9.7 - CMS Incentive Reward Winframe Database (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The IRP database was designed to track rewards that could be paid for information about fraud or abuse of the Medicare Trust Fund. Access to the IRP database is through the Winframe file server located at the CMS data center and is controlled through password and access codes. Cases can be entered into the IRP system by any PSC and ZPIC, or managed care organization contractor, or by the OIG. When the PSC and the ZPIC BI unit refers a case to the OIG, for which the complaint is eligible for the IRP, they shall update the IRP system with all available information. The database contains the current status of all Medicare fraud/abuse cases pending reward. Some cases may be closed without a reward, based on final disposition of the case. PSC and ZPIC BI units and CMS ROs have oversight responsibility for this system. The database provides the following information:

- On-demand management reports
- Duplicate complaints submitted for reward
- Audit trail of overpayments recovered as a result of the reward program

The IRP database user instructions are found in PIM Exhibit 5.3.

4.9.8 - Updating the Incentive Reward Database (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units shall be responsible for updating the incentive reward database on overpayment recovery and reward amounts. PSC and ZPIC BI units shall regularly follow up with the OIG to obtain information on recovery of complaints

referred to them that originated from an IRP complainant. The PSC and the ZPIC BI units shall follow up on referrals to the OIG when no action is taken within 90 calendar days. The tracking system database shall be updated as information becomes available. Updates shall be entered, at a minimum, on a quarterly basis.

The IRP screens may be viewed in PIM Exhibit 5.9.

4.10 - Fraud Alerts

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

Fraud Alerts are issued when circumstances arise that indicate a need to advise the ZPICs, MACs, law enforcement, state Medicaid agencies, and other appropriate stakeholders about an activity that resulted in the filing of inappropriate and potentially false Medicare claims. If the ZPIC identifies the need for a Fraud Alert, it shall provide the COR and IAG BFL a summary of the circumstances. CMS will evaluate the need to issue a Fraud Alert. All Fraud Alerts will be disseminated by CMS to the appropriate stakeholders and supplied to the ZPICs in the FID.

4.10.1 - Reserved For Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.10.2 - Reserved For Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.10.3 - Reserved For Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.10.4 - Reserved For Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.10.5 - Reserved For Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.11 – FID Entries

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

For this entire section, the ZPIC shall utilize the FID for all of its investigation and case tracking activities. The ZPIC shall follow these established guidelines described below. UPICs shall utilize the Unified Case Management (UCM) system as described in the UPIC USOW.

Note: The FID captures ZPIC work related to investigations and cases (i.e., investigations referred to law enforcement). The UCM will not capture investigations

and cases as two distinct work products. Instead, the UCM will capture investigations and all related activities associated with that investigation, including referrals to law enforcement. Other activities include, but are not limited to, screening leads, administrative actions, and requests for information/assistance that will also be captured in UCM.

4.11.1 - Background

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

The FID is a nationwide database that ZPICs use to enter and update Medicare fraud, waste, and abuse investigations initiated by the ZPIC, cases, payment suspensions, and requests for information (RFIs) fulfilled by ZPICs at the request of law enforcement, CMS, or other stakeholders.

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

- ZPICs
- National Benefit Integrity Medicare Drug Integrity Contractor (NBIMEDIC)
- MAC provider enrollment units
- CMS
- FBI
- DOJ
- HHS/OIG
- Medicaid Program Integrity Directors, State Utilization Review (SUR) officials, and Provider Enrollment units
- Medicaid Fraud Control Units (MFCUs)
- Other federal and state partners seeking to address program integrity concerns in judicial or state health care programs

Investigations initiated by the ZPIC shall be saved in the FID and shall contain identifying information on the potential subject of an investigation, as well as general information on activities performed by the ZPIC to substantiate the allegation of potential fraud, waste, or abuse. Cases initiated by the ZPIC shall contain a summary of the pertinent information on the case referral as well as any activities and resolution of the case.

Payment suspensions shall contain a summary of the pertinent information on the suspension, including date implemented, rebuttal information, extensions, terminations, attachments representing notices, rebuttals, Administrative Action Request forms, etc. and amounts in suspense. Fields required to be entered in order to save a payment suspension in the FID are indicated in the payment suspension module. Required fields are also listed in the FID User Guide, which is located under the Help menu in the FID.

RFIs shall contain information on the requester, details of the request, details on the fulfillment of the request, and all pertinent dates related to the request.

The FID also has monitoring and reporting capabilities, and contains Medicare Fraud Alerts and a resource guide by state, of contacts at the ZPICs, Medicaid Program Integrity Directors and MFCUs, and law enforcement agencies.

4.11.1.1 - Information Not Captured in the FID

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

Individual complaints (statements alleging improper entitlement), simple overpayment recoveries (not involving potential fraud), complaints that are returned to the AC or MAC second-level screening staff (or PSC or ZPIC, if applicable), and medical review abuses shall not be captured in the FID.

4.11.1.2 - Entering OIG Immediate Advisements into the FID

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall enter all available information into the FID, similar to an investigation, by adding the “Immediate Advisement to OIG” action on the Actions/Narratives tab. An immediate advisement shall be entered into the FID once the ZPIC has determined further investigation is warranted, and has vetted and received approval from CMS to open the investigation. Investigations shall be entered into the FID within seven (7) calendar days of such notification by CMS after the advisement was made. Subsequent to these actions, the ZPIC shall decide whether to further develop the lead/investigation or close the immediate advisement.

If the OIG accepts or declines the immediate advisement, the ZPIC shall enter the appropriate action in the FID.

If the OIG decides to accept the immediate advisement, the ZPIC shall develop the advisement as a regular investigation, if warranted, and follow the procedures for documentation of an investigation.

4.11.1.3 - Documentation of Identity Theft and Compromised HICNs in the FID

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

When entering identity theft investigations into the FID, the ZPIC shall enter the information for the “Compromised” provider/supplier number as the primary subject (i.e., the false or “compromised” number; the provider/supplier who stole the identity; the “false front” provider/supplier; the new provider/supplier location for which the real provider/supplier did not submit a Form CMS-855 change request; and/or the group practice to which a physician attests he/she did not reassign his/her benefits). This information shall include both the NPI and PTAN associated with that provider/supplier as well as the street address and as much detail as possible (e.g., ownership, employer identification number (EIN), electronic funds transfer (EFT), bank account,

revocation/deactivation information, billing company, registered agent). The ZPIC shall clearly indicate the information associated with the “Compromised” provider/supplier number, the primary subject. The ZPIC shall differentiate this from the number and information associated with the “Legitimate” provider/supplier number.

The ZPIC shall enter information on the provider’s/supplier’s “Legitimate” provider/supplier number (i.e., the “real” number of the provider/supplier whose identity was stolen or compromised) only in the narrative, including the NPI and PTAN associated with the provider/supplier along with the street address and all of the background information (ownership, EIN, EFT, bank account, revocation/deactivation information, billing company, registered agent, etc.), clearly displaying it as associated with the “Legitimate” provider/supplier number.

4.11.2 – Investigation, Case, Payment Suspension, and Request for Information Entries

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

It is not appropriate for an OIG or FBI agent, the DOJ, or an Assistant United States Attorney to request that a ZPIC not enter or update an investigation, case, payment suspension, or RFI initiated by the ZPIC in the FID, except in rare circumstances. The ZPICs shall inform law enforcement agents making such requests that they are required by CMS to maintain the FID and that they do not have the discretion to do otherwise. The ZPIC shall contact the COR and IAG BFL to resolve the matter.

However, information regarding law enforcement activities that are, or could be considered to be, of a sensitive nature shall not be entered into the FID. These activities include, but are not limited to, planned search warrants, undercover operations and activities, and executed search warrants, where only some of the search warrants have been executed.

4.11.2.1 - Initial Entry Requirements for Investigations

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

An investigation shall be entered into the FID after the ZPIC has vetted and received approval from CMS to open the investigation. Investigations approved by CMS shall be entered into the FID within seven (7) calendar days of such notification by CMS. Information entered by the ZPIC regarding investigations shall capture ongoing work by the ZPIC.

Investigations shall be saved in the FID and shall not be converted to a case by the ZPIC, until and unless the investigation results in a referral to the OIG, DOJ, FBI, or AUSA. When an investigation is saved, the FID will assign it an investigation number, starting with the letter N. Any complaints that are returned to the MAC second-level screening staff (or ZPIC, if applicable) shall not be entered into the FID. Such complaints are returned because they pertain to issues other than potential fraud, waste, and abuse.

Fields required to be entered in the database to save an investigation in the FID are indicated in the investigation module. Required fields are also listed in the FID User Guide, which is located under the Help menu in the FID.

The ZPIC shall be responsible for ensuring that all data entered into the FID investigation module are entered correctly. This requirement includes the spelling of names and accuracy of addresses and identifiers entered.

4.11.2.2 – Initial Entry Requirements for Cases Referred to Law Enforcement

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Once the ZPIC has referred a case to the OIG, DOJ, FBI, or AUSA, the investigation shall be saved as a case within seven (7) calendar days of referral. The investigation will automatically be converted by the FID to a case and assigned a new FID number. If the ZPIC refers the investigation to any agency other than the OIG, the DOJ, the FBI, or the AUSA, it remains as a case in the FID.

The ZPIC shall be responsible for ensuring that all data entered into the FID case module are entered correctly. This requirement includes the correct spelling of names and the accuracy of addresses and identifiers entered.

4.11.2.3 – Initial Entry Requirements for DMEPOS Payment Suspensions

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

When one ZPIC implements a DMEPOS payment suspension, all of the ZPICs shall place that supplier under payment suspension as well. However, instead of having each ZPIC enter separate payment suspensions in the FID to track the payment suspension, only one FID entry is made and all of the ZPICs shall update that entry with information from their zone. The ZPIC that originates the payment suspension shall become the “Lead Contractor.” The Lead ZPIC shall enter all appropriate information into the FID Payment Suspension Module when requesting a payment suspension.

Fields required to be input in order to save a payment suspension in the FID are indicated in the payment suspension module. Required fields are also listed in the FID User Guide, which is located under the Help menu in the FID.

The ZPIC shall be responsible for ensuring that all data entered into the FID payment suspension module are entered correctly. This requirement includes the correct spelling of names and accuracy of addresses and identifiers entered.

4.11.2.3.1 - Initial Entry Requirement for Non-DMEPOS Payment Suspensions

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

Fields required to be input in order to save a payment suspension in the FID are indicated in the payment suspension module. Required fields are also listed in the FID User Guide, which is located under the Help menu in the FID.

The ZPICs shall be responsible for ensuring that all data entered into the FID payment suspension module are entered correctly. This requirement includes the correct spelling of names and accuracy of addresses and identifiers entered.

4.11.2.3.2 - Initial Entry Requirements for Requests for Information and Requests for Assistance

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall enter information on RFIs and RFAs into the “FID RFI” Module within seven (7) calendar days of the receipt date of the RFI. The receipt date is counted as day one and the ZPIC has an additional six (6) calendar days to enter the RFI into the FID before it will be counted as a late entry.

Fields required to be input to save an RFI in the FID are indicated in the RFI module. Required fields are also listed in the FID User Guide, which is located under the Help menu in the FID.

The ZPIC shall be responsible for ensuring that all data entered into the FID RFI module are entered correctly. This requirement includes the spelling of names and accuracy of addresses and identifiers entered.

4.11.2.4 – Update Requirements for Investigations

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

There are no mandatory systematic update requirements for investigations entered in FID, but the ZPIC shall enter updates no later than every 30 days to make the FID entry complete, accurate, and current with the major activities that are contained in the investigation tracking system files. For the FID investigation entries, the ZPIC shall document all major activities it has performed in order to substantiate any allegations of potential fraud, waste, or abuse. For example, on-site visits, medical review, and data analysis shall be documented on the Actions/Narratives tab, along with dates for each action. When possible, actions should be documented using actions available in the “Actions” section. If an option is unavailable or further detail needs to be provided, the ZPIC can use the narrative section for further documentation.

4.11.2.5 - Update Requirements for Cases

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

For cases referred to the OIG, DOJ, FBI, or AUSA, updates to the FID case shall be made within the following parameters:

- Upon notice from law enforcement on the status of the referral, FID updates shall be made within 7 calendar days;
- If the case is accepted and the contractor has ongoing or pending administrative actions, the ZPIC shall update the status when information is communicated to the ZPIC by either law enforcement or CMS;
- If the case is accepted and the contractor has no ongoing or pending administrative actions, the ZPIC shall close the case as prescribed in section 4.11.2.9 of this chapter.

If problems that interfere with the ZPIC's ability to get updated information are encountered, this matter shall be discussed with the appropriate COR and IAG BFL. As applicable, the following tabs/sections shall be updated:

- Referrals accepted by the OIG, DOJ, FBI or AUSA are assigned a case number by their agency. It shall be the responsibility of the ZPIC to obtain and enter the case number into the FID Claims tab.
- The information on the FID "Actions/Narratives" tab shall clearly identify the alleged fraudulent activity, all investigation actions, and referral activities performed on the case by the ZPIC. The FID "Actions/Narratives" tab shall also include updated summary information after the case is referred to law enforcement. This information shall include the status of the referral and, when appropriate, actions taken by law enforcement. If the ZPIC is not able to obtain a status on investigations referred to law enforcement, this shall be brought to the attention of the COR and IAG BFL.
- All corrective and/or administrative actions taken by the MAC or ZPIC shall be entered into the FID.
- The ZPIC shall enter any updated financial information related to the case including, but not limited to, estimated overpayment amount and total overpayment amount (recoupment is performed by the MAC), as appropriate. The ZPIC shall also update settlement, restitution, and conviction information, when available, even if the case has been closed in the FID.

The ZPIC shall also be responsible for:

- Capturing and documenting subsequent law enforcement referrals (e.g., OIG declines case, ZPIC refers case to FBI, FBI accepts case);
- Keeping apprised of MR/provider audit and reimbursement actions if they are taking actions on a case; and/or

Entering related FID entry numbers.

4.11.2.6 – Update Requirements for National DMEPOS Payment Suspensions

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The Lead Contractor, as well as all other ZPICs, shall update, at a minimum, the “As of Date” field, “Suspended Amount” field, and the “Number of Claims Suspended” field as of the last calendar day of each month.

Updates regarding the money withheld shall be completed in the FID by the ZPICs within 7 calendar days following the last calendar day of each month. The ZPICs shall always enter an update, even if there was no change in the dollar amount or number of claims suspended, to show that an update was made. In such an instance, the “As of Date” will still change to reflect the correct update period. Each ZPIC shall be responsible for establishing a routine for timely obtaining these data from their associated MAC for input into the payment suspension module.

Non-lead ZPICs shall update payment suspensions by selecting the “Payment Suspension for non-Lead DMEPOS Contractor” link under the “View/Update” section on the FID home page. ZPICs will then have the ability to update the “Suspended Amount” field, the “Number of Claims Suspended” field, and the “As of Date” field for the suspension selected, which the FID will automatically populate to a table and calculate total amounts in the Lead ZPIC’s original payment suspension entry.

The lead ZPIC shall enter updates to the narrative section and other available fields, as necessary, to make the FID payment suspension entry complete, accurate, and current with what is contained in the suspension tracking system files. The FID payment suspension entries shall document all major activities performed by the ZPIC(s), including communication with the COR and BFLs and law enforcement, as applicable.

All requests for extensions or terminations shall be entered in the FID no later than 14 calendar days before the expiration date (as denoted in the FID) of the payment suspension.

4.11.2.6.1 - Update Requirements for Non-DMEPOS Payment Suspensions

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall update, at a minimum, the “As of Date” field, “Suspended Amount” field, and the “Number of Claims Suspended” field as of the last calendar day of each month.

Updates regarding the money withheld shall be completed in the FID by the ZPIC within 7 calendar days following the last calendar day of each month. The ZPIC shall always enter an update, even if there was no change in the dollar amount or number of claims suspended, to show that an update was made. In such an instance, the “As of Date” will still change to reflect the correct update period. Each ZPIC is responsible for establishing

a routine for timely obtaining these data from their associated MAC for input into the payment suspension module.

The ZPIC shall enter updates to the narrative section and other available fields, as necessary, to make the FID payment suspension entry complete, accurate, and current with what is contained in the suspension tracking system files. The FID payment suspension entries should document all major activities performed by the ZPIC, including communication with the COR and BFLs and law enforcement, as applicable.

All requests for extensions or terminations shall be entered in the FID no later than 14 calendar days before the expiration date (as denoted in the FID) of the payment suspension.

4.11.2.6.2 - Update Requirements for Requests for Information and Requests for Assistance

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall update the RFI and RFA entry when it submits the requested information in total to the requesting agency. At that time, the ZPIC shall input the fulfilled date on the “Completion” tab, which automatically changes the status of the RFI to “Fulfilled.” Once the entry has been saved after this date has been entered, the “Hours to Complete” and “Cost to Complete” fields become enabled and the ZPIC is able to input numbers into these fields.

The FID will automatically convert the status of the RFI from “Active” to “Overdue” once the current date has exceeded the due date of the RFI, calculated by the FID based on the date of receipt and the Type of RFI (e.g., OIG Priority I, OIG Priority II, etc.). If an RFI cannot be timely fulfilled, the ZPIC shall communicate with law enforcement and make sure it is aware of the status and expected completion time. This communication shall be documented in the narrative section of the RFI module, including the date when such communication took place and the reasons why the RFI could not be timely submitted. The ZPIC shall use the narrative section to document any other information pertinent to the RFI that CMS should be aware of at all times.

4.11.2.7 - OIG Non-Response to or Declination of Case Referral

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

If the ZPIC does not receive a response from the OIG within the first 60 calendar days following a referral, the ZPIC shall pursue a subsequent referral, if it has merit, to the FBI, if appropriate. For instances when a FBI referral is not warranted or if the FBI declines or does not respond to the referral within 45 calendar days, the ZPIC shall request any outstanding overpayments and take any additional administrative actions necessary. If the FBI declines the case, the ZPIC may refer the investigation to any other law enforcement agency with interest in the case. Once all subsequent activities are complete, the ZPIC may close the case in the FID accepted or there are no subsequent administrative actions to pursue.

Note: When a case is referred to the FBI or other LE entities, it shall be considered an update to the existing FID case, reflecting a subsequent action taken on the case, and not a new FID case. That is, subsequent referrals of the same case to other law enforcement agencies shall not be counted as new case entries in the FID, nor are they counted for workload purposes as new referrals to law enforcement.

4.11.2.8 – Closing Investigations

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Investigations shall be closed in accordance with section 4.7.2 of this chapter. The ZPIC shall enter all appropriate administrative actions taken as part of the disposition of the investigation, as well as any updated financial information available, prior to closing the investigation in the FID.

Not all investigations will result in a referral to law enforcement; therefore, an investigation that does not result in a law enforcement referral shall be closed by entering information as to why the investigation is being closed in the “Outcome” narrative field and the “Investigation Closed” action in the “Actions/Narratives” tab.

4.11.2.9 – Closing Cases

Closing Cases Referred to Law Enforcement

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Once a referral has been made to the appropriate law enforcement agencies, law enforcement has either declined the case or has not responded to the referral by the designated response timeframe, and the ZPIC has effectuated and concluded all necessary administrative actions (to include demand of any overpayment), the ZPIC shall close the case in the FID. If, however, law enforcement has accepted a referral and the overpayment determined by the ZPIC has not been issued, the case shall remain open in the FID.

The ZPIC shall close the case and support law enforcement through the RFI process outlined in section 4.4 of this chapter if the ZPIC cannot pursue any additional actions after the case has been referred and accepted by law enforcement.

Note that after a case is closed, it can still be updated to reflect any additional activity that takes place (i.e., indictments, convictions, restitution, and settlement information).

4.11.2.10 – Removing Payment Suspensions

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

When a payment suspension is removed, the ZPIC shall change the status of the payment suspension changes from “Active” to “Removed.” Even after a suspension becomes inactive, updated information on the “Actual Overpayment Amount,” “Amount Recovered,” and other pertinent information shall be entered as it becomes available.

4.11.2.10.1 - Closing Requests for Information and Requests for Assistance

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall close an RFI or RFA in the FID within 30 calendar days of fulfilling the request. The ZPIC shall enter the hours and cost to complete the RFI or RFA on the “Completion” tab in the RFI module. Once these fields have been filled and the entry has been saved, the FID will automatically convert the status of the RFI to “closed.”

4.11.2.11 - Duplicate Entries

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

A duplicate entry exists when a ZPIC inadvertently enters a provider, supplier, or beneficiary as the subject of an investigation, case, payment suspension, or RFI more than once; absent different allegations or other differentiating criteria requiring a separate investigation, case, payment suspension or RFI entry.

For investigations, cases, payment suspensions, and RFIs, it shall not be considered a duplicate entry if multiple ZPICs enter the same provider/supplier as the subject of an investigation, investigation referred to law enforcement, payment suspension, or RFI. These entries, however, shall reflect a coordinated effort by all ZPICs involved and investigating the provider/supplier. FID numbers shall be referenced in the “Related Entries” tab, and the narratives shall reflect this coordination. The FID provides a list of potential related entries that a user can select from, based on similar identifiers and names, and allows the user to enter a new entry number or to search and select FID entry numbers directly from the “Related Entries” tab. Additionally, the FID automatically links entries that have been related. Therefore, when a user inputs a related entry into a FID record, the FID automatically populates all related entries with that FID number, so that the user does not have to manually enter each related entry and relate it back to the original record.

If a new investigation or case is initiated on a provider/supplier that was already the subject of a closed investigation or case, a new investigation or case shall be opened after CMS approves the lead through the vetting process. The closed investigation or case, however, shall be mentioned in the “Actions/Narratives” tab and cross-referenced to the old investigation or case number on the “Related Entries tab.”

The target, whether a business or individual, shall be entered as the subject of the investigation or case. All related providers, suppliers, beneficiaries, etc., who are in any way affiliated with the subject of the case shall be identified under “AKAs, DBAs, and Affiliates.” However, if these individuals are the primary subjects/targets of the investigation or case and independent investigations or cases are made against them, then individual investigations or cases shall be established in the FID.

If a new payment suspension is being requested on a provider/supplier that was already the subject of an earlier payment suspension, the ZPIC shall discuss this with its CORs and BFLs to receive further guidance.

The ZPIC shall check for potential duplicate entries of investigations, investigations referred to law enforcement, payment suspensions, and RFIs.

4.11.2.12 – Deleting Investigations, Cases, or Suspensions (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Investigations, investigations referred to law enforcement, payment suspensions, or RFIs can be deleted from the FID only by users with the system administrator designation. The ZPIC shall contact its COR and BFLs to discuss the need for deleting an entry. If the CORs and BFL agree that the entry should be deleted, the ZPIC's contractor system administrator has the ability to delete any entries that are assigned to the contractor number and task order numbers, over which they have been given authority in their profile. Otherwise, the ZPIC shall send an e-mail to the FID mailbox at FID@cms.hhs.gov, copying its CORs and BFLs, requesting that the entry be deleted. Once the entry has been deleted by a CMS FID Administrator, the CORs, BFLs, and ZPIC will receive an e-mail response from the FID mailbox verifying that the entry has been completed. The CMS administrators will coordinate with the CORs and BFLs to do random checks of deleted entries to ensure that appropriate approvals are being obtained before ZPICs are deleting entries and can provide reports, upon request, to CORs, BFLs, or other CMS officials.

4.11.3 - Operational Issues (Rev. 71, 04-09-04)

4.11.3.1 - Access (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

If ZPICs and others eligible to access the FID have never applied for access to the FID system and require authorization, an "Application for Access to CMS Computer Systems" shall be completed, submitted, and approved.

This form may be acquired from <http://www.cms.hhs.gov/InformationSecurity/downloads/euaaccessform.pdf>. It shall be submitted to the appropriate CMS Access Administrator (CAA) for all CMS central and regional offices, and to the COR for the ZPIC or to CMS IAG for all law enforcement personnel or other users.

Once an individual has received a CMS user ID and password, a system administrator must enter a user profile in the FID before access to the system is granted. Each ZPIC shall have a Contractor System Administrator (CSA), which has the ability to enter profiles for users in their contracts and task orders. If individuals are unaware of their

contractor system administrator or one is not available, an e-mail can be sent to the FID mailbox at FID@cms.hhs.gov requesting that a profile be set up.

For issues with passwords, users can access PassPort to reset their passwords or contact the CMS IT Service Desk at 1-800-562-1963 or 410-786-2580.

4.11.3.2 - The FID Testing Group

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The CMS has approximately two large FID releases each year. Testing for each release is done in a test environment before the release and, when possible, users from the ZPICs are contacted and given the option of participating in testing. Participation in testing is optional and open to all FID users. Participants receive advance notice of upcoming changes to the database and a chance to provide feedback. Many enhancements to the system are derived from comments received from FID testers. Anyone interested in joining in testing can send an e-mail to the FID mailbox at FID@cms.hhs.gov at any time to receive instruction on how to get involved. Additional connectivity to validation and test environments is required and can take some time to address due to firewall issues; the earlier the process starts, therefore, the better chance a user has of being able to actually participate.

Periodically, CMS may hold a User's Group meeting. Notice of these meetings will be posted as a "News Item" in the FID at least 1 (one) week prior to the meeting. Meeting minutes will be posted as a "News Item" prior to the meeting for those unable to attend. Participation in the meeting is open to all users. Meetings will be held to discuss programming changes in the FID (e.g., enhancements, upgrades, changes to entry requirements) and user questions and concerns. Programming changes are also communicated via "News Items" posted in the FID.

4.11.3.3 – ZPIC FID CSA

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall designate up to 1-3 people per task order for each contract to serve as a CSA. The CSA will have additional privileges in the FID and will have more routine meetings with the CMS FID team to keep apprised of FID changes and report issues and concerns that CMS needs to address. The additional functions the CSA will be able to perform include, but are not limited to, the following functions in addition to regular contractor user functions:

- Ability to add users to their assigned contract and task order
- Ability to delete certain entries into the FID
- Ability to transfer entries between task orders under their contract; and
- Ability to reassign user IDs.

CSAs will be the main point of contact for CMS to disseminate FID-related information to the ZPICs, outside of posting "News Items" in the FID. CMS may also provide

specific training directly to CSAs for them to share with their contracts: the intent is to use these staff members as FID experts and points of contact for questions and comments on the FID. The CSAs shall be responsive to FID questions from ZPICs and law enforcement personnel within their zone.

4.11.3.4 - The Fraud Investigation Database Mailbox

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

Questions, comments, or suggestions regarding the FID may be sent via the FID to FID@cms.hhs.gov

4.12 - Reserved for Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.12.1 - Reserved for Future Use

(Rev. 472, Issued: 06-21-13, Effective: 07-23-13, Implementation: 07-23-13)

4.12.2 - Reserved for Future Use

(Rev. 472, Issued: 06-21-13, Effective: 07-23-13, Implementation: 07-23-13)

4.12.3 - Reserved for-Future Use

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

4.12.4 - Reserved for-Future Use

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

4.13 - Administrative Relief from Program Integrity Review in the Presence of a Disaster

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

During a governmentally declared disaster, whether manmade or otherwise, the ZPIC shall continue every effort to identify cases of potential fraud. Therefore, if the ZPIC suspects fraud of a provider/supplier who cannot furnish medical records in a timely manner due to a disaster, the ZPIC shall ensure that the provider/supplier is not attempting to harm the Medicare Trust Fund by taking an unreasonable amount of time to furnish records. The ZPIC shall request and review verification documentation in all instances where fraud is suspected.

In the case of complete destruction of medical records/documentation where backup records exist, the ZPIC shall accept reproduced medical records from microfiched, microfilmed, or optical disk systems that may be available in larger facilities, in lieu of the original document. In the case of complete destruction of medical records where no backup records exist, the ZPICs shall consult with its COR and IAG BFL to determine the appropriateness of the request to reconstruct the medical records. If the COR and IAG BFL determine that medical review is appropriate, the ZPIC shall instruct

providers/suppliers to reconstruct the records as completely as possible with whatever original records can be salvaged. Providers/suppliers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

4.14 - Provider/Supplier Contacts by the ZPIC (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

A ZPIC may determine that the resolution of an investigation does not warrant administrative action and that an educational meeting with the provider/supplier is more appropriate. The ZPIC shall inform the provider/supplier of the questionable or improper practices, the correct procedure to be followed, and that continuation of the improper practice may result in administrative actions. The ZPIC shall document contacts and/or warnings with written reports and correspondence to the provider/supplier and place them in the investigation file.

If the provider/supplier continues aberrant billing practices, the ZPIC shall initiate the appropriate administrative actions. If the ZPIC meets with a provider/supplier, the ZPIC shall prepare a detailed report for the investigation file. The report shall include the information in A, B, and C below.

A. Background of Provider/Supplier (Specialty)

The ZPIC shall include a list of all enterprises in which the subject had affiliations, the states where the provider/supplier is licensed, all past complaints, and all prior educational contacts/notices.

B. Total Medicare Earnings

The ZPIC shall include a report of the subject provider's/supplier's total Medicare earnings for the past 12 months.

The report shall include the following:

- Earnings for the procedures or services in question;
- Frequency of billing for these procedures/services; and
- Total number of claims submitted for these procedures/services.

C. Extent of Review Performed

The ZPIC shall include in the detailed report, to be placed in the investigative file, the number and type of reviews performed, as well as the specific information outlined below:

- A report of the review process, including methodologies utilized, reason for the review, and findings;
- Any administrative actions implemented (e.g., overpayments identified); and
- Recommendation(s).

D. Report of Meeting

The ZPIC shall include information pertaining to the meeting(s) conducted with the provider/supplier. This report shall include the following:

- Minutes from the meeting describing the problems and/or aberrancies discussed with the provider/supplier and the education provided to the provider/supplier to correct those problems based on the ZPIC's medical review.
- Copies of educational materials given to the provider/supplier before, during, or subsequent to the meeting.

4.16 – MAC and ZPIC Coordination on Voluntary Refunds (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs and MACs, as indicated.

Voluntary refund checks payable to the Medicare program shall not be returned to the provider/supplier, regardless of the amount of the refund. The ZPIC shall communicate with the MAC staff responsible for processing voluntary refunds to obtain information on the checks received. The MAC shall refer to Pub. 100-06, Financial Management Manual, for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers.

The ZPIC shall perform an investigation on any voluntary refund where there is suspicion of inappropriate payment or if a provider/supplier is under an active investigation.

Should the ZPIC receive a voluntary refund check in error, the ZPIC shall coordinate the transfer of voluntary refund checks to the MAC through the JOA.

Through the JOA, the ZPIC shall establish a mechanism whereby the MAC notifies the ZPIC on a regular basis of all voluntary refunds it received. The ZPIC or MAC shall send one letter annually (calendar year) to any provider/supplier that submits a voluntary refund during that calendar year, advising the provider/supplier of the following:

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

The ZPIC and MAC shall establish in the JOA which contractor sends the above language. The MACs may send the language above on a voluntary refund acknowledgement letter or on a Remittance Advice, if this capability exists.

The ZPIC shall refer to section 4.4.1(G) and (H) of this chapter for law enforcement requests for voluntary refund information.

4.17 – Reserved for Future Use

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.18 – Referral of Cases to Other Entities for Action

(Rev. 71, 04-09-04)

4.18.1 - Referral of Cases to the OIG/OI

(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall identify cases of potential fraud and shall make referrals of such cases, as appropriate, to the OIG/OI, regardless of dollar thresholds or subject matter. Prior to making such referrals, the ZPIC shall, unless otherwise instructed by CMS, implement any administrative actions, except for requesting the collection of an overpayment from the MAC that is directly related to the underlying reason for the referral. Matters shall be referred when the ZPIC has documented allegations including, but not limited to, a provider, beneficiary, supplier, or other subject, a) engaged in a pattern of improper billing, b) submitted improper claims with suspected knowledge of their falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity.

When a case has been referred to the OIG/OI, OIG/OI has 60 calendar days to accept or decline the referral. The ZPIC shall continue to monitor the need for administrative action prior to the elapsing of the 60 calendar days. During this 60-day period, the ZPIC shall refrain from implementing any additional administrative actions against the provider/supplier without CMS approval. The ZPIC shall implement any additional administrative actions, if appropriate, to include issuing an overpayment demand to the MAC when:

- The OIG/OI does not accept the referral or the ZPIC does not receive a response from the OIG/OI within 60 calendar days following a referral, and

Other law enforcement agencies do not accept the referral within 45 calendar days following such referral.

Once a referral has been made to the appropriate law enforcement agencies, law enforcement has either declined, returned or has not responded to the referral by the designated response timeframe, and the ZPIC has effectuated and concluded all necessary administrative actions (to include demand of any overpayment), the ZPIC shall close the case in the FID.

When the OIG/OI conducts an investigation, it will usually initiate ongoing consultation and communication with the ZPIC to establish evidence (i.e., data summaries, statements, bulletins) that a statutory violation has occurred. If the ZPIC has completed all of the appropriate administrative actions to include referral of an overpayment to the MAC (if appropriate) and the case has been accepted by OIG, the ZPIC shall still close the case and fulfill all other LE activities through the RFI process noted in section 4.4 of this chapter.

4.18.1.1 - Reserved for Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.18.1.2 - Immediate Advisements to the OIG/OI

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall notify the OIG/OI of an immediate advisement within two (2) business days of identifying a lead or investigation that meets the following criteria. The ZPIC shall maintain internal documentation on these advisements when it receives allegations with one or more of the following characteristics:

- Indications of ZPIC or MAC employee fraud
- Allegations of kickbacks or bribes, discounts, rebates, and other reductions in price
- Allegations of a crime committed by a federal or state employee in the execution of their duties
- Indications of fraud by a third-party insurer that is primary to Medicare

For complaints received from the OIG Hotline, the ZPIC shall not send an immediate advisement to the OIG/OI unless other information is available to the ZPIC that is not contained in the initial OIG Hotline complaint.

The ZPIC shall continue to develop the lead as appropriate. If the ZPIC determines that a lead warrants further investigation, it shall follow the processes described above in section 4.6.4 of this chapter. If the ZPIC already had an open investigation and refers the subject to OIG/OI as an immediate advisement, it shall follow the processes described above in section 4.7 of this chapter.

When an immediate advisement is required, all available documentation received with the allegation shall be forwarded to the OIG. The initial forwarding of the applicable information does not equate to the ZPIC completing the full referral package as defined in the PIM (refer to PIM Exhibit 16.1) and does not equate to a referral to law enforcement.

4.18.1.3 - Payment Suspension

(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall refer to PIM, chapter 8, for payment suspension instructions.

4.18.1.3.1 - Suspension

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

If payment has not been suspended before OIG/OI accepts a case, PSC and ZPIC BI units shall discuss suspending payments with OIG/OI where there is reliable and substantive evidence that overpayments have been made and are likely to continue. Where OIG/OI disagrees with the suspension on the grounds that it will undermine their law enforcement action and there is disagreement, PSC and ZPIC BI units shall discuss the matter with their designated SME. The SME will then decide, after consulting with OIG/OI, whether the PSC and the ZPIC BI unit should proceed with the suspension. Suspension of payment should not be delayed in order to increase an overpayment amount in an effort to make the case more attractive to law enforcement.

Continuing to pay claims submitted by a suspect provider for this purpose is not an acceptable reason for not suspending payment.

The PSC and the ZPIC BI units shall refer to PIM, chapter 3, §3.9ff for suspension of payment instructions.

A. Record of Suspended Payments Regarding Providers Involved in Litigation

The PSC and the ZPIC BI units shall provide OIG/OI with current information, as requested, regarding total payments due providers on monies that are being withheld because those cases are being referred for fraud prosecution. (The OIG/OI sends notification of which potential fraud cases have been referred for prosecution.) These monies represent potential assets, against which offset is made to settle overpayments or to satisfy penalties in any civil action brought by the government. The total amount of withheld payments is also pertinent to any determination by the DOJ whether civil fraud prosecution action is pursued or a negotiated settlement attempted.

4.18.1.3.2 - Denial of Payments for Cases Referred to and Accepted by OIG/OI

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

Where it is clear that the provider has not furnished the item or services, denial is the appropriate action. (See PIM Exhibit 14.) Before recommending denying payments, PSCs and ZPICs consult with their Primary GTL, Associate GTL, and SME.

4.18.1.3.3 - Recoupment of Overpayments

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units shall seek to initiate recoupment of overpayments whenever there is a determination that Medicare has erroneously paid. Once an overpayment has been determined, the statute and regulations require that the

overpayment be recovered, especially if the overpayment is not related to the matter that was referred to law enforcement (see PIM, chapter 3, §3.8ff). The ACs and MACs shall perform recoupment of all overpayments including sending the demand letter.

4.18.1.4 - OIG/OI Case Summary and Referral

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC should use the following format when preparing summaries for referral to the OIG/OI, including when additional civil, criminal, or sanctions action appears appropriate. The ZPIC shall forward the referral and summary report to the OIG and shall retain a copy of the summary in the investigation file.

A Case Referral Fact Sheet Format can be found in PIM Exhibit 16.1. A Case Summary Format can be found in PIM Exhibit 16.2.

4.18.1.5 - Referral to Other Law Enforcement Agencies

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

If the OIG/OI declines a case that the ZPIC believes has merit, the ZPIC shall refer the case to other law enforcement agencies, such as the FBI or MFCU, as appropriate.

4.18.1.5.1 - Continue to Monitor Provider and Document Case File

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units shall not close a case simply because it is not accepted by OIG/OI. Since the subject is likely to continue to demonstrate a pattern of fraudulent activity, they shall continue to monitor the situation and to document the file, noting all instances of suspected fraudulent activity, complaints received, actions taken, etc. This will strengthen the case if it is necessary to take further administrative action or there is a wish to resubmit the case to OIG/OI at a later date. If PSC and the ZPIC BI units do resubmit the case to OIG/OI, they shall highlight the additional information collected and the increased amount of money involved.

4.18.1.5.2 - Take Administrative Action on Cases Referred to and Refused by OIG/OI

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units take immediate action to implement appropriate administrative remedies, including the suspension or denial of payments, and the recovery of overpayments (see PIM, chapter 3, §3.8ff). Because the case has been rejected by law enforcement, PSCs and ZPICs shall consult with the Primary GTL, Associate GTL, and SME concerning the imposition of suspension. They pursue administrative and/or civil sanctions by OIG where law enforcement has declined a case.

A. Denial/Referral Action for Erroneous Payment(s), Cases Not Meeting the Referral Threshold

Many instances of erroneous payments cannot be attributed to fraudulent intent. There will also be cases where there is apparent fraud, but the case has been refused by law enforcement. Where there is a single claim, deny the claim and collect the overpayment. Where there are multiple instances, deny the claims, collect the overpayment, and warn the provider. PSC and ZPIC BI units shall refer the provider, as appropriate, to provider relations, medical review, audit, etc.

4.18.1.5.3 - Refer to Other Law Enforcement Agencies (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

If the OIG/OI declines a case that the PSC and the ZPIC BI unit believes has merit, the PSC and the ZPIC BI unit may refer the case to other law enforcement agencies, such as the FBI, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), RRB/OIG, and/or the MFCU.

The PSC and the ZPIC BI units should recommend administrative and/or civil sanctions (including exclusions) to the OIG where law enforcement has declined the case.

4.18.2 - Referral to State Agencies or Other Organizations (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall refer instances of apparent unethical or improper practices or unprofessional conduct to state licensing authorities, medical boards, the QIO, or professional societies for review and possible disciplinary action.

In each state there is a Medicare survey and certification agency. This agency is typically within the state's Department of Health. The survey agency has a contract with CMS to survey and certify institutional providers, indicating whether they meet or do not meet applicable Medicare health and safety requirements, called "conditions of participation." Providers not meeting these requirements are subject to a variety of adverse actions, including bans on new admissions to termination of their provider agreements. These administrative sanctions are imposed by the Regional Office, typically after an onsite survey by the survey agency.

The ZPIC's and the MAC's MR staffs shall confer before such referrals, to avoid duplicate referrals. The ZPIC shall gather available information and leave any further investigation, review, and disciplinary action to the appropriate professional society or State board. Consultation and agreement between the ZPIC's and the MAC's MR staffs shall precede any referral to these agencies.

The ZPIC shall notify its CORs and IAG BFL of these referrals.

4.18.3 - ZPICs and QIOs

(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Communication with the QIO is essential to discuss the potential impact of efforts to prevent abuse, as well as ensure efforts are made to improve quality of care and access to such care.

If potential patient harm is discovered during the course of screening a lead or through the investigation process, the ZPIC shall refer those instances to the QIO, state medical board, or state licensing agency. In addition to making the appropriate referrals, the ZPIC shall notify the COR and IAG BFL within two (2) business days once the potential patient harm issue is discovered.

If the ZPIC refers a provider to the State licensing agency or medical society (i.e., those referrals that need immediate response from the State licensing agency), the ZPIC shall also send a copy of the referral to the QIO.

If a claim has been reviewed by the QIO, the decision made is final and binding on CMS, and the specific decision rendered by the QIO shall not be overturned by the ZPIC.

4.19 - Administrative Sanctions

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The term “sanctions” represents the full range of administrative remedies and actions available to deal with questionable, improper, or abusive practices of practitioners, providers, and suppliers under the Medicare and Medicaid programs or any state health care programs as defined under §1128(h) of the Act. There are two purposes for these sanctions. First, they are designed to be remedial, to ensure that questionable, improper, or abusive practices are dealt with appropriately. Practitioners, providers, and suppliers are encouraged to correct their behavior and operate in accordance with program policies and procedures. Second, the sanctions are designed to protect the programs by ensuring that improper payments are identified and recovered and that future improper payments are not made.

The primary focus of this section is sanctions authorized in §1128 and §1128A of the Act (exclusions and CMPs). Other, less severe administrative remedies may precede the more punitive sanctions affecting participation in the programs. The corrective actions PSCs, ZPICs, ACs, and MACs shall initially consider are:

- Provider education and warnings
- Revocation of assignment privileges
- Suspension of payments (refer to PIM, chapter 3, §3.9ff)
- Recovery of overpayments (refer to PIM, chapter 3, §3.8ff)
- Referral of situations to state licensing boards or medical/professional societies

4.19.1 - The Program Safeguard Contractor's, Zone Program Integrity Contractor's, AC's, and Medicare Administrative Contractor's Role (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The AC and MAC shall be responsible for:

- Ensuring that no payments are made to provider/suppliers for a salaried individual who is excluded from the program. OIG, as it becomes aware of such employment situations, notifies providers that payment for services furnished to Medicare patients by the individual is prohibited and that any costs (salary, fringe benefits, etc.) submitted to Medicare for services furnished by the individual will not be paid. A copy of this notice is sent to the PSC or the ZPIC BI unit and to the appropriate RO.

The PSC and the AC, the ZPIC and the AC, the PSC and the MAC, and the ZPIC and the MAC shall work out the following in their JOA:

- Furnishing any available information to the OIG/OI with respect to providers/suppliers requesting reinstatement.
- Reporting all instances where an excluded provider/supplier submits claims for which payment may not be made after the effective date of the exclusion.

The PSC and the ZPIC BI unit shall also be responsible for:

- Contacting OIG/OI when it determines that an administrative sanction against an abusive provider/supplier is appropriate.
- Providing OIG/OI with appropriate documentation in proposed administrative sanction cases.

4.19.2 - Authority to Exclude Practitioners, Providers, and Suppliers of Services (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

Section 1128 of the Act provides the Secretary of DHHS the authority to exclude various health care providers, individuals, and businesses from receiving payment for services that would otherwise be payable under Medicare, Medicaid, and all federal health care programs. This authority has been delegated to the OIG.

When an exclusion is imposed, no payment is made to anyone for any items or services in any capacity (other than an emergency item or service provided by an individual who does not routinely provide emergency health care items or services) furnished, ordered, or prescribed by an excluded party under the Medicare, Medicaid, and all federal health care programs. In addition, no payment is made to any business or facility, e.g., a hospital, that submits claims for payment of items or services provided, ordered, prescribed, or referred by an excluded party.

The OIG also has the authority under §1128(b)(6) of the Act to exclude from coverage items and services furnished by practitioners, providers, or other suppliers of health care services who have engaged in certain forms of program abuse and quality of care issues. In order to prove such cases, the PSC and the ZPIC BI unit shall document a long-standing pattern of care where educational contacts have failed to change the abusive pattern. Isolated instances and statistical samples are not actionable. Medical doctors must be willing to testify.

Authority under §1156 of the Act is delegated to OIG to exclude practitioners and other persons who have been determined by a QIO to have violated their obligations under §1156 of the Act. To exclude, the violation of obligation under §1156 of the Act must be a substantial violation in a substantial number of cases or a gross and flagrant violation in one or more instances. Payment is not made for items and services furnished by an excluded practitioner or other person. Section 1156 of the Act also contains the authority to impose a monetary penalty in lieu of exclusion. Section 1156 exclusion actions and monetary penalties are submitted by QIOs to the OIG/OI.

Payment is not made for items and services furnished by an excluded practitioner or other person.

4.19.2.1 - Basis for Exclusion Under §1128(b)(6) of the Social Security Act (Rev. 71, 04-09-04)

Exclusions under §1128(b)(6) of the Act are effected upon a determination that a provider has done one of the following:

- Submitted or caused to be submitted claims or requests for payment under Medicare or a state health care program containing charges (or costs) for items or services furnished substantially in excess of its usual charges (or costs).
- Furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Medicare or under a state health care program) substantially in excess of the needs of such patients or of a quality that does not meet professionally recognized standards of health care.

For purposes of the exclusion procedures, “furnished” refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items or services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

4.19.2.2 - Identification of Potential Exclusion Cases

(Rev. 264; Issued: 08-07-08; Effective Date: 08-01-08; Implementation Date: 08-15-08)

The PSC and the ZPIC BI unit shall review and evaluate abuse cases to determine if they warrant exclusion action. Examples of abuse cases suitable for exclusion include, but are not limited to:

- Providers who have a pattern of adverse QIO, AC, or MAC findings.
- Providers whose claims must be reviewed continually and are subsequently denied because of repeated instances of overutilization.
- Providers who have been the subject of previous cases that were not accepted for prosecution because of the low dollar value
- Providers who furnish or cause to be furnished items or services that are substantially in excess of the beneficiary's needs or are of a quality that does not meet professionally recognized standards of health care (whether or not eligible for benefits under Medicare, Medicaid, title V or title XX).
- Providers who are the subject of prepayment review for an extended period of time (longer than 6 months) who have not corrected their pattern of practice after receiving educational/warning letters.
- Providers who have been convicted of a program related offense (§1128(a) of the Social Security Act).
- Providers who have been convicted of a non-program related offense (e.g., a conviction related to neglect or abuse of a beneficiary, or related to a controlled substance) (§1128(a) of the Social Security Act).

Also, §1833(a)(1)(D) of the Act provides that payment for clinical diagnostic laboratory tests is made on the basis of the lower of the fee schedule or the amount of charges billed for such tests. Laboratories are subject to exclusion from the Medicare program under §1128(b)(6)(A) of the Act where the charges made to Medicare are substantially in excess of their customary charges to other clients. This is true regardless of the fact that the fee schedule exceeds such customary charges.

Generally, to be considered for exclusion due to abuse, the practices have to consist of a clear pattern that the provider/supplier refuses or fails to remedy in spite of efforts on the part of the PSC, ZPIC, AC, MAC, or QIO groups. An exclusion recommendation is implemented only where efforts to get the provider/supplier to change the pattern of practice are unsuccessful. The educational or persuasive efforts are not necessary or desirable when the issues involve life-threatening or harmful care or practice.

If a case involves the furnishing of items or services in excess of the needs of the individual or of a quality that does not meet professionally recognized standards of health

care, PSC and ZPIC BI units shall make every effort to obtain reports confirming the medical determination of their medical review from one or more of the following:

- The QIO for the area served by the provider/supplier
- State or local licensing or certification authorities
- QIO committees
- State or local professional societies
- Other sources deemed appropriate

4.19.2.3 - Development of Potential Exclusion Cases

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

A. Case Considerations

When PSC and ZPIC BI units recommend cases to OIG/OI for exclusion, they shall consider:

- The nature and seriousness of the acts in question
- Actions taken to persuade the provider/supplier to abstain from further questionable acts
- The experience gained from monitoring payments to the provider/supplier after corrective action was taken
- The degree of deterrence that might be brought about by exclusion
- The effects of exclusion on the delivery of health care services to the community
- Any other factors deemed appropriate

In cases recommended to OIG/OI for exclusion where there has **not** been a conviction, see 42 U.S.C. 1320 a-7(b).

Documentation for excessive services and charges shall include the length of time that the problem existed and the dollars lost by the program. Documentation of excessive services or poor quality of care requires a medical opinion from a qualified physician who must be willing to testify. All cases involving excessive services or poor quality of care shall also contain documentation of prior unsuccessful efforts to correct the problem through the use of less serious administrative remedies.

B. Notification to Provider

If, as a result of development of potential fraud or abuse, a situation is identified that meets one or more of the criteria in PIM Chapter 4, §4.19.2.1, PSC and ZPIC BI units shall consult the OIG/OI/OCIG (Office of Counsel to the Inspector General) contact

person. The OIG prepares and sends a written notice to the provider containing the following information:

- Identification of the provider.
- The nature of the problem.
- The health care services involved.
- The basis or evidence for the determination that a violation has occurred. In cases concerning medical services, make every effort to include reports and opinions from a QIO or a QIO committee, or a state/local professional society.
- The sanction to be recommended.
- An invitation to discuss the problem with PSC and ZPIC BI units and OIG/OI staff, or to submit written information regarding the problem.
- A statement that a recommendation for consideration of sanctions will be made to the OIG/OI within 30 days, if the problems are not satisfactorily resolved.

If the provider/supplier accepts the invitation to discuss the issues, PSC and ZPIC BI units shall make a report of the meeting for the record. This does not have to be a professionally transcribed report. Copies of the letter to the provider/supplier and the provider response, or the summary of the meeting, shall be in the file.

The PSC and the ZPIC BI units shall refer cases that demonstrate a strong fraud potential to OIG/OI for investigation.

The PSC and the ZPIC BI units notify OIG/OI of any cases that reach the level where a provider/supplier is notified of a problem in accordance with this section, even if the provider is convinced that there was a legitimate reason for the problem or that the problem has been corrected. PSC and ZPIC BI units do not refer these cases to OIG/OI unless requested to do so.

The PSC and the ZPIC BI units document and refer cases involving harmful care as rapidly as possible. They handle OIG/OI requests for additional information as priority items.

C. Additional Information

Additional information that may be of value in supporting a proposal to exclude includes any adverse impact on beneficiaries, the amount of damages incurred by the programs, and potential program savings.

D. Mitigating Circumstances

Any significant factors that do not support a recommendation for exclusion or that tend to reduce the seriousness of the problem may be found in 42 CFR Part 1001 and are also considered. One of the primary factors is the impact of the sanction action on the availability of health care services in the community. PSC and ZPIC BI units shall bring mitigating circumstances to the attention of OIG/OI when forwarding their sanction recommendation.

4.19.2.4 - Contents of Sanction Recommendation

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC and the ZPIC BI units shall include in the sanction recommendation (to the extent appropriate) the following information:

- Identification of the subject, including the subject's name, address, date of birth, social security number, and a brief description of the subject's special field of medicine. If the subject is an institution or corporation, include a brief description of the type of services it provides and the names of its officers and directors.
- A brief description of how the violation was discovered.
- A description of the subject's fraudulent or abusive practices and the type of health service(s) involved.
- A case-by-case written evaluation of the care provided, prepared by the PSC's, ZPIC's, AC's, or MAC's MR staff, which includes the patient's medical records. This evaluation shall cite what care was provided and why such care was unnecessary and/or of poor quality. (The reviewer may want to consult with someone from their RO OCSQ.) Medicare reimbursement rules shall not be the basis for a determination that the care was not medically necessary. The reviewer shall identify the specific date, place, circumstance, and any other relevant information. If possible, the reviewer should review the medical records of the care provided to the patient before and after the care being questioned.

NOTE: A minimum of 10 examples shall be submitted in support of a sanction recommendation under §1128(b)(6)(B). In addition, none of the services being used to support the sanction recommendations shall be over 2 years old.

- Documentation supporting the case referral, e.g., records reviewed, copies of any letters or reports of contact showing efforts to educate the provider, profiles of the provider who is being recommended for sanction, and relevant information provided by other program administrative entities.
- Copies of written correspondence and written summaries of the meetings held with the provider regarding the violation.
- Copies of all notices to the party.

- Information on the amount billed and paid to the provider for the 2 years prior to the referral.
- Data on program monies on an assigned/non-assigned basis for the last 2 years, if available.
- Any additional information that may be of value in supporting the proposal to exclude or that would support the action in the event of a hearing.

NOTE: All documents and medical records should be legible.

4.19.2.5 - Notice of Administrative Sanction Action (Rev. 71, 04-09-04)

When OIG receives the sanction recommendation, it is reviewed by medical and legal staff to determine whether the anticipated sanction action is supportable.

OIG then develops a proposal and sends it to the provider, advising it of the recommended sanction period, the basis for the determination that excessive or poor-quality care has been provided, and its appeal rights. The provider is also furnished with a copy of all the material used to make the determination. This is the material that was previously forwarded to OIG with the initial sanction recommendation.

The provider has 30 days from the date on the proposal letter to submit:

- Documentary evidence and written argument against the proposed action, or
- A written request to present evidence or argument orally to an OIG official

OIG may extend the 30-day period. All additional information is reviewed by OIG, as well as by medical and/or legal personnel when necessary. In the event the provider requests an in-person review, it is conducted by OIG in Washington, D.C.

When a final determination is made to exclude a provider, OIG sends a written notice to the provider at least 20 days prior to the effective date of the action (see 42 CFR §1001.2003 for exceptions to the 20 day notice). The notice includes:

- The basis for the exclusion.
- The duration of the exclusion and the factors considered in setting the duration.
- The earliest date on which OIG accepts a request for reinstatement, and the requirements and procedures for reinstatement.
- Appeal rights.

- A statement that, should claims continue to be submitted during the period of sanction for which payments may not be made, the provider/supplier may be criminally prosecuted, subject to a CMP action and/or denied reinstatement.

4.19.2.5.1 - Notification to Other Agencies (Rev. 71, 04-09-04)

Concurrent with the mailing of the notice to the provider, OIG sends a notice to the state agency administering or supervising the administration of each state health care program, the appropriate state licensing board, and CMS. CMS is responsible for ensuring proper effectuation of sanction actions.

OIG also notifies the appropriate licensing agency, the public, and all known employers of the sanctioned provider.

The effective date of exclusion is 20 days from the date of the notice to the provider (see 42 CFR §1001.2003 for exceptions to the 20 day notice).

4.19.2.6 - Denial of Payment to an Excluded Party (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSCs and the ZPICs shall not recommend payments to the AC or MAC, and ACs and MACs shall not make payment on any excluded individual or entity for items or services furnished, ordered, or prescribed in any capacity on or after the effective date of exclusion, except in the following cases:

- For inpatient hospital services or post-hospital SNF care provided to an individual admitted to a hospital or SNF before the effective date of the exclusion, make payment, if appropriate, for up to 30 days after that date.
- For home health services provided under a plan established before the effective date of exclusion, make payment, if appropriate, for 30 days after the date on the notice.
- For emergency items and services furnished, ordered, or prescribed (other than an emergency item or service furnished, ordered, or prescribed in a hospital emergency room) payment may be made to an excluded provider on or after the effective date of exclusion.

4.19.2.6.1 - Denial of Payment to Employer of Excluded Physician (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

If an excluded physician is employed in a hospital setting and submits claims for which payment is prohibited, the AC or MAC Part B carrier surveillance process usually detects and investigates the situation.

However, in some instances an excluded physician may have a salary arrangement with a hospital or clinic, or work in group practice, and may not directly submit claims for payment. If this situation is detected, Part B ACs and MACs:

- Contact the hospital/clinic/group practice and inform them that they are reducing the amount of their payment by the amount of federal money involved in paying the excluded physician
- Develop and refer to the PSC and the ZPIC BI unit as a CMP case.

Upon referral from the AC or MAC, the PSC or the ZPIC BI unit shall finalize the case and refer it to the OIG.

4.19.2.6.2 - Denial of Payment to Beneficiaries and Others (Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

If claims are submitted after the effective date of the exclusion by a beneficiary for items or services furnished, ordered, or prescribed by an excluded provider in any capacity, ACs and MACs shall:

- Pay the first claim submitted by the beneficiary and immediately give notice of the exclusion.
- Not pay the beneficiary for items or services provided by an excluded party more than 15 days after the date of the notice to the beneficiary or after the effective date of the exclusion, whichever is later. The regulatory time frame is 15 days; however, CMS allows an additional 5 days for mailing.

If claims are submitted by a laboratory or DME supplier for any items or services ordered by a provider in any capacity excluded under §1156, or any items or services ordered or prescribed by a physician excluded under §1128, ACs and MACs shall handle the claims as above.

A. Notice to Beneficiaries

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, ACs and MACs shall include the following language in the notice:

“We have received your claim for services furnished or ordered by _____ on _____. Effective _____, _____ was excluded from receiving payment for any items and services furnished in any capacity to Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services furnished by _____ if rendered more than 20 days from the date of this notice.”

B. Notice to Others

The Medicare Patient and Program Protection Act of 1987 provides that payment is denied for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156. It also provides that payment cannot be denied until the supplier of the items and services has been notified of the exclusion.

If claims are submitted by a laboratory or a DME company for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156, ACs and MACs shall:

- Pay the first claim submitted by the supplier and immediately give notice of the exclusion.
- Do not pay the supplier for items or services ordered or prescribed by an excluded provider in any capacity if such items or services were ordered or prescribed more than 20 days after the date of notice to the supplier, or after the effective date of the exclusion, whichever is later.

To ensure that the notice to the supplier indicates the proper reason for denial of payment, ACs and MACs shall include the following language in the notice:

“We have received your claim for services ordered or prescribed by _____ on _____. Effective _____, _____ was excluded from receiving payment for items or services ordered or prescribed in any capacity for Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services ordered or prescribed by _____ if ordered or prescribed more than 20 days from the date of this notice.”

4.19.3 - Appeals Process **(Rev. 71, 04-09-04)**

An excluded provider may try to have the decision reversed or modified, through the appeals process. The Departmental Appeals Board is responsible for processing hearing requests received from sanctioned providers except in very limited circumstances. Exclusions remain in effect during the appeals process (see 42 CFR §§1001.901 (false claims), 1001.951 (kickbacks), 1001.1601 (violations of the limitation on physician charges), or 1001.1701 (billing for services of assistant-at-surgery during cataract operations)).

4.19.4 - Reinstatements **(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)**

A provider may apply for reinstatement when the basis for exclusion has been removed, at the expiration of the sanction period, or any time thereafter. PSC and ZPIC BI units shall refer all requests they receive for reinstatement to the Office of Investigation of the OIG. Also, they furnish, as requested, information regarding the subject requesting

reinstatement. OIG notifies the PSC or the ZPIC BI unit in the State where the subject lives/practices of all reinstatements.

4.19.4.1 - Monthly Notification of Sanction Actions

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The Medicare Exclusion Database is a standard format, cumulative exclusion database that contains information on all exclusions and reinstatement actions in Medicare, Medicaid, and other Federal health care programs. CMS receives this information from the Office of Inspector General monthly.

The PSCs, ZPICs, ACs, and MACs shall use the information contained in the MED and the GAO Debarment list to:

- Determine whether a physician/practitioner/provider or other health care supplier who seeks approval as a provider of services in the Medicare/Medicaid programs is eligible to receive payment
- Ensure that sanctioned providers are not being inappropriately paid

The dates reflected on the MED are the effective dates of the exclusion. Exclusion actions are effective 20 days from the date of the notice. Reinstatements or withdrawals are effective as of the date indicated.

The MED shows the names of a number of individuals and entities where the sanction period has expired. These names appear on the MED because the individual or entity has not been granted reinstatement. Therefore, the sanction remains in effect until such time as reinstatement is granted.

The PSCs, ZPICs, ACs, and MACs shall check their systems to determine whether any physician, practitioner, provider, or other health care worker or supplier is being paid for items or services provided subsequent to the date they were excluded from participation in the Medicare program. In the event a situation is identified where inappropriate payment is being made, they shall notify OIG and take appropriate action to correct the situation. Also, PSC and ZPIC BI units shall consider the instructions contained in the CMP section of the PIM (PIM, chapter 4, §4.20ff).

The PSCs and the ZPICs shall work with ACs and MACs to document a process in the JOA to make the AC and MAC aware of any payments to an excluded provider.

The ACs and MACs shall ensure that no payments are made after the effective date of a sanction, except as provided for in regulations at 42 CFR 1001.1901(c) and 489.55.

The ACs and MACs shall check payment systems periodically to determine whether any individual or entity who has been excluded since January 1982 is submitting claims for which payment is prohibited. If any such claims are submitted by any individual in any

capacity or any entity who has been sanctioned under §§1128, 1862(d), 1156, 1160(b) or 1866(b) of the Act, PSC and ZPIC BI units shall forward them to OIG/OI.

Also, ACs and MACs shall refer to the RO all cases that involve habitual assignment violators. In cases where there is an occasional violation of assignment by a provider, they shall notify the provider in writing that continued violation could result in a penalty under the CMPL.

4.20 - Civil Monetary Penalties **(Rev. 71, 04-09-04)**

4.20.1 - Background **(Rev. 71, 04-09-04)**

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

4.20.1.1 - Basis of Authority **(Rev. 71, 04-09-04)**

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 monetary 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 & Medicaid Services and the Office of the Inspector General. CMS was delegated the responsibility for implementing CMPs that involve program compliance. The OIG was delegated the responsibility for implementing CMPs that involve threats to the integrity of the Medicare or Medicaid programs, i.e., those that 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 non-compliance, 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.

4.20.1.2 - Purpose **(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)**

The central purpose of the CMP process is to promote compliance with the program rules and regulations. To achieve this, CMS and its PSCs, ZPICs, ACs, and MACs shall enforce the regulatory standards and requirements.

The ACs and MACs shall educate the industry and the public regarding compliance. PSCs, ZPICs, ACs, and MACs shall have a statutory obligation to ensure compliance with regulations. Therefore, the efforts of ACs and MACs to achieve compliance shall 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 shall be referred to the appropriate agency.

4.20.1.3 - Enforcement (Rev. 71, 04-09-04)

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. First, 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.

4.20.1.4 - Administrative Actions (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSCs, ZPICs, ACs, and MACs 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), ACs and MACs shall 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) shall be issued by the AC or MAC. This notice shall be sent by certified mail (return receipt required) to ensure its receipt by the provider. The notice shall indicate that previous notifications sent to the provider failed to correct the problem, and that this is a final warning. Additionally, it shall 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 shall indicate that this is one type of sanction that may be applied.

4.20.1.5 - Documents (Rev. 71, 04-09-04)

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

4.20.2 - Civil Monetary Penalty Authorities **(Rev. 71, 04-09-04)**

The following sections list the authorities under which CMS's Program Integrity Group and the OIG may impose civil money penalties, assessments, and/or exclusions for program non-compliance.

4.20.2.1 - Civil Monetary Penalties Delegated to CMS **(Rev. 71, 04-09-04)**

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 only 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 non-participating 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 non-participating 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 only cause an exclusion.)
- Section 1834(j)(2)(A)(iii) - Any durable 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 non-assigned 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 non-participating physician billing for an elective surgical procedure on a non-assigned basis, who 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 non-participating 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 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 if 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 non-standard 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 to automatically reinstate the policy as of the date the policyholder loses medical assistance eligibility (and the policyholder 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 who fails 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 non-payment of premiums; 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.)

4.20.2.2 - Civil Monetary Penalties Delegated to OIG

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

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, Prospective Payment System (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) Section 1919(b)(3)(B)	False statement in assessment of functional capacity of skilled nursing facility (SNF) resident.
Section 1819(g)(2)(A) Section 1919 (g)(2)(A)	Notice to SNF/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 1860D-31(i)(3)	Engaged in false or misleading marketing practices under the Medicare prescription drug discount card program; or overcharge prescription drug enrollees; or misuse of transitional assistance funds.
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) Section 1903(m)(5)(A)(i) Section 1857(g)(1)(A)	Failure by Health Maintenance Organization (HMO)/competitive medical plan/MCO to provide necessary care affecting beneficiaries.
Section 1876(i)(6)(A)(ii) Section 1903(m)(5)(A)(ii) Section 1857(g)(1)(B)	Premiums by HMO/competitive medical plan/MCO in excess of permitted amounts.
Section 1876(i)(6)(A)(iii)	HMO/competitive medical plan/MCO

Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(C)	expulsion/refusal to re-enroll individual per prescribed conditions.
Section 1876(i)(6)(A)(iv) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(D)	HMO/competitive medical plan/MCO practices to discourage enrollment of individuals.
Section 1876(i)(6)(A)(v) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(E)	False or misrepresenting HMO/competitive medical plan/MCO information to Secretary.
Section 1876(i)(6)(A)(vi) Section 1903(m)(5)(A)(v) Section 1857(f)	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) Section 1857(g)(1)(G)	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 of 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 the Health Care Quality Improvement Act (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.

4.20.3 - Referral Process (Rev. 71, 04-09-04)

4.20.3.1 - Referral Process to CMS (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

Compliance is promoted through both administrative and formal legal actions. Administrative compliance action shall first be attempted by ACs and MACs 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 AC and MAC shall make a referral to the PSC or the ZPIC who shall forward it to the Primary GTL, Associate GTL, and SME and the CMS CO Director of the Division of Benefit Integrity Management Operations (see PIM Chapter 4, §4.20.3.2).

It is important for ACs and MACs to promote program compliance in their respective jurisdictions. The ACs and MACs 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 shall also be allowed the opportunity to present additional facts that may represent mitigating circumstances. PSC and ZPIC BI units shall consider this information in an objective manner before proceeding with a CMP referral to CMS.

When a PSC and ZPIC BI unit elects to make a CMP referral to CMS, the initial referral package shall consist of a brief overview of the case; supportive documentation 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 medical 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 PIM Chapter 4, §4.20.2.1).

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 the beneficiary(ies), respectively.
6. A brief chronological listing of events depicting communication (oral and written) between the AC or MAC 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.
9. The name and phone number of contacts at the PSC or the ZPIC BI unit.

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

If CMS declines the referral, the PSC or the ZPIC shall communicate this to the AC or the MAC to continue in their efforts to educate and promote compliance by the provider. The PSC and the ZPIC BI unit shall 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, ACs and MACs shall initiate the appropriate steps for recovery.

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

4.20.3.2 - Referrals to OIG

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

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, ZPIC shall contact the OIG/OI Field Office to discuss the potential case. If this contact results in a referral, the ZPIC shall follow the same referral format as described in PIM, chapter 4, §4.18.1.4. If a referral is not made or a referral is declined, the ZPIC 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 appropriate Medicare payments have been identified, MACs shall initiate the appropriate steps for recovery.

The ZPIC 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)(1) of the Social Security Act.

The ZPIC shall send to the CMS Provider Enrollment and Oversight Group all cases where ZPIC believes that misuse has occurred of the Medicare name, symbols, emblems, or other violations as described in §1140 of the Social Security Act and in 42 CFR 1003.102(b)(7).

4.20.4 - CMS Generic Civil Monetary Penalties Case Contents (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

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 (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).
 - c. Provider's address (street, city, state, and zip code). If violator is an entity, identify address where principal operator personally receives 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 the AC or MAC and provider.
6. Copies of provider's applicable bills to beneficiaries and/or ACs and MACs, and associated payment histories.
7. Copies of any complaints regarding provider and disposition of the complaint.

8. Copies of all publications (e.g., bulletins, newsletters) sent to provider by the PSC, ZPIC, AC, or MAC who 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 PSC or ZPIC BI unit contact.

4.20.5 - Additional Guidance for Specific Civil Monetary Penalties (Rev. 71, 04-09-04)

4.20.5.1 - Beneficiary Right to Itemized Statement (Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

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 an AC or MAC 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 5 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 AC or MAC may contact the provider.

Once the AC or MAC confirms that the complaint is valid, the AC or MAC shall initiate steps to assist the beneficiary in getting the provider to furnish the itemized statement. ACs and MACs shall 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 intervention of the AC or MAC 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 intervention of the AC or MAC prove unsuccessful, the AC or MAC shall consider referral to the PSC or the ZPIC BI unit for

subsequent referral of the potential CMP case to CMS, following the guidelines established in PIM Chapter 4, §§4.20.3.1 and 4.20.4. There may be instances where a beneficiary receives an itemized statement and the AC or MAC receives the beneficiary's request (written or oral) to review discrepancies on his/her itemized statement. ACs and MACs shall follow their normal operating procedures in handling these complaints. ACs and MACs shall determine whether itemized services or items were provided, or if any other irregularity (including duplicate billing) resulted in improper Medicare payments. If so, the AC or MAC shall recover the improper payments.

4.20.5.2 - Medicare Limiting Charge Violations

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

The Omnibus Budget Reconciliation Act of 1989 (OBRA) established a limitation on actual charges (balanced billing) by non-participating physicians. (Refer to §1848(g) of the Act, and Medicare Carriers Manual §§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 the Limiting Charge Monitoring Report, the discontinuance of sending compliance monitoring letters and Refund/Adjustment Verification Forms), developing a Limiting Charge CMP case shall require the following additional information:

- Contact with the provider - Based on CMS instructions, ACs and MACs 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 that 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.) The provider's letter should also include information that 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.

- Limiting Charge Monitoring Reports (LCMRs) - Produce LCMRs for all limiting charge violations respective to the provider and which encompasses the last three years. ACs and MACs shall also identify those beneficiaries appearing on the reports who have requested assistance in obtaining a refund from their provider.

4.21 - Monitor Compliance

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

The ZPIC shall monitor future claims and related actions of the provider at least 6 months after the ZPIC has closed its investigation to ensure the propriety of future payments. In addition to internal screening of the claims, if previous experience or future billings warrant, they shall periodically interview a sampling of the provider's patients to verify that billed services were actually furnished.

If, at the end of a 6-month period, there is no indication of a continuing aberrant pattern, the ZPIC shall discontinue the monitoring.

4.21.1 - Resumption of Payment to a Provider - Continued Surveillance After Detection of Fraud

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

After completion of the investigation and appropriate legal action, all determined overpayments are recouped by either direct refund or offset against payments being held in suspense. Once recoupment is completed, PSC and ZPIC BI units shall release any suspended monies that are not needed to recoup determined overpayments and, if applicable, penalties.

PSC and ZPIC BI units shall monitor future claims and related actions of the provider for at least 6 months, to assure the propriety of future payments. In addition to internal screening of the claims, if previous experience or future billings warrant, they shall periodically interview a sampling of the provider's patients to verify that billed services were actually furnished.

If, at the end of a 6-month period, there is no indication of a continuing aberrant pattern, PSC and ZPIC BI units shall discontinue the monitoring.

4.22 - Discounts, Rebates, and Other Reductions in Price

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

A PSC or ZPIC 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.

4.22.1 - Anti-Kickback Statute Implications

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, hospital incentive or bribe) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a person for the furnishing or arranging for the furnishing of any item or service for which

payment may be made in whole or in part under Medicare, Medicaid or a State health care program, or in return for purchasing, leasing, or ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Medicare, Medicaid or a State health program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both. 42 U.S.C. 1320a-7b(b), §1128B(b) of the Act.

Discounts, rebates, or other reductions in price may violate the anti-kickback statute because such arrangements induce the purchase of items or services payable by Medicare or Medicaid. However, some arrangements are clearly permissible if they fall within a safe harbor. One safe harbor protects certain discounting practices. For purposes of this safe harbor, a “discount” is the reduction in the amount a seller charges a buyer for a good or service based on an arms-length transaction. In addition, to be protected under the discount safe harbor, the discount must apply to the original item or service that is purchased or furnished (i.e., a discount cannot be applied to the purchase of a different good or service than the one on which the discount was earned). The definition of discount under the anti-kickback statute does not include “bundled” goods or services. As a result, a discount may apply to the purchase of different goods or services other than the one on which the discount was earned, when they are bundled together to induce the purchase of that good or service without coming under the anti-kickback statute. Additionally, the discount offered for bundled goods or services to induce the purchase of a different good or service would not come under the anti-kickback statute only when both items are subject to the same reimbursement methodology under Medicare or Medicaid. A “rebate” is defined as a discount that is not given at the time of sale. A “buyer” is the individual or entity responsible for submitting a claim for the item or service that is payable by the Medicare or Medicaid programs. If the buyer is an entity that reports its costs on a cost report required by the Department or state health care program, it must comply with all of the following standards:

The discount must be earned based on purchases of that same good or service bought within a single fiscal year.

The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year.

The buyer must fully and accurately report the discount in the applicable cost report.

The buyer must provide, upon request by the Secretary or a state agency, information provided by the seller as specified in 42 CFR §1001.952 (h)(2)(ii) of this section, or information provided by the offeror as specified in 42 CFR §1001.952 (h)(3)(ii).

A “seller” is the individual or entity that offers the discount.

4.22.1.1 - Marketing to Medicare Beneficiaries

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

Certain marketing or solicitation practices could be in violation of the Medicare anti-kickback statute, 42 U.S.C. 1320a-7b(b). All marketing practices shall comply with the Medicare anti-kickback statute and with the Office of the Inspector General's (OIG's) Compliance Program Guidance for the DMEPOS industry.

Marketing practices may influence Medicare beneficiaries who use 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 MACs.

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 or the propriety of marketing or advertising material.

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

4.22.2 - Cost-Based Payment (Intermediary and MAC Processing of Part A Claims): Necessary Factors for Protected Discounts

(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This applies to ZPICs and MACs.

For a discount to be protected, certain factors must exist. These factors assure that the benefit of the discount or rebate will be reported and passed on to the programs. If the buyer is a Part A provider, it must fully and accurately report the discount in its cost report. The buyer may note the submitted charge for the item or service on the cost report as a "net discount." In addition, the discount must be based on purchases of goods or services bought within the same fiscal year. However, the buyer may claim the benefit of a discount in the fiscal year in which the discount is earned, or in the following fiscal

year. The buyer is obligated, upon request by the HHS or a state agency, to provide information given by the seller relating to the discount.

The following types of discounts may be protected if they comply with all of the applicable standards in the discount safe harbor:

- Rebate check
- Credit or coupon directly redeemable from the seller
- Volume discount or rebate

The following types of discounts are not protected:

- Cash payment
- Furnishing one good or service free of charge or at a reduced charge in exchange for any agreement to buy a different good or service
- Reduction in price applicable to one payer but not to Medicare or a State health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

Note: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services. (Refer to 42 CFR §1001.952(k)(1).)

4.22.3 - Charge-Based Payment (MAC Processing of Part B Claims): Necessary Factors for Protected Discounts (Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs and MACs.

For a discount program to be protected for Part B billing, certain factors must exist. These factors ensure that the benefit of the discount or other reduction in price is reported and passed on to the Medicare or Medicaid programs. A rebate rendered after the time of sale is not protected under any circumstances. The discount must be made at the time of sale of the good or service. In other words, rebates are not permitted for items or services if payable on the basis of charges. The discount must be offered for the same item or service that is being purchased or furnished. The discount must be clearly and accurately reported on the claim form.

The following types of discounts may be protected if they comply with all of the applicable standards in the discount safe harbor:

Credit or coupon directly redeemable from the seller

The following types of discounts are not protected:

- Rebates offered to beneficiaries
- Cash payment

- Furnishing an item or service free of charge or at a reduced charge in exchange for any agreement to buy a different item or service
- Reduction in price applicable to one payer but not to Medicare or a State health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

NOTE: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services. (Refer to 42 CFR §1001.952(k)(1).)

4.22.4 - Risk-Based Provider Payment: Necessary Factors for Protected Discounts

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

If the buyer is a health maintenance organization or a competitive medical plan acting in accordance with a risk contract or under another state health care program, the buyer does not need to report the discount, except as otherwise required under the risk contract.

4.23 - Identity Theft – Physicians

(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

ZPICs shall conduct investigations of potential fraud, waste, or abuse of physician identities. An example of physician identity theft may include a physician's identity having been stolen and used to establish a new billing number (reassignment), causing inappropriate Medicare payments to unknown person(s) and potential Internal Revenue Service (IRS) issues for the victimized physician.

The ZPIC shall discuss the identity theft case with the COR and IAG BFL. If claims are still being submitted and Medicare payments are being made, consider requesting a prepayment review, auto-denial edit, or immediate payment suspension.

The IAG BFL will determine if the physician will be treated as a victim of identity theft and will coordinate the referral of correcting the inaccurate information to the appropriate CMS component.

The ZPIC shall provide the following information to the COR and IAG BFL, if appropriate:

Name, fraudulent address, ID number, and tax identification number (TIN).

Name, correct address, ID number, and TIN.

A signed attestation from the physician indicating that there was no knowledge that identity information was stolen and used to establish a Medicare billing number. Furthermore, the physician attests that he/she did not receive any of the potential fraudulent reimbursements, either directly or indirectly.

A brief summary of how the fraud occurred and was discovered.

The total dollars paid (by calendar year) under the fraudulent number.

Name of MAC involved.

Amount of money that has been recovered by the MAC.

The amount of money seized and being held by law enforcement

4.24 - Reserved for Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.25 - Participation Agreement and Limiting Charge Violations

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

Section 2306 of the Deficit Reduction Act of 1984 established a physician/supplier participation program. The Omnibus Budget Reconciliation Act of 1989 established a limitation on actual charges by non-participating physicians (see §1848(g) of the Act). Participating physicians/suppliers who violate their participation agreements, and non-participating physicians who knowingly, willfully, and repeatedly increase their charges to Medicare beneficiaries beyond the limits, are liable for action in the form of CMPs, assessments, and exclusion from the Medicare program for up to 5 years, or both. Criminal penalties also apply to serious violations of the participation agreement provisions.

For further discussion of the participation agreement and limiting charge provisions, see IOM Pub.100-04, chapter 1, §§30.3 and 30.3.12.3.

4.26 – Supplier Proof of Delivery Documentation Requirements

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

Suppliers are required to maintain proof of delivery documentation in their files. Documentation must be maintained in the supplier's files for 7 years.

Proof of delivery is required in order to verify that the beneficiary received the DMEPOS. Proof of delivery is one of the supplier standards as noted in 42 CFR, 424.57(12). Proof of delivery documentation must be made available to the DME MAC upon request. For any services, which do not have proof of delivery from the supplier,

such claimed items and services shall be denied and overpayments recovered. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG for investigation and/or imposition of sanctions.

4.26.1 - Proof of Delivery and Delivery Methods

(Rev. 641, Issued: 02-19-16, Effective: 03-19-16, Implementation: 03-19-16)

For the purpose of the delivery methods noted below, **designee** is defined as:

“Any person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary.”

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The relationship of the designee to the beneficiary should be noted on the delivery slip obtained by the supplier (i.e., spouse, neighbor). The signature of the designee should be legible. If the signature of the designee is not legible, the supplier/shipping service should note the name of the designee on the delivery slip.

Suppliers may deliver directly to the beneficiary or the designee. An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include: 1) The patient's name; 2) The quantity delivered; 3) A detailed description of the item being delivered; 4) The brand name; and 5) The serial number. The long description of the HCPCS code, for example, may be used as a means to provide a detailed description of the item being delivered; though suppliers are encouraged to include as much information as necessary to adequately describe the delivered item. The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply shall be the date of service on the claim.

If the supplier utilizes a shipping service or mail order, an example of proof of delivery would include the service's tracking slip, and the supplier's own shipping invoice. If possible, the supplier's records should also include the delivery service's package identification number for that package sent to the beneficiary. The shipping service's tracking slip should reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and if possible, the date delivered. If a supplier utilizes a shipping service or mail order, suppliers shall use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery. The descriptive information concerning the DMEPOS item (i.e., the patient's name, the quantity, detailed description, brand name, and serial number) as well as the required signatures from either the beneficiary or the beneficiary's designee should be included on this invoice as well.

For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill. This shall be done to ensure that the refilled item is necessary and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills shall take place no sooner than 14 calendar days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier shall deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

For those patients that are residents of a nursing facility, upon request from the DME MAC, suppliers should obtain copies of the necessary documentation from the nursing facility to document proof of delivery or usage by the beneficiary (e.g., nurse's notes):

- Contractors shall, when evaluating usage by the beneficiary to satisfy the proof of delivery requirements for items supplied in bulk, accept evidence that the patient utilized the supplied item (i.e., documentation generally supports that the amount ordered correlates with the amount provided and billed).
- For example, this could be demonstrated through documentation provided in the nursing notes or in the medication administration record indicating beneficiary receipt of the DMEPOS item or supply. Contractors are not required to identify an exact match between the items ordered by the physician and delivered to the nursing facility with those utilized by the beneficiary.

Contractors shall continue to ensure that any bills for the DMEPOS item(s) are consistent with the order(s) written by the physician or other eligible practitioner. Questionable billing patterns or practices shall be referred to the appropriate entity for additional enforcement.

4.26.2 – Exceptions

(Rev. 83, Issued: 08-27-04, Effective: 09-27-04, Implementation: 09-27-04)

Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from a hospital or nursing facility. A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (Patient's Home). The item must be for subsequent use in the patient's home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

A supplier may not bill for drugs or other DMEPOS items used by the patient prior to the patient's discharge from the hospital or a Medicare Part A nursing facility stay. Billing

the DMERC for surgical dressings, urological supplies, or ostomy supplies that are provided in the hospital or during a Medicare Part A nursing facility stay is not allowed. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the patient from the hospital or nursing facility. Any attempt by the supplier and/or facility to substitute an item that is payable to the supplier for an item that, under statute, should be provided by the facility, may be considered to be fraudulent. These statements apply to durable medical equipment delivered to a patient in hospitals, skilled nursing facilities (Place of Service = 31), or nursing facilities providing skilled services (Place of Service = 32).

A supplier may deliver a DMEPOS item to a patient's home in anticipation of a discharge from a hospital or nursing facility. The supplier may arrange for actual delivery of the item approximately 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (Patient's Home).

4.27 - Reserved for Future Use

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

4.28 - Joint Operating Agreement

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs, MACs, Recovery Auditors (RAs), and QICs, as indicated.

A Joint Operating Agreement (JOA) is a document developed between two entities (CMS contractors) that delineates the roles and responsibilities of each entity regarding their interactions with each other on CMS contracts.

ZPICs shall have JOAs with the following contractors:

QICs (refer to PIM Exhibit 45 for a sample JOA between the ZPIC and the QIC)

RAs (refer to PIM Exhibit 44 for a sample JOA between the ZPIC and the RA)

State agencies with regard to the Medicare and Medicaid Data Match Program (Medi-Medi) Task Order 2 (refer to the Medi-Medi Policies and Procedures Manual).

MACs, as specified below

Pricing, Data Analysis, and Coding Contractor (PDAC)

NSC

National Benefit Integrity Medicare Drug Integrity Contractor

A. ZPICs and MACs Joint Operating Agreement

As it applies to the ZPIC's task orders, the JOA with the MACs shall, at a minimum, provide information on assigned responsibilities, timeframes, processes and procedures, and coordination (as indicated below):

- Identify the JOA participants.
- Include JOA workgroup meetings.
- Describe the roles and responsibilities of the ZPIC and the MAC.
- Include a description and documentation of processes/workflows that illustrate how the ZPIC and the MAC intend to interact with one another to complete each of the tasks outlined in the task order on a daily basis.
- Clearly define the dispute resolution processes.
- Describe communication regarding CMS' changes.
- Establish responsibility for the contractor who shall request medical records/documentation not submitted with the claim.
- Establish responsibility for how medical records/documentation that have been submitted without being requested shall be stored and tracked.
- Establish responsibility for how medical records/documentation that have been submitted without being requested shall be provided to the ZPIC if the documentation becomes necessary in the review process.
- Mitigate risk of duplicate medical records/documentation requests.
- Ensure that there is no duplication of effort by the ZPIC and the MAC (e.g., the MAC must not re-review the ZPIC's work).
- Include prepayment reviews.
- Include data to evaluate the ZPIC edit effectiveness via a monthly report from the MAC.
- Include postpayment reviews.
- Include data analysis.
- Include payment suspension.
- Include excluded providers/suppliers.
- Include overpayments processing.
- Include systems information.
- Include system edits and audits.
- Include securing e-mail information.
- Include training and education.
- Include complaint screening and processing (including the immediate referral by the MAC second-level screening staff of provider/supplier complaints and immediate advisements to the ZPIC).

- Include the OIG Hotline referrals.
- Include voluntary refunds.
- Include the Incentive Reward Program
- Include appeals.
- Include provider enrollment.
- Include deactivation and/or revocation of Provider Transaction Access Numbers (PTANs) (refer to chapter 15 of Pub. 100-08).
- Include Freedom of Information Act and Privacy Act responsibilities.
- Ensure that the MAC communicates to the ZPIC any interaction with law enforcement on requests for cost report information.
- Include interaction with law enforcement.
- Include requests for information.
- Include fraud investigations.
- Include Senior Medicare Patrols.
- Include self-disclosures.
- Include coordination on provider/supplier outreach and education (POE).
- Include supporting the Health Care Fraud Prevention and Enforcement Action Team (HEAT) task forces.
- Contain other items identified by CMS, the ZPIC, and/or the MAC.

4.29 - Reserved for Future Use

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

4.30 – Reserved for Future Use

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

4.31 – Vulnerabilities

(Rev. 667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)

This section applies to ZPICs.

Program vulnerabilities can be identified through a variety of sources such as the chief financial officer's (CFO) audit, Fraud Alerts, the Government Accountability Office (GAO), the Office of Inspector General (OIG), data driven studies, and ZPIC and Medicare contractor operations, as examples. The ZPIC shall submit any identified program vulnerabilities in the appropriate narrative in the ZPIC monthly cost report. The ZPICs shall also send identified vulnerabilities to the vulnerability mailbox, using the template in Exhibit 46. ZPICs shall submit any identified program vulnerabilities to the vulnerability mailbox regardless of risk level, as soon as possible after they are

depends on timely and accurate information reporting by the ZPICs, as well as by claims processing contractors and by the RAs themselves.

To prevent RA interference with active investigations or cases, ZPICs shall enter suppressions in the RA Data Warehouse to temporarily mark entire providers/suppliers or subsets of a provider's/supplier's claims as "off-limits" to the RAs. Individual claims that have been previously reviewed (or that are part of an extrapolated settlement universe) shall be excluded to permanently block them from repeat reviews by a RA.

The RA Data Warehouse allows users to enter suppressions on any combination of provider ID, Diagnostic Related Group (DRG), International Classification of Diseases-9/10 (ICD-9/10) procedure code, Healthcare Common Procedure Coding System (HCPCS) code, State, or ZIP code although CMS requires that suppressions be tailored as narrowly as possible. ZPICs shall suppress targeted procedure codes from specific providers/suppliers associated with open investigations/cases. Suppressions of one or more procedure codes across an entire geographic area may be considered in egregious situations of widespread fraud and abuse of specific codes or types of services (e.g., infusion therapy in South Florida).

The Data Warehouse can accept suppressions on a rendering provider, supplier, or institution ID. Suppressions on referring, ordering, billing (for professional DME claims) and attending providers (institutional claims) are not currently supported.

Whether suppressing an entire provider or only a portion of a provider's claims, the ZPIC shall indicate the nature of the provider being suppressed (i.e., hospital, individual physician, physician group, home health agency, etc.) in the provider type field, using the codes specified in the Data Warehouse. The ZPIC shall also indicate the name of the provider being suppressed in the comment field, which can accommodate up to 256 characters.

When entering a suppression on a six-digit provider/supplier ID, the ZPIC shall also enter the provider's/supplier's practice State. States are not required for NPIs, NSC numbers, alphanumeric or PTANs that are other than six digits long; but six-digit PTANs potentially overlap with six-digit CMS institutional provider numbers. Having the provider/supplier-state will help CMS suppression reviewers to differentiate among multiple providers/suppliers with the same ID.

Specific suppression start and end dates are also mandatory. Suppressions can extend up to three (3) years into the past and one (1) year forward from date of entry (the start date is initially fixed at 10/1/2007, which is the earliest start date that RAs can select for their reviews). Users will be notified as their suppressions approach the expiration dates and can renew them if necessary. CMS expects users to release them sooner if the underlying investigations/cases are closed.

Once a suppression is lifted or expires, ZPICs are also responsible for entering any necessary exclusions. Any claims for which the ZPIC has requested medical records

shall be excluded to prevent re-review by a RA, unless the ZPIC's review resulted in a full denial. In this case, exclusion is unnecessary because the provider/supplier will either appeal and the redetermination entity will enter the exclusion, or the provider/supplier will allow the decision to stand. The exclusion will be unnecessary because the RAs are unlikely to pursue zero-dollar claims).

Below are examples of suppressions and exclusions in various circumstances: this list is not all-inclusive. The ZPIC staff may need to consult with its respective CMS COR and BFLs and/or CMS RA liaison to determine the appropriate level of suppression or exclusion.

4.34 - Suppression and/or Exclusion – Examples

(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)

This section applies to ZPICs/*UPICs* and RACs, as indicated.

- Suppressions of providers/suppliers that the ZPIC/*UPIC* has referred to law enforcement and are the subject of a law enforcement investigation should remain effective until the provider's/supplier's case is returned with a declination for prosecution from law enforcement and without a request for ZPIC/*UPIC* administrative action. The suppression may be entered using one of the following methods:

Suppression at the provider/supplier and/or geographic level requires the user to supply detailed justification for each request; in addition to provider name/type, start/end dates, and other fields as specified in the RAC Data Warehouse User's Guide. ZPICs/*UPICs* shall routinely monitor accepted suppression records to ensure that the suppressions remain relevant/appropriate and that they are ultimately released in a timely manner.

Suppression at the procedure code level for individual providers/suppliers may be done without providing justification, due to the narrower scope of the suppression. Suppressions at this level still require the user to supply a DRG, ICD-9/10 procedure or HCPCS code, provider/supplier identifiers, start and end dates, and any additional information as defined in the RAC Data Warehouse User's Guide.

Note: The RACs can review claims paid as early as 10/1/2007, which is before NPI submission became mandatory. Therefore, ZPICs/*UPICs* are strongly encouraged to enter suppressions on both NPIs and legacy provider/supplier numbers for suppressions that cover the period of October 2007 through May 2008.

Suppression/Exclusion for postpayment review where extrapolation may or may not be performed – In the event that the ZPIC/*UPIC* is unable to determine at the time of review whether any overpayments that are identified will be extrapolated to the parent claim universe, the ZPIC/*UPIC* shall enter a suppression on the

relevant provider/supplier ID and service code(s). If the ZPIC/*UPIC* does ultimately assess an extrapolated overpayment, the ZPIC/*UPIC* shall release the suppression and exclude the entire universe. If the overpayment is computed based only on the sampled claims (i.e., the overpayment is not projected to the entire universe), the ZPIC/*UPIC* shall release the suppression and exclude only the sample claims that were actually reviewed.

Exclusion for prepayment edits or clinically unlikely edits (CUEs) – Claims that have been subjected to automated edits only are still eligible for RAC review and should generally not be excluded. Claims that have subsequently undergone *medical record* review do require exclusion.

Exclusion for prepayment review – In those instances in which a provider/supplier is under investigation and is subject to 100% prepayment review, a suppression will not be necessary because the RACs do not receive claim data in real time. However, all individual claims that were reviewed shall be excluded (this requirement applies whether the provider/supplier was on 100% prepayment review, or a lesser fraction of that provider's/supplier's claims were being reviewed).

For access to the RAC Data Warehouse, contact the system administrators at rac@cms.hhs.gov. Current suppression/exclusion file layouts and the user's guide are available from the help desk staff or by download from the system itself.

The ZPICs/*UPICs* shall have a JOA with the RACs. Refer to PIM Exhibit 44 for the JOA between the ZPICs/*UPICs* and the RACs. The ZPICs/*UPICs* shall include in the JOA quarterly meetings with the RAC in their zone, at a minimum, to discuss trends in possible fraudulent billing. If ZPICs/*UPICs* or RACs have any recommendations for modifying the JOA, they shall provide these modifications to their respective CORs.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R721PI</u>	06/09/2017	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews	07/11/2017	9809
<u>R675PI</u>	09/09/2016	Update to Chapter 4, Pub. 100-08	12/12/2016	9426
<u>R667PI</u>	08/08/2016	Revisions to Instructions Regarding the Fraud Investigation Database (FID) and Other Program Integrity Procedures	11/08/2016	9436
<u>R641PI</u>	02/19/2016	Proof of Delivery in Nursing Facilities	03/19/2016	9524
<u>R635PI</u>	02/04/2016	Clarification to Language Regarding Proof of Delivery Requirements in Pub. 100-08, Chapter 4, Section 4.26.1	03/04/2016	9487
<u>R608PI</u>	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
<u>R495PI</u>	12/13/2013	Recalcitrant Provider Procedures	01/15/2014	8394
<u>R472PI</u>	06/21/2013	Elimination of SMART FACTS for PSCs/ZPICs (SMP Program)	07/23/2013	8312
<u>R467PI</u>	05/31/2013	Requirements for the Closing of Complaints After Transfer to the PSCs and ZPICs in the Office of the Inspector General (OIG) Hotline Complaint Database	07/01/2013	8288
<u>R466PI</u>	05/17/2013	Requirements for Sending Immediate Advisements to the OIG/OI (Office of the Inspector General/Office of Investigations)	06/18/2013	8287
<u>R432PI</u>	08/31/2012	Timeframes for Handling OIG Hotline Complaints Uploaded into the OIG Hotline Database; Requirements for the Transfer and Closing of Cases in the OIG Hotline Complaint Database System	10/01/2012	7852
<u>R389PI</u>	09/30/2011	Proof of Delivery and Delivery Methods	10/31/2011	7410
<u>R311PI</u>	11/13/2009	Recovery Audit Contractors (RACs)	12/14/2009	6684
<u>R265PI</u>	08/08/2008	Medicare Fraud Edit Module Phase 3	04/06/2009	6135
<u>R264PI</u>	08/07/2008	Transition of Responsibility for Medical Review From Quality Improvement Organizations (QIOs)	08/15/2008	5849
<u>R262PI</u>	07/01/2008	Flagging Health Insurance Claim Numbers (HICN) in the Medicare Carrier System (MCS) for Pre-Payment Review/Audit	07/07/2008	5644

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R259PI</u>	06/13/2008	Benefit Integrity Updates	07/07/2008	6003
<u>R252PI</u>	04/11/2008	Flagging Health Insurance Claim Numbers (HICN) in the Medicare Carrier System (MCS) for Pre-Payment Review/Audit - Rescinded and replaced by Transmittal 262	07/07/2008	5644
<u>R241PI</u>	02/08/2008	Flagging Health Insurance Claim Numbers (HICN) in the Medicare Carrier System (MCS) for Pre-Payment Review/Audit – Rescinded and Replaced by Transmittal 252	04/07/2008	5644
<u>R213PI</u>	06/29/2007	Various Benefit Integrity Revisions	07/30/2007	5630
<u>R211PI</u>	06/22/2007	Medicare Benefit Vulnerability Reporting	07/23/2007	5581
<u>R210PI</u>	06/15/2007	High Risk Areas	07/16/2007	5626
<u>R176PI</u>	11/24/2006	Various Benefit Integrity (BI) Revisions	12/26/2006	5368
<u>R174PI</u>	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
<u>R170PI</u>	11/03/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 174	10/06/2006	5275
<u>R163PI</u>	09/29/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 170	10/06/2006	5275
<u>R160PI</u>	09/25/2006	Complaint Screening	10/02/2006	5335
<u>R144PI</u>	03/31/2006	Various Benefit Integrity (BI) Revisions	05/01/2006	4247
<u>R127PI</u>	10/28/2005	Complaint Screening Revisions	11/28/2005	4118
<u>R118PI</u>	08/12/2005	Various Benefit Integrity (BI) Clarifications	09/12/2005	3896
<u>R101PI</u>	01/28/2005	Benefit Integrity (BI) PIM Revisions	02/28/2005	3579
<u>R099PI</u>	01/21/2005	Waivers Approved by the Regional Office (RO) by Replacing Regional Office with Central Office (CO)	02/22/2005	3646
<u>R096PI</u>	01/14/2005	Consent Settlements	02/14/2005	3626
<u>R083PI</u>	08/27/2004	Miscellaneous Revisions for Chapter 4	09/27/2004	3379
<u>R080PI</u>	07/16/2004	PIM Fraud and Abuse Complaint Screening Revisions	08/16/2004	3341
<u>R071PI</u>	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
<u>R016PIM</u>	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund Checks, Anti-Kickback Statute Implications	11/28/2001	1732
<u>R003PIM</u>	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R001PIM</u>	06/2000	Initial Release of Manual	NA	931

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