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## Medicare and Medicaid Enrollment Under Heightened CMS Scrutiny

Best Practices to Obtain and Maintain Enrollment and Billing Privileges

WEDNESDAY, APRIL 20, 2011

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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# Medicare and Medicaid Enrollment Under Heightened CMS Scrutiny

Hae-Won Min Liao Sidley Austin LLP April 20, 2011

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## Overview

#### Enrollment

- Purpose of Enrollment and Re-Validation Requirements
- Provider screenings Risk levels
- Other gate-keeping mechanisms
  - Application fee
  - Temporary moratoria on enrollment
  - Security bonds
  - Accreditation requirements

#### Enforcement

- Payment suspension
- Termination of participation or deactivation
- Responding to notice of enrollment suspension/termination
- Appealing a termination or deactivation decision
- Corrective action plans



## Overview (cont'd)

- Best Practices for Providers and Suppliers
  - Effective compliance program
  - Personnel training



## Purpose

- Recognizing the problem:
  - The government's health care fraud prevention and enforcement efforts recovered more than \$4 billion in taxpayer dollars in FY 2010.
- Designing the solution:
  - New enrollment and re-validation requirements developed under health care reform reflect a broadening paradigm in efforts to combat fraud and abuse.
    - Traditional "Pay and Chase" Framework + Emerging Focus on "Prevention"
  - "Thanks to the new law, CMS now has additional resources to help detect fraud and stop criminals from getting into the system in the first place."

CMS Administrator Donald Berwick, M.D.

- Focusing on the Ultimate Goal:
  - The overall objective is to promote compliance with applicable statutes/regulations and ensure high quality of patient care.



## Purpose (cont'd)

- Broad observations regarding the enrollment and revalidation requirements objectives:
  - Ensures that qualified individuals and organizations are allowed to enroll and maintain billing privileges;
  - Targets those providers and suppliers who have been identified as posing a high risk of fraud and abuse, both on a categorical level and individualized basis;
  - Checks that providers and suppliers meet applicable performance and quality standards;
  - Creates "minimum floors," not ceilings, for compliance;
  - Provides agencies with additional tools to address fraud-inthe-making; and
  - Shifts some duties and administrative costs to providers and suppliers.





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## Medicare Enrollment

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Testimony of Daniel R. Levinson, Inspector General, before the House Committee on Energy and Commerce, Subcommittee on Health (September 22, 2010)

Testimony of Lewis Morris, Chief Counsel, OIG, before the House Committee on Ways and Means, Subcommittees on Health and Oversight (June 15, 2010)

- 1. Enrollment: Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment or reenrollment in the health care programs.
- 2. Payment: Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.
- 3. Compliance: Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.
- 4. Oversight: Vigilantly monitor the programs for evidence of fraud, waste, and abuse.
- 5. Response: Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.





- Very important to use the most current version of the enrollment forms
- Must be kept updated by the provider/ supplier
- CMS 855 forms type will vary (e.g., 855B for clinics/group practices, 855S for DMEPOS suppliers, 855A for institutional providers)
- Additional forms
  - CMS 460 Participating provider agreement
  - CMS 588 Electronic funds transfer agreement

## Gatekeeping Enrollment



### CMS Final Rule (CMS-6028-FC)

Feb. 2, 2011- Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers

#### Guidance on final rule:

http://www.cms.gov/MLNMattersArticles/downloads/MM7350.pdf

#### Other recent CMS rulemaking

August 27, 2010 - Medicare Program; establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards

May 5, 2010 - Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements

January 2, 2009 - Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)



# **Provider Screening**

- Provider Screening by CMS
- Risk levels

**Limited Risk** 

**Moderate Risk** 

High Risk

## **Limited Risk**



## Hospitals

Physician or nonphysician practitioners and medical groups or clinics

Ambulatory surgical centers

End-stage renal disease (ESRD) facilities

Federally qualified health centers

Rural health clinics

Skilled nursing facilities

Others: Radiation therapy centers; Pharmacies newly enrolling or revalidating (CMS-855B); Histocompatibility laboratories; Indian Health Service programs; Mass immunization roster billers; Organ procurement organizations; Religious non-medical health care institutions; Competitive Acquisition Program/Part B Vendors.



## CMS Screening – Limited Risk

- Verify that all applicable Federal/State requirements met for the provider/supplier type
- Conduct license verifications, including across
   State lines
- Conduct database checks pre- and post-enrollment to ensure providers/suppliers continue to meet enrollment criteria

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## **Moderate Risk**

- Ambulance service suppliers
- Community mental health centers
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers
- Revalidating home health agencies and DMEPOS suppliers



## CMS Screening – Moderate Risk

 Perform all the screening requirements for "Limited Risk"

Conduct an on-site visit



# High Risk

Prospective (newly enrolling) home health agencies

Prospective (newly enrolling) DMEPOS suppliers



## CMS Screening – High Risk

- Perform all the ``Limited Risk'' and ``Moderate Risk'' screening requirements
- For all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier
  - Require submission of fingerprints for a national background check
  - Conduct a fingerprint-based criminal history record check against FBI Integrated Automated Fingerprint Identification System

## Other Gatekeeping Mechanisms



- Application fees
  - \$505 for CY2011, increases with CPI-U
  - not required for physicians and nonphysician practitioners or organizations
- Proof of accreditation for DMEPOS, when accreditation applies

https://www.cms.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAcreditiationDeadline.pdf

- Temporary Moratoria
- Surety bond and application certification standards requirements for DMEPOS



## Temporary Moratoria on Enrollment

- Can involve providers/suppliers of a particular type
- Can be restricted to new practice locations of a particular type in a particular geographic area
- May be for 6 months or longer
- CMS can work with the OIG to determine



## **DMEPOS Surety Bonds**

- \$50,000 per NPI -- for organizational DMEPOS suppliers, this means one bond per practice location
  - 20 practice locations = \$1 million surety bond
- DMEPOS suppliers exempt from bonding requirement
  - Physicians and non-physician practitioners if the DMEPOS items are furnished only to patients as part of their professional service
  - Physical and occupational therapists if: (1) the business is solely-owned and operated by the therapist, and (2) if the DMEPOS items are furnished only to his or her patients as part of his or her professional service.
  - Government-owned suppliers with comparable surety bond under state law
  - State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics <u>if</u> the business is solely-owned and operated by them and is billing only for orthotic, prosthetics, supplies



## **DMEPOS Standards**

- Must certify in enrollment application that standards at 42 CFR 424.57(c) have been met
- DMEPOS standards include, among others:
  - Maintain a facility on an appropriate site that is open to the public
  - Meet certain signage and space requirements (e.g., must post hours)
  - Maintain primary business phone that is not a cell phone
  - Restrictions on direct solicitation Medicare beneficiaries
  - Restrictions on co-location with other Medicare providers



## Recertification Requirements

- Requirement to resubmit and recertify every 5 years for most providers/suppliers
- DMEPOS suppliers must revalidate every 3 years (i.e., must complete a new application for billing privileges 3 years after its last revalidation)

# Payment Suspension



## Pre-PPACA Authority to Suspend Medicare Payments

- Historically, HHS' broad authority to promulgate rules necessary to the efficient administration of the Medicare program has been used to suspend payments to providers when CMS or a contractor "possesses reliable information" that:
  - Fraud or willful misrepresentation has occurred; or
  - An overpayment has occurred; or
  - Payments may not be correct

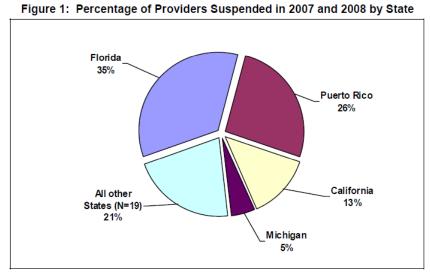
61 Fed. Reg. 3,740 (Dec. 2, 1996).

 In 2010, CMS told the OIG that the types of information it considers when evaluating whether to suspend payments to a provider "include[] whether the provider's billing number was revoked, the amount of pending Medicare payments, and whether the provider's claims are being reviewed prior to payment." The Use of Payment Suspensions To Prevent Inappropriate Medicare Payments, OEI-01-09-00180 (Nov. 1, 2010).



# The "Reliable Information" Standard: Medicare Payment Suspension Statistics

- The OIG's 2010 report on Medicare payment suspensions concluded:
  - 74% of suspended providers showed questionable billing patterns. Examples of questionable billing patterns included:
    - Aberrantly high amounts of services provided within a short period of time;
    - Spikes in billing resulting from multiple claims submitted for the same beneficiary;
    - Billing for services using beneficiary identification numbers known to have been compromised; and
    - Submitting claims for medical equipment ordered by neurosurgeons, pediatricians, and pathologists, specialists who do not typically order such equipment.
  - 63% of suspensions were supported by information from beneficiaries or other providers
  - 79% of payment suspensions involved Providers in California, Florida, Michigan, and Puerto Rico
    - More than half of the payment suspensions involved Medicare Fraud Strike Force areas



Source: OIG analysis of payment suspension documents, 2010



## Post-PPACA Medicare Payment Suspension

- The PPACA revised the standard for suspending payment in the case of suspected fraud.
  - "(1) In General The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.
    - (2) Consultation The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier."

42 U.S.C. § 1395y(o).

- On February 2, 2011, CMS promulgated its final rule implementing the PPCA's changes. The rule provides that CMS may suspend payment if:
  - CMS or the contractor "possesses reliable information that an overpayment exists or that the payments to be made may not be correct"; or
  - CMS or the contractor has consulted with the OIG and, if appropriate, the DOJ, and "determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments".

76 Fed. Reg. 5,862 (Feb. 2, 2011) (revising 42 C.F.R. § 405.371).



## Post-PPACA Medicare Payment Suspension (cont'd)

- The February 2011 Final Rule defines a "credible allegation of fraud" as "an allegation from any source, including but not limited to the following:
  - (1) Fraud hotline complaints.
  - (2) Claims data mining.
  - (3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

Allegations are considered to be credible when they have **indicia of reliability**."



# Post-PPACA Medicaid Payment Suspension

 Historically, HHS has exercised its broad authority with respect to the Medicaid program to permit states to withhold Medicaid payments "upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud or willful misrepresentation under the Medicaid program."

52 Fed. Reg. 48,814 (Dec. 28, 1987).

• The PPACA **prohibits** payments to states "with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished— ... by any individual or entity to whom the State has **failed to suspend payments** under the plan during any period when there is pending an investigation of a **credible allegation of fraud** against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary ... unless the State determines in accordance with such regulations there is **good cause** not to suspend such payments".

42 U.S.C. § 1396b(i)(2).



# Post-PPACA Medicaid Payment Suspension (cont'd)

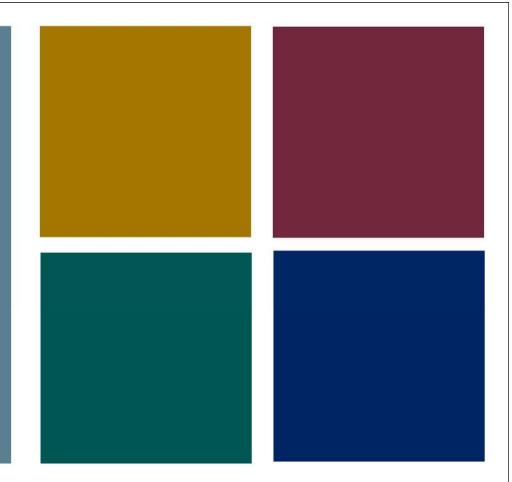
- The February 2, 2011 Final Rule provides that [t]he State Medicaid agency must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part."
- "A State may find that good cause exists not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:
  - (1) Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or **jeopardize an investigation**.
  - (2) **Other available remedies** implemented by the State more effectively or quickly protect Medicaid funds.
  - (3) The State determines, based upon the **submission of written evidence** by the individual or entity that is the subject of the payment suspension, that the suspension should be removed.
  - (4) **Recipient access** to items or services would be jeopardized by a payment suspension because of either of the following:
    - (i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.
    - (ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.
  - (5) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section."
  - (6) The State determines that payment suspension is not in the **best interests of the Medicaid program**.

# Post-PPACA Medicaid Payment Suspension (Cont'd)

- The February 2, 2011 Final Rule also permits states to determine "that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:
  - (1) Recipient access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:
    - (i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.
    - (ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.
  - (2) The State determines, based upon the **submission of written evidence** by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part.
  - (3)(i) The credible allegation focuses solely and definitively on only a **specific type of claim** or arises from only a **specific business unit** of a provider; and
    - (ii) The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.
  - (4) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.
  - (5) The State determines that payment suspension only in part is in the **best interests** of the Medicaid program.



Medicare and Medicaid Enrollment Under Heightened CMS Scrutiny April 20, 2010



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## **Overview**

- Adverse Enrollment Actions
- Responding to Adverse Enrollment Actions
  - Rebuttal Process
  - Appeals Process
  - Corrective Action Plans

## **Adverse Enrollment Actions**

- Denial
- Revocation
- Rejection
- Deactivation
- Corrective Action Plans

## **Enrollment Denials**

- Bases include not being in compliance with Medicare enrollment requirements or failing to pay application fee after notification that hardship waiver not approved.
- Some overlap with OIG exclusion bases
- Effective 30 days from notification of denial
- Opportunity to submit corrective action plan
- Decision may be appealed
- Not a "termination" under Section 6501 of PPACA
- Note: State strict liability for enrollment information can result in denial; 1 year (or more) application bars may apply.

### Revocation of Enrollment

- Bases include not being in compliance with Medicare enrollment requirements and failure to furnish complete and accurate re-verification information
- Some overlap with OIG exclusion bases
- Effective 30 days from notification of denial
- Opportunity to submit corrective action plan
- Decision may be appealed.
- Terminates provide agreement
- 1- 3 year re-enrollment bar

# Revocation Example: Failure to Update Information

- Notification of change to enrollment information required, often within 30 days:
  - Adverse legal actions
  - Location
  - Change of ownership or managing control information
- For physicians, non-physician practitioners, and their organizations; IDTFs, and institutional providers, all other changes must be reported within 90 days.
- For DMEPOS suppliers, <u>all</u> changes must be reported within 30 days.
- Potential sanctions include: revocation of billing privileges and/or assessment of overpayment.

# Revocation Example: Surprise Site Visits

- Facility closed on two days that surprise site visits conducted.
- Resulted in revocation
- Corrective Action Plan rejected
- "South Florida Effect"

Note: May need to educate person conducting site visit.

## Rejection

- Bases include when enrollment application was incomplete, application fee not paid (or hardship waiver not requested) or additional or corrected information was not received in a timely manner.
- Contractor has discretion to extend period of time to supply information if supplier is "actively working with the contractor to resolve any outstanding issues."
- Must complete and submit new enrollment application and all supporting documentation.
- Decision may not be appealed.

### **Deactivation**

- Bases includes failure to report changes of information in timely fashion.
- Reactivation requires new enrollment application or recertification of existing enrollment information.
- Does not affect provider agreement
- Rebuttal is permitted, but there are no appeal rights.
- In some circumstances, provider/supplier may obtain a retrospective billing date, but it is not common.

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### **Deactivation**

- Currently ~25,000 deactivated each month with 1/4 to 1/3 re-enrolling. Common with certain specialties (pediatric specialties, reproductive medicine, etc.) and teaching institutions
- If provider has not billed in previous 12 months automatically deactivate (but temporarily suspended)
- Reporting that some providers receiving new numbers after deactivation because if same number immediately deactivates because no billing within prior 12 months
  - Need to ensure that effective dates cover entire time period (i.e., no gaps)

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# Deactivation Example: State Licensing Issues

- Can be basis for deactivation by NSC.
- Particular issue for DMEPOS providers
- National Supplier Clearinghouse addresses state licensing requirements on its website, but not complete or definitive.

http://www.palmettogba.com/palmetto/statelicensure.nsf

- Should suppliers be entitled to rely on NSC database for enrollment purposes?
- Supplier Standard 'a supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.'

# Responding to Adverse Enrollment Actions

- Rebuttal Process
- Corrective Action Plan
- Appealing Adverse Enrollment Actions

### **Rebuttal Process**

- Rebuttal available for deactivation actions
- Same process for responding to payment suspensions, offsets, or recoupments.
- Opportunity to explain why deactivation should not be imposed.
- Typically 15-days to submit rebuttal, but shorter or longer period may be offered or imposed for cause.

### **Corrective Action Plans**

- May submit CAP for consideration and negotiation
- Verifiable evidence of compliance and sufficient assurances of intent to comply
- Reinstatement after CAP is accepted is typically effective date CMS approves the CAP and compliance is determined (i.e. prior items /services non-billable)

### **Appealing Adverse Enrollment Actions**

- 42 C.F.R. Section 498.5:
  - Initial Determination
  - Revised Initial Determination
  - Reconsideration
  - ALJ Hearing
  - Departmental Appeals Board Review
  - Judicial review Federal district court

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### Termination and Reenrollment

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# The Math -Revocation = Termination



- Medicare provider agreement is terminated
  - Termination effective as of the date of revocation
     But that's not all . . .
- Automatic review of all other related Medicare enrollment files that the revoked provider/supplier has an association with (for example, as an owner or managing employee)
- Barred from the Medicare program until end of "reenrollment bar"

### **Medicaid Repercussions**



- Termination from Medicare results in termination from Medicaid and denial of Medicaid enrollment
- "Termination" means:
  - the Medicare program has revoked the provider/supplier's billing privileges, and all appeal rights have been exhausted or the time for appeal has expired, and
  - there is no expectation on the part of the provider or supplier or the Medicare program that the revocation is temporary
- Applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to-- (i) Fraud; (ii) Integrity; or (iii) Quality
- Reenrollment is required to reinstate billing privileges

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#### Reactivation

- Non submission of claims as basis for deactivation
  - Recertify enrollment information on file is correct
  - Furnish missing information
  - Meet all current Medicare requirements
- Any other basis for deactivation
  - New enrollment application required
  - Or "when deemed appropriate" at a minimum, recertify that the enrollment information currently on file with Medicare is correct
- Special process for deactivated HHAs
  - must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.



#### Reenrollment

- Reenrollment bar lasts 1 to 3 years
- Duration depends on severity of basis for revocation
- Must reapply as new provider/supplier
- Must be resurveyed and recertified as a new provider

### Watch Out for "Technicalities"



Telephone number or address change

CMS views old office – not "operational"

Letters returned to CMS as not deliverable

Revalidation never received by CMS

Letter from Medicare informing provider/supplier of information that is lacking from enrollment application sent but never received

Problems with surety bond

Insufficient funds in bank account to pay enrollment fee



### Beyond termination . . .

"The breadth and scope of health care reform alter the oversight landscape in many critical respects, and as a result OIG will assume a range of expanded oversight responsibilities."

"Ensuring the integrity of information is also crucial, and the Affordable Care Act provides new accountability measures toward this end. For example, section 6402 authorizes OIG to exclude from the Federal health care programs entities that provide false information on any application to enroll or participate in a Federal health care program.

"The ACA also provides new civil monetary penalties for making false statements on enrollment applications . . . ."

Testimony of Daniel R. Levinson, Inspector General, before the House Committee on Energy and Commerce, Subcommittee on Health (September 22, 2010)

Testimony of Lewis Morris, Chief Counsel, OIG, before the House Committee on Ways and Means, Subcommittees on Health and Oversight (June 15, 2010)



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#### **Best Practices**



### Best Practices: Effective Compliance Program

- Fundamental Steps
  - Draft and distribute a compliance manual
  - Appoint a compliance officer
  - Identify responsibilities for the compliance team
  - Establish additional SOPs or policies as needed



### Best Practices: Effective Compliance Program (cont'd)

- Monitoring
  - Annual updates to established manual and policies
  - Create mechanism for employees to voice complaints
    - Escalation policies
    - Anonymous compliance hotline
  - Conduct audits and investigations of problem areas
    - Respond thoroughly and quickly to any identified complaints
    - Review OIG Work Plan priorities for target areas
- Consequences to actions
  - Maintain clear records of allegations, investigations and disciplinary actions taken against substantiated allegations of misconduct



### Best Practices: Personnel Training

- Familiarizing employees with enrollment, revalidation, and other requirements
  - Often missed: change of information
- Clearly identifying employee responsible for meeting and monitoring enrollment and re-validation requirements
  - Compliance team's input and involvement
  - Additional support from HR staff



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