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Recent Enforcement Actions in Radiology:

Lessons Learned and Problems to Avoid

December 10, 2014

Increasing number of cases and
investigations filed against
imaging centers and radiologists



Government devoting more
resources to investigations
and enforcement actions

Affordable Care Act's Impact on Enforcement

- **Tough new rules and sentences:** The law increases federal sentencing guidelines for health care fraud by 20 percent – 50 percent for crimes with more than \$1 million in losses
- **Enhanced screening:** Providers and suppliers who may pose a higher risk of fraud or abuse are now required to undergo more scrutiny, including license checks and site visits
- **Use of technology:** To target resources to highly suspect behaviors, the Centers for Medicare & Medicaid Services now uses advanced *predictive modeling technology*
- **New resources:** The law provides an additional \$350 million over 10 years to boost anti-fraud efforts



Recent Fraud and Abuse Cases Involving the Delivery of Radiology Services

FCA Cases Involving Diagnostic Imaging

**United States
Department of
Justice has
been vigilant in
pursuing False
Claims cases**

- The False Claims Act is the government's primary civil remedy to redress false claims for government funds
- U.S. Department of Justice obtained a record \$5.69 billion in settlements and judgments from civil cases involving fraud and false claims against the government in 2014
- **False claims against federal health care programs such as Medicare and Medicaid accounted for \$2.3 billion in settlements and judgments**

"In the past three years, we have achieved the three largest annual recoveries ever recorded under the [FCA]. This sustained success demonstrates . . . a continuous commitment year after year to pursue those who defraud taxpayers and to remain vigilant in identifying those who would unlawfully obtain money from the federal [government]."

**Stuart Delery,
Assistant Attorney General for U.S. Department of
Justice's Civil Division**

FCA Cases Involving Diagnostic Imaging

FCA cases brought in recent years assert violations arising from a wide range of activities, including:

Improper Billing

- Billing for services not actually provided
- Unbundling of codes
- Double billing for procedures/services

Improper Relationships with Referring Physicians

- Paying salaries for employees of referring physicians in exchange for referrals
- Employing or contracting with referring physicians for medical director services
 - Paying physician at rate greater than FMV
 - Physician provides few or no medical director services
- Tracking of and paying for referrals from physicians
- Equipment or facility lease arrangements below FMV
- Paying referring physicians more than FMV for professional reads

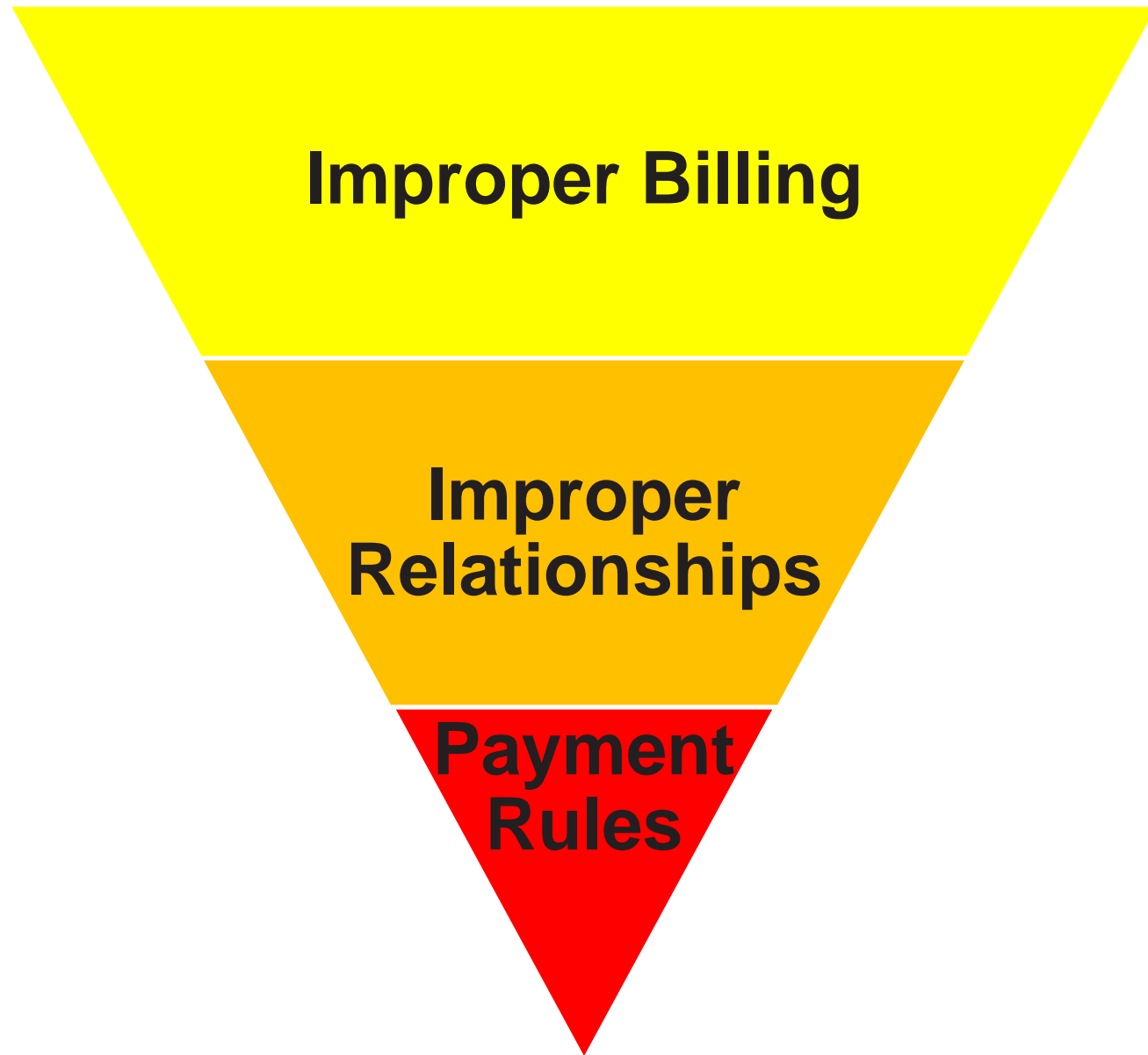
Failure to Comply with Coverage/Payment Rules

- Lack of required supervision

Types of Cases

**Most common
and easiest to
identify**

**Least common
type of case
and most
difficult to
identify**



Improper Billing Cases

Peter Tsai and Advanced Family Medical Center

Coal Grove, Ohio
August 2014

- The four people involved plead guilty to one count of conspiracy to commit health care fraud.
- Two defendants forced to pay \$999,000 in restitution
- Defendants were accused of having performed diagnostic CT scans that were **medically unnecessary**, including multiple scans of the same body part for the same patient, weeks apart
- Also accused of performing and billing for CT scans related to **medically unnecessary** injections, and ignoring and/or stopping documentation of statements and complaints from patients that the injections were not working or were not wanted

Improper Billing Cases (cont.)

***Thomas
Stephenson,
M.D.***

Rochester, N.Y.

September 23, 2014

- U.S. Attorney's office charged Thomas Stephenson, M.D., of Rochester, N.Y., with health care fraud
- The charge carries a maximum sentence of 20 years in prison, a fine of \$250,000, or both
- Stephenson **falsely represented** on multiple occasions that he had performed and interpreted two X-rays, when in fact he had only performed and interpreted single X-ray images
- Government alleged that Stephenson fraudulently claimed reimbursements from the three health care plans in the amount of \$183,279.30

Improper Billing Cases (cont.)

***United States ex
rel. Brown v.
Holy Spirit
Hospital of the
Sisters of
Christian
Charity,
No. 1:12-cv-1197
(M.D. Pa.)***

- Whistleblower alleged that Holy Spirit Hospital billed for diagnostic tests that were never performed
- After being notified, hospital administration decided to stop billing for the tests, but also decided not to repay the government
- Holy Spirit Hospital faced potential liability under the FCA for failing to report the overpayment to the government within 60 days
- **This case offers another factor to consider:** *not only should the practices resulting in overpayment be stopped, but the overpayment should also be reported and refunded within 60 days to avoid potential FCA liability*
- Case was dismissed on May 15, 2014; United States declined to intervene on May 14, 2015

Improper Relationship Cases

***U.S. ex rel.
Holderith, et al.
v. One Step
Diagnostic, Inc.,
et al.,
Case No. 12-CV-
2988 (S.D. Tex.)***

- One Step Diagnostic agreed to pay **\$1.2 million** to settle allegations that it violated the Stark Statute and the False Claims Act
- Accused of entering into sham consulting and medical director agreements with physicians who referred patients to One Step Diagnostic Centers
- Complete Imaging Solutions agreed to pay **\$1.45 million** to settle allegations it violated the False Claims Act
- Accused of engaging in improper financial relationships with referring physicians

Two settlements arose from a lawsuit filed by three whistleblowers under the qui tam provisions of the False Claims Act.

Improper Relationship Cases (cont.)

***Orange
Community MRI
Clinic,***
April – June 2004

- Owner and medical director of facility paid cash to physicians for referrals of MRI, CT, US, echocardiograms and DEXA scans (including tests covered by Medicare and Medicaid)
- Cash payments to physicians were based on monthly reports generated by facility showing number of referrals each physician made for each test
- Sentenced **to 46 months** in prison and **three years** supervised release, and ordered to forfeit more than **\$2 million**
- As of June 2014, 18 total defendants, including 16 physicians, had been convicted in this ongoing investigation

Improper Relationship Cases (cont.)

Diagnostic Imaging Affiliates (DIA) of Hackensack

- New Jersey attorney general alleged that the organization paid more than \$300,000 in illegal kickbacks to multiple medical practitioners in return for patient referrals to testing centers for advanced imaging services (e.g., MRIs and PET scans)
- These alleged kickbacks were paid using **checks from "shell" corporations** and **gift cards/certificates**
- Defendant also alleged to have **disguised** the payment of **kickbacks by providing physicians with free services** (e.g., patient transportation)
- By obtaining referrals through the alleged kickback scheme, the government alleged that the defendant generated millions of dollars in illegal profits

Improper Relationship Cases (cont.)

***United States ex
rel. McDonough
v. Symphony
Diagnostic
Servs., Inc.,***

2014 BL 223365

(S.D. Ohio Aug. 12,
2014)

- Federal district court in Ohio dismissed FCA lawsuit against Mobilex, rejecting a whistleblower's contention that Mobilex was undercharging skilled nursing facilities (SNFs) for X-ray services to Medicare Part A patients in exchange for business from more lucrative Part B patient services
- Whistleblower alleged that a low Part A rate for mobile X-ray services negotiated between SNFs and Mobilex was an illegal inducement under the anti-kickback law
- The court rejected whistleblower's argument that company's Part A fees must include fixed costs relating to the entire company's infrastructure and operations, noting that an "incremental cost" method was previously endorsed by another federal district court

Improper Relationship Cases (cont.)

U.S. v. Millennium Radiology,

U.S. District Court,
S.D. Ohio,
Case No.
1:11-CV-825.
(Sept. 30, 2014)

- Former radiologist claimed that group participated in an exclusive referral and marketing system with Mercy Health Partners of Southern Ohio and Mercy Hospital West, which violated the anti-kickback statute and False Claims Act
- Whistleblower alleges that beginning in 2010, the group assisted in marketing Mercy's services to other physicians in the area
- Whistleblower employee claims that group performed these marketing services and provided a medical director at two of Mercy's hospitals for free, in exchange for the referral of patients from Mercy
- In a separate lawsuit, the whistleblower claims he was fired because of age discrimination

Lack of Required Supervision Cases

***U.S. ex rel.
Hobbs v.
Medquest
Associates,***
711 F.3d 707
(6th Cir. April 1,
2013)

- 6th Circuit threw out \$11.1 million judgment against medical imaging company alleging that company submitted more than 1000 claims using physician supervisors who were not Medicare-approved, billed using another physician's number
- 6th Circuit found no FCA violation because these were conditions of participation, not payment
- Conditions of participation do not trigger FCA liability

“[We have] little sympathy for MedQuest, which sometimes skirted and appears to have often ignored applicable regulations in the conduct of its centers....At the same time...because [these] regulations are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, *including suspension and expulsion from the Medicare program.*” (emphasis added)

Lack of Required Supervision Cases (cont.)

Lack of Supervision Cases

- **Universal Imaging (January 2012)**
 - Government sued seeking \$150 million in damages under FCA
 - *Allegations of lack of supervision*, generation of 90 percent or more of business by paying kickbacks to physicians, and improper lease arrangements
 - Also settled with 14 physicians who were paid for referrals
- **Bedside Imaging, LLC/Raymack Enterprises Inc. (January 2013)**
 - \$16 million default judgment against mobile radiology clinics
 - *Allegations of lack of proper medical supervision*; failure to report change of ownership when taking over another practice
- **Diagnostic Systems, Inc. dba Open MRI of Savannah, et al.**
 - \$1.2 million settlement with government following civil investigation
 - *Allegations of lack of proper supervision for contrast studies*

Billing Company Case

***U.S. ex rel.
Vaughn v.
Medical
Business***

Service, Inc.,

U.S. District Court,
S.D. Ohio

Case No.

1:10-CV-2953

(September 2014)

- Billing company agreed to pay **\$1.95 million** to settle claims that it violated the False Claims Act in October 2014
- Government alleged that company:
 - Required its employees to review every claim denied on medical necessity grounds to consider whether the diagnosis code should be changed and the claim resubmitted for payment
 - Assigned the re-coding task to entry-level employees who receive *no training in coding or medicine*, and had little or no access to patient medical records
 - *Conducted no review* of the altered codes before the claims were resubmitted
 - *Failed to adopt basic compliance measures* that would have detected the fraudulent coding practices

U.S. ex rel. Drakeford v. Tuomey Healthcare System

- **\$237 million** judgment awarded against hospital
- Hospital engaged a consultant to assist it in evaluating the potential loss from competing physician-owned ASC, and to design a plan to make up the difference. The result was a part-time employment arrangement involving 19 local specialists, who were all:
 - Only employees of the hospital when they performed outpatient procedures, but given full-time benefits
 - Contractually bound to bring all of their outpatient procedures to the hospital and not otherwise compete with the hospital
 - Compensated through base salaries and productivity bonuses of 80 percent of net collections. The package resulted in the physicians receiving approximately 131 percent of the professional revenue generated by them on the cases performed at the hospital outpatient center.
- Numerous lawyers gave conflicting advice. The hospital seemed to be “opinion shopping.”
- Consultant issued a cursory FMV analysis that did not reflect the pertinent facts
- Whistleblower case filed by a physician with whom the hospital was unable to contract

Tuomey Lessons

- Potential liability for Stark missteps can be **astronomical**
 - Be proactive in identifying problems with referring physician relationships and self-report
- Any compensation paid to referring physicians must not be based upon the volume or value of anticipated referrals
- Compensation must meet both the FMV *and* commercial reasonableness tests
- Not all fair market analyses are created equal. In *Tuomey*, the FMV report was deficient on its face.
- Reconsider your arrangement when confronted with conflicting legal opinions
- Use “new and improved” structures cautiously
- The generous *Tuomey* compensation structure appeared to the jury to be merely a scheme to buy surgical cases

Lessons Learned from Recent Cases

What do these cases say about the current regulatory environment in imaging?



1. **Continued focus on improper billing cases**
 - Billing for procedures not medically necessary
 - Billing for exams that were not completed
2. **Government increasingly going after the less obvious improper relationship cases**
3. **Billing companies are now under the microscope**
4. **Government is implementing stiffer penalties**
5. **More whistleblowers**
6. **Stark Law violations are costly**
7. **Refunding overpayments subject to liability under the False Claims Act**

Mandatory Return of Overpayments

- ACA added new section to the Social Security Act addressing “Reporting and Returning of Overpayments”
- The provision provides that a person or entity receiving an “overpayment” is required to:
 - Report and return it to the secretary or the state Medicaid Agency or the appropriate contractor; and
 - Notify the agency or contractor of the reason for the overpayment

Overpayment must be reported and returned within 60 days of the date on which it was identified, or the date any corresponding cost report is due (if applicable), whichever is later.

Mandatory Return of Overpayments (cont.)

- “Overpayment” is defined as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled
- Any overpayment retained past the deadline is an “obligation” (as defined in, and for purposes of, the reverse false claims provision of the False Claims Act)
- Failing to report or return a known overpayment is also a violation of the Civil Monetary Penalties statute – subject to fine of up to \$10,000, and potential for exclusion
- Under a *proposed change* to the Civil Monetary Penalty rules, OIG could impose penalty up to \$10,000 for *each day* a person fails to report and return an overpayment

Mandatory Return of Overpayments (cont.)

***Kane v.
Healthfirst, Inc.
et al***

Case No.
1:11-CV-02325-ER
(S.D.N.Y.)

- DOJ and whistleblower Robert Kane allege that Continuum Health Partners failed to take necessary steps to identify 900 or so overpayments
- Kane, former Continuum employee, sent an email to Continuum's vice president that contained an analysis of 900 potential overpayments
- Four days after Kane sent the email, Continuum fired Kane and, according to the complaint, Continuum did nothing with Kane's analysis
- DOJ and Kane further allege that Continuum only paid back half of the overpayments in March 2013, well after the government issued Continuum a civil investigative demand seeking information relating to the overpayments
- Thus, DOJ and Kane claim that Continuum acted intentionally or recklessly with respect to the overpayments
- The DOJ and Kane are **seeking an \$11,000 penalty for each overpayment, plus treble damages.**

Mandatory Return of Overpayments (cont.)

***Kane v.
Healthfirst, Inc.
et al***

Case No.
1:11-CV-02325-ER
(S.D.N.Y.)

- Under 42 U.S.C. § 1320, an Affordable Care Act (ACA) overpayment must be reported, explained and returned within 60 days after the date it was “identified”
- Providers have had a very difficult time determining when the 60-day overpayment clock starts ticking because the ACA does not explain what it means to “identify” an overpayment
- Failing to comply with the ACA’s overpayment mandates can turn a routine administrative overpayment into a False Claims Act (FCA) violation
- Under the FCA, government can pursue civil penalties against providers who fail to return an overpayment to the government
- This case centers on what events trigger the start of the 60-day clock for providers to return overpayments under the ACA

Mandatory Return of Overpayments (cont.)

What Triggers 60 Day Overpayment Obligation?

- **Overpayment is considered “identified” when the provider or supplier:**
 1. Has actual knowledge of the existence of the overpayment; or
 2. Acts in reckless disregard or deliberate ignorance of the overpayment
- **CMS has provided examples of when an overpayment has been “identified”:**
 - Reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement
 - Learns that a patient death occurred prior to the service date on a claim that has been submitted for payment
 - Learns that services were provided by an unlicensed or excluded individual
 - Performs an internal audit and discovers that overpayments exist
 - Is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry
 - Experiences a significant increase in Medicare revenue and there is no apparent reason for the increase

Improper Billing Cases (cont.)

What Triggers 60 Day Overpayment Obligation?

- Thus, 60-day period for reporting and repayment appears to begin when there is actual knowledge of the overpayment or when a reasonable inquiry reveals an overpayment
- The threshold for what is a “reasonable” inquiry looks fairly high
- Providers may have significant audit obligations
- Even were an audit or investigation was made, reckless disregard or deliberate ignorance could exist if there is a failure to conduct the inquiry with all “deliberate speed” after learning about a potential overpayment
- **The Continuum FCA case will further clarify and set the standard on what triggers the 60-day period for reporting and repayment of ACA Overpayments**

Medicare Supervision Rules



Physician Offices

IDTFs

Provider-Based Entities
– HOPPS

Do not apply to hospital inpatients

Teaching physician
regulations

Supervision and interpretation
of interventional procedures





Levels of Supervision

General Supervision

Direct Supervision

Personal Supervision

Level 1: General Supervision

The supervising physician need not be present for the test, but he/she has overall responsibility for the control and direction of the service.

Level 2: Direct Supervision

The supervising physician need not be in the room when the procedure is performed, but must be present in the same office suite and immediately available to assist if required.

Level 3: Personal Supervision

The supervising physician must be in the same room where the test is performed throughout the procedure.

Supervision of Diagnostic Tests (cont.)

Non-Physicians

- Nurse Practitioners, Clinical Nurse Specialists and Physician Assistants may *not* function as supervising physicians under Medicare's Diagnostic Test Benefit
- They may *perform* diagnostic tests pursuant to state Scope of Practice laws



Supervision of Diagnostic Tests (cont.)

Radiologist Assistants and Radiology Practitioner Assistants

- Cannot supervise test for Medicare patient
- Cannot perform an invasive or surgical procedure for Medicare patients who are then billed under the NPI of a radiologist
- **Note:** “Incident to” services may be billed only in a physician’s office - *not* in the hospital - and only for *non-test* services that are performed for patients being treated by the practice



Supervision of Diagnostic Tests (cont.)

HOPPS Direct Physician Supervision

Physician Supervision of Medicare Hospital Outpatient Diagnostic Tests

Standard varies based on location:

- In the hospital or an on-campus provider-based department
- Off-campus provider-based department
- Under arrangement services

Supervision of Diagnostic Tests (cont.)

HOPPS Direct Physician Supervision 2011 Rule

In the hospital or an on-campus provider-based department

- "Direct supervision" means
 - Immediately available to furnish assistance and direction *throughout* the performance of the procedure (i.e., services)
- Does not require physical proximity
- "Immediately available" – no specific spatial or temporal standard

Supervision of Diagnostic Tests (cont.)

HOPPS Direct Physician Supervision 2011 Rule

Off-campus provider-based department

- "Direct supervision" means
 - Immediately available to furnish assistance and direction throughout the performance of the procedure (i.e., services)
- Does not require physician proximity

Supervision of Diagnostic Tests (cont.)

HOPPS Direct Physician Supervision

Non-hospital location, i.e., mobile or fixed-site diagnostic testing facility furnishing services "under arrangements"

- "Direct supervision" means
 - Physician present *in the office suite*
 - Immediately available to furnish assistance and direction throughout the performance of the procedure (i.e., services)
- Does not require presence in the room

Supervision of Diagnostic Tests (cont.)

HOPPS Direct Physician Supervision

- **Qualifications:** Does the supervising physician for imaging services have to be a radiologist?
- Physician must be qualified to furnish “assistance and direction”
- **HOPPS Rule:** “knowledgeable” about the test
- Transmittal 128, May 28, 2010
- Transmittal 137, December 30, 2010

Best Practices

1. Understand the basic federal and state rules (i.e., Stark Law, anti-kickback, anti-markup, supervision)
2. Monitor and routinely audit billing practices
3. Adopt, implement and update compliance plan, policies and procedures
4. Train your workforce on compliance matters and code of ethics at time of new hire and annually thereafter
5. Encourage employees to report potential problems without fear of retribution

Best Practices (cont.)

6. Investigate and fix reported problems
7. Return overpayments promptly
8. Analyze new and/or novel marketing activities
9. Consider how to avoid creating a potential whistleblower when terminating problematic employees
10. Discuss identified regulatory matters with your legal counsel under attorney-client privilege

If a Government Investigator Contacts You

- Immediately notify person in charge of compliance or his/her designee or attorney
- Follow facility procedures and instructions in any legal request (e.g., subpoena or Civil Investigative Demand)
- If a government agent does not produce a search warrant, subpoena or investigative demand, you have the right not to provide any information to the government, but it's generally advisable to comply with the request to the extent possible
- You should not respond to an oral request to produce documents because there could be issues later as to what was requested
- Ask for all such requests to be issued in writing (e.g., an email)

What Not To Do

- Destroy or alter any facility document or record
- Lie or make false or misleading statements to any government agent or investigator
- Attempt to persuade any other employee, or any other individual, to provide false or misleading information to a government audit or investigation, or to refuse to cooperate with a government investigation

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