| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-08 Medicare Program Integrity | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 667** | **Date: August 8, 2016** |
| | **Change Request 9436** |

**SUBJECT: Revisions to Instructions Regarding the Fraud Investigation Database (FID) and Other Program Integrity Procedures**

**I. SUMMARY OF CHANGES:** The purpose of this change request (CR) is to update the instructions in chapter 4 of Pub. 100-08 regarding the FID and other program integrity procedures.

**EFFECTIVE DATE: November 8, 2016**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: November 8, 2016**

***Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| R | 4/Table of Contents/Program Integrity |
| R | 4/4.8/Disposition of Cases Referred to Law Enforcement |
| R | 4/4.8.1/Reversed Denials by Administrative Law Judges on Open Cases |
| R | 4/4.8.2/Production of Medical Records and Documentation for an Appeals Case File |
| R | 4/4.9/Incentive Reward Program |
| R | 4/4.9.1/ZPIC Responsibilities for the Incentive Reward Program |
| R | 4/4.9.2/Guidelines for Processing Incoming Complaints |
| R | 4/4.9.3/Guidelines for Incentive Reward Program Complaint Tracking |
| R | 4/4.10/Fraud Alerts |
| R | 4/4.10.1/Reserved For Future Use |
| R | 4/4.10.2/Reserved For Future Use |
| R | 4/4.10.3/Reserved For Future Use |
| R | 4/4.10.4/Reserved for Future Use |
| R | 4/4.10.5/Reserved for Future Use |
| R | 4/4.11/FID Entries |
| R | 4/4.11.1/Background |
| R | 4/4.11.1.2/Entering OIG Immediate Advisements into the FID |
| N | 4/4.11.1.3/Documentation of Identity Theft and Compromised HICNs in the FID |
| R | 4/4.11.2/Investigation, Case, Payment Suspension, and Request for Information Entries |
| R | 4/4.11.2.1/Initial Entry Requirements for Investigations |
| R | 4/4.11.2.2/Initial Entry Requirements for Cases Referred to Law Enforcement |
| R | 4/4.11.2.3/Initial Entry Requirements for DMEPOS Payment Suspensions |
| N | 4/4.11.2.3.1/Initial Entry Requirement for Non-DMEPOS Payment Suspensions |
| N | 4/4.11.2.3.2/Initial Entry Requirements for Requests for Information and Requests for Assistance |
| R | 4/4.11.2.4/Update Requirements for Investigations |
| R | 4/4.11.2.5/Update Requirements for Cases |
| R | 4/4.11.2.6/Update Requirements for National DMEPOS Payment Suspensions |

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| N | 4/4.11.2.6.1/Update Requirements for Non-DMEPOS Payment Suspensions |
| N | 4/4.11.2.6.2/Update Requirements for Requests for Information and Requests for Assistance |
| R | 4/4.11.2.7/OIG Non-Response to or Declination of Case Referral |
| R | 4/4.11.2.8/Closing Investigations |
| R | 4/4.11.2.9/Closing Cases Referred to Law Enforcement |
| R | 4/4.11.2.10/Removing Payment Suspensions |
| N | 4/4.11.2.10.1/Closing Requests for Information and Requests for Assistance |
| R | 4/4.11.2.11/Duplicate Entries |
| R | 4/4.11.2.12/Deleting Investigations, Cases, or Suspensions |
| R | 4/4.11.3.1/Access |
| R | 4/4.11.3.2/The FID Testing Group |
| R | 4/4.11.3.3/ZPIC FID CSA |
| R | 4/4.12/Reserved for Future Use |
| R | 4/4.13/Administrative Relief from Program Integrity Review in the Presence of a Disaster |
| R | 4/4.14/Provider/Supplier Contacts by the ZPIC |
| R | 4/4.16/MAC and ZPIC Coordination on Voluntary Refunds |
| R | 4/4.18.1/Referral of Cases to the OIG/OI |
| R | 4/4.18.1.1/Reserved for Future Use |
| R | 4/4.18.1.2/Immediate Advisements to the OIG/OI |
| R | 4/4.18.1.3/Payment Suspension |
| R | 4/4.18.1.4/OIG/OI Case Summary and Referral |
| R | 4/4.18.1.5/Referral to Other Law Enforcement Agencies |
| R | 4/4.18.2/Referral to State Agencies or Other Organizations |
| R | 4/4.18.3/ZPICs and QIOs |
| R | 4/4.20.3.2/Referrals to OIG |
| R | 4/4.21/Monitor Compliance |
| R | 4/4.22.1/Anti-Kickback Statute Implications |
| R | 4/4.22.1.1/Marketing to Medicare Beneficiaries |

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| R | 4/4.22.2/Cost-Based Payment (Intermediary and MAC Processing of Part A Claims): Necessary Factors for Protected Discounts |
| R | 4/4.22.3/Charge-Based Payment (MAC Processing of Part B Claims): Necessary Factors for Protected Discounts |
| R | 4/4.22.4/Risk-Based Provider Payment: Necessary Factors for Protected Discounts |
| R | 4/4.23/Identity Theft – Physicians |
| R | 4/4.24/Reserved for Future Use |
| R | 4/4.27/Reserved for Future Use |
| D | 4/4.27.1/Issues to Consider Before Referring a Recalcitrant Provider Case to CMS |
| D | 4/4.27.2/CMS Approval/Disapproval for Notification for a Recalcitrant Provider/Supplier Case Submission |
| D | 4/4.27.3/Case Format for Referring Recalcitrant Providers/Suppliers |
| R | 4/4.28/Joint Operating Agreement |
| R | 4/4.31/Vulnerabilities |
| R | 4/4.32/Reserved for Future Use |
| D | 4/4.32.1/Action Taken in High-Risk Areas |
| R | 4/4.33/ZPIC Coordination With Recovery Auditors (RAs) |
| N | 4/4.34/Suppression and/or Exclusion – Examples |

**III. FUNDING:**

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

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**
**Manual Instruction**

# Attachment - Business Requirements

| Pub. 100-08 | Transmittal: 667 | Date: August 8, 2016 | Change Request: 9436 |
|---|---|---|---|

**SUBJECT: Revisions to Instructions Regarding the Fraud Investigation Database (FID) and Other Program Integrity Procedures**

**EFFECTIVE DATE: November 8, 2016**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: November 8, 2016**

## I. GENERAL INFORMATION

**A. Background:** Chapter 4 of Pub. 100-08 contains instructions regarding the FID. This CR will update these instructions and address other issues contained in sections 4.13 through 4.34 of chapter 4.

**B. Policy:** This CR does not involve any legislative or regulatory policies and is restricted to clarifications in operational procedures.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 9436.1 | The Zone Program Integrity Contractor (ZPIC) shall refer investigations to law enforcement when it has substantiated allegations of fraud including, but not limited to, the circumstances described in section 4.8 of chapter 4. | | | | | | | | | ZPICs |
| 9436.1.1 | Prior to making such referrals, the ZPIC shall, unless | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | otherwise instructed by CMS, effectuate all appropriate administrative actions, except for requesting the collection of an overpayment from the Medicare Administrative Contractor (MAC) that is directly related to the underlying reason for the referral. | | | | | | | | | |
| 9436.2 | The MAC shall refer potential fraud, waste, and abuse incoming complaints to the ZPIC for investigation. | X | X | X | X | | | | | |
| 9436.3 | If the ZPIC identifies the need for a Fraud Alert, it shall provide the Contracting Officer's Representative (COR) and Investigations & Audits Group (IAG) Business Function Lead (BFL) a summary of the circumstances. | | | | | | | | | ZPICs |
| 9436.4 | For sections 4.11 through 4.11.3.3 | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | of chapter 4, the ZPIC shall utilize the FID for all of its investigation and case tracking activities and shall follow the guidelines established in said sections. | | | | | | | | | |
| 9436.4.1 | The ZPIC shall ensure that any ZPIC-initiated investigation entered into the FID contains general information on activities performed by the ZPIC to substantiate the allegation of potential fraud, waste, or abuse, | | | | | | | | | ZPICs |
| 9436.4.2 | For Office of Inspector General (OIG) immediate advisements, 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. | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 9436.4.2.1 | The ZPIC shall enter an immediate advisement into the FID once the ZPIC has determined that 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. | | | | | | | | | ZPICs |
| 9436.4.2.2 | Subsequent to the actions described in business requirements 9436.4.2 and 9436.4.2.1, the ZPIC shall decide whether to further develop the lead/investigation or close the immediate advisement. | | | | | | | | | ZPICs |
| 9436.4.2.3 | If the OIG accepts or declines the immediate advisement, the ZPIC shall enter the appropriate | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | action in the FID. | | | | | | | | | |
| 9436.4.2.4 | 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. | | | | | | | | | ZPICs |
| 9436.4.3 | When entering identity theft investigations in the FID, the ZPIC shall enter the information described in (and in accordance with) section 4.11.1.3 of chapter 4. | | | | | | | | | ZPICs |
| 9436.4.4 | As stated in section 4.11.2.1 of chapter 4, the ZPIC shall enter an investigation into the FID after the ZPIC has vetted and received approval from CMS to open the investigation. | | | | | | | | | ZPICs |
| 9436.4.4.1 | The ZPIC shall enter investigations | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | approved by CMS into the FID within seven (7) calendar days of the notification described in business requirement in 9436.4.4. | | | | | | | | | |
| 9436.4.4.2 | The ZPIC shall ensure that information it enters into the FID regarding investigations captures ongoing work by the ZPIC. | | | | | | | | | ZPICs |
| 9436.4.5 | Once the ZPIC has referred a case to the OIG, Department of Justice (DOJ), Federal Bureau of Investigation (FBI), or Assistant United States Attorney (AUSA), the ZPIC shall save the investigation as a case within seven (7) calendar days of referral. | | | | | | | | | ZPICs |
| 9436.4.6 | The ZPIC shall be responsible for ensuring that all data entered into the FID investigation module are entered correctly; | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | this includes the spelling of names and accuracy of addresses and identifiers entered. | | | | | | | | | |
| 9436.4.7 | When one ZPIC implements a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) payment suspension, all of the ZPICs shall place that supplier under payment suspension as well. | | | | | | | | | ZPICs |
| 9436.4.7.1 | 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. | | | | | | | | | ZPICs |
| 9436.4.7.2 | The ZPIC that originates the payment suspension shall become the “Lead Contractor,” and the lead ZPIC shall enter all | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | appropriate information into the FID Payment Suspension Module when requesting a payment suspension. | | | | | | | | | |
| 9436.4.8 | The ZPIC shall enter information on requests for information (RFI) and requests for assistance into the "FID RFI" Module within seven (7) calendar days of the receipt date of the RFI. | | | | | | | | | ZPICs |
| 9436.4.9 | As stated in section 4.11.2.4 of chapter 4, 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. | | | | | | | | | ZPICs |
| 9436.4.10 | For the FID investigation entries, the ZPIC shall document all major activities it has performed in | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | order to substantiate any allegations of potential fraud, waste, or abuse. | | | | | | | | | |
| 9436.4.11 | The ZPIC shall enter and update the information described in sections 4.11.2.5 through 4.11.2.6.2 of chapter 4 in accordance with the requirements and timeframes specified in those sections. | | | | | | | | | ZPICs |
| 9436.4.12 | If a Request for Information (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. | | | | | | | | | ZPICs |
| 9436.4.13 | For instances when an 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 | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | overpayments and take any additional administrative actions necessary. | | | | | | | | | |
| 9436.4.14 | 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 into the FID. | | | | | | | | | ZPICs |
| 9436.4.15 | The ZPIC shall close an investigation that does not result in a law enforcement referral 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. | | | | | | | | | ZPICs |
| 9436.4.16 | Once a referral has been made to the appropriate | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | 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. | | | | | | | | | |
| 9436.4.17 | The ZPIC shall close the case and support law enforcement through the RFI process outlined in section 4.4 of chapter 4 if the ZPIC cannot pursue any additional actions after the case has been referred and accepted by law enforcement. | | | | | | | | | ZPICs |
| 9436.4.18 | When a payment suspension is removed, the ZPIC shall change the status of the payment | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | suspension from "Active" to "Removed." | | | | | | | | | |
| 9436.4.19 | Even after a payment suspension becomes inactive, the ZPIC shall enter updated information on the "Actual Overpayment Amount," "Amount Recovered," and other pertinent information as it becomes available. | | | | | | | | | ZPICs |
| 9436.4.20 | The ZPIC shall: (1) close an RFI or RFA in the FID within 30 calendar days of fulfilling the request, and (2) enter the hours and cost to complete the RFI or RFA on the "Completion" tab in the RFI module. | | | | | | | | | ZPICs |
| 9436.4.21 | The ZPIC shall contact its COR and BFLs to discuss the need for deleting an entry. | | | | | | | | | ZPICs |
| 9436.4.22 | Each ZPIC shall have a Contractor | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | System Administrator (CSA), which has the ability to enter profiles for users in their contracts and task orders. | | | | | | | | | |
| 9436.4.22.1 | The ZPIC shall designate up to 1-3 people per task order for each contract to serve as a CSA. | | | | | | | | | ZPICs |
| 9436.4.23 | In the case of complete destruction of medical records where no backup records exist, the ZPIC shall consult with its COR and IAG BFL to determine the appropriateness of the request to reconstruct the medical records. | | | | | | | | | ZPICs |
| 9436.5 | For the reports described in section 4.14 of this chapter, the ZPIC shall include the information described in sections 4.14(C) and (D). | | | | | | | | | ZPICs |
| 9436.6 | Prior to making the referrals described in | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | section 4.18.1 of chapter 4, 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. | | | | | | | | | |
| 9436.6.1 | During the 60 calendar day period the OIG/Office of Investigations (OI) has to accept or decline the referral, the ZPIC shall: (1) continue to monitor the need for administrative action prior to the elapsing of the 60 calendar days, and (2) refrain from implementing any additional administrative actions against the provider/supplier without CMS approval. | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 9436.6.2 | The ZPIC shall implement any additional administrative actions, if appropriate, to include issuing an overpayment demand to the MAC when: (1) 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 (2) other law enforcement agencies do not accept the referral within 45 calendar days following such referral. | | | | | | | | | ZPICs |
| 9436.6.3 | 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 | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | necessary administrative actions (to include demand of any overpayment), the ZPIC shall close the case in the FID. | | | | | | | | | |
| 9436.6.4 | 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 the OIG, the ZPIC shall still close the case and fulfill all other law enforcement activities through the RFI process noted in section 4.4 of chapter 4. | | | | | | | | | ZPICs |
| 9436.7 | 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 criteria described in section 4.18.1.2 of chapter 4. | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME<br><br>MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 9436.7.1 | The ZPIC shall continue to develop the lead as appropriate. | | | | | | | | | ZPICs |
| 9436.7.2 | If the ZPIC determines that a lead warrants further investigation, it shall follow the processes described in section 4.6.4 of chapter 4. | | | | | | | | | ZPICs |
| 9436.7.3 | 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 in section 4.7 of chapter 4. | | | | | | | | | ZPICs |
| 9436.7.4 | 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. | | | | | | | | | ZPICs |
| 9436.7.5 | If the ZPIC does not receive a response from the | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | 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. | | | | | | | | | |
| 9436.8 | If potential patient harm is discovered during the course of screening a lead or through the investigation process, the ZPIC shall: (a) refer those instances to the Quality Improvement Organization, state medical board, or state licensing agency, and (b) notify the COR and IAG BFL within two (2) business days of when the potential patient harm issue is discovered. | | | | | | | | | ZPICs |
| 9436.9 | The ZPIC shall conduct investigations of potential fraud, waste, or abuse of physician identities. | | | | | | | | | ZPICs |
| 9436.9.1 | The ZPIC shall discuss the | | | | | | | | | ZPICs |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | identity theft case with the COR and IAG BFL. | | | | | | | | | |
| 9436.9.2 | The ZPIC shall provide the information described in section 4.23 of chapter 4 to the COR and IAG BFL, if appropriate. | | | | | | | | | ZPICs |
| 9436.10 | If the DME MAC or ZPIC identifies a supplier that has a pattern of failure to maintain proof of delivery, the DME MAC or ZPIC shall refer the matter to the National Supplier Clearinghouse. | | | | X | | | | | ZPICs |
| 9436.11 | ZPICs shall have JOAs with the contractors identified in section 4.28 of chapter 4. | | | | | | | | | ZPICs |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| | None | | | | | |

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements:**

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|

**Section B: All other recommendations and supporting information:** N/A

## V. CONTACTS

**Pre-Implementation Contact(s):** Frank Whelan, 410-786-1302 or frank.whelan@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

# Medicare Program Integrity Manual
## Chapter 4 - *Program* Integrity

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***(Rev. 667)***

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## 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 verif*ies* 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* learn*s* 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. *T*he 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.*

## 4.10 - 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 p*rovider enrollment units
- CMS
- FBI

- DOJ
- HHS/OIG
- Medicaid *P*rogram *I*ntegrity *D*irectors, *S*tate *U*tilization *R*eview *(SUR)* officials, and *P*rovider *E*nrollment units
- Medicaid *F*raud *C*ontrol *U*nits *(MFCUs)*
- Other *f*ederal and *s*tate partners seeking to address program integrity concerns in judicial or *s*tate 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 *r*esource *g*uide by *s*tate, of contacts at *the* ZPIC*s*, Medicaid Program Integrity *D*irectors and *MFCUs*, and law enforcement agencies.

### 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* ZPIC*s* 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* includ*e,* 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 i*f *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: W*hen 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 *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 ZPIC*s* 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 ZPIC*s* 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*" t*ab 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. *A*ll 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.*

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

If ZPIC*s* 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.*

## 4.12 - *Reserved for Future Use*
### *(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)*

## 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 *s*tates 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 check~~s~~ 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.

## 4.18.1 - 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 *s*tate 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.*

### 4.18.1.4 - 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 whe*n* 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.*

## 4.18.2 - 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 *S*tate 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.

## 4.20.3.2 - 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).

## 4.21 - 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 *en*sure 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.

## 4.22.1- 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 *F*ederal 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 *S*tate 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 *S*tate 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)***

## 4.27 - *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 order*s*, 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 process*es*/workflows that illustrate how the ZPIC and the MAC intend to interact with one another to complete each of the tasks outlined in the *t*ask *o*rder 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 I*ncentive 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 communicate*s* 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 S*enior* M*edicare* P*atrols*.
- Include *s*elf-*d*isclosures.
- Include coordination on *p*rovider*/supplier o*utreach and *e*ducation *(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.

## 4.31 – *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 discovered, however no less than on a *weekly* basis *(by close of business each Friday, if any are identified)*. *The templates* should be submitted sooner if the vulnerability requires immediate consideration. *ZPICs* are not prohibited from initiating any actions in regards to fraud, waste, or abuse situations regardless of whether the vulnerability has been reported yet. The aforementioned vulnerability mailbox is at CPIVulnerabilityIntake@cms.hhs.gov.

***Vulnerability Template***

***Date Submitted:***

***Submitted by***

*Name:* *Organization:*
*Phone:* *Email:*

***Vulnerability***

*Vulnerability Name:*

*Description:*

*Proposed Action:*

*Source (i.e. person/organization that first identified it):*

*FPS Model-Related (Y/N):*

** If yes, simultaneously report the information consistent with requirements of the FPS.*

*List Attachments:*

## *4.32 - Reserved for Future Use*
## *(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)*

## 4.33 – *ZPIC Coordination with* Recovery *Auditors (RAs)*
## *(Rev.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)*

*This section applies to ZPICs and RAs, as indicated.*

*The* CMS established the *RA* Data Warehouse to track *RA* activity and prevent conflicts between *RA* reviews and other program integrity activities. *The success of this* mission 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. *S*uppressions 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 *S*tate. States are not required for NPIs, NSC numbers, alphanumeric or PTANs that are other than six digits long*;* but six-digit *PTAN*s 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. *S*uppressions 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*. T*he *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.667, Issued: 08-08-16, Effective: 11-08-16 Implementation: 11-08-16)*

*This section applies to ZPICs and RAs, as indicated.*

- *Suppressions of providers/suppliers that the ZPIC 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 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 RA Data Warehouse User's Guide. ZPICs 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 RA Data Warehouse User's Guide.*

***Note:** The RAs can review claims paid as early as 10/1/2007, which is before NPI submission became mandatory. Therefore, ZPICs 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 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 shall enter a suppression on the relevant provider/supplier ID and service code(s). If the ZPIC does ultimately assess an extrapolated overpayment, the ZPIC 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 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 RA review and should generally not be excluded. Claims that have subsequently undergone complex 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 RAs 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 RA 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 shall have a JOA with the RAs. Refer to PIM Exhibit 44 for the JOA between the ZPICs and the RAs. The ZPICs shall include in the JOA quarterly meetings with the RA in their zone, at a minimum, to discuss trends in possible fraudulent billing. If ZPICs or RAs have any recommendations for modifying the JOA, they shall provide these modifications to their respective CORs.*