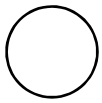
COMPLIANCE, REPAYMENT AND SELF-DISCLOSURE

HEALTH CARE COMPLIANCE ASSOCIATION HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE WASHINGTON, DC

NOVEMBER 3, 2019



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AGENDA

- **What is an Overpayment?**
- **Overview of the Law**
  - **The False Claims Act (FCA)**
  - **Affordable Care Act (ACA)**
  - **The 60-Day Rule**
- **Rule Limitations**
- **Enforcement Examples**
- **Options for Handling an Overpayment (Reporting and Returning)**
- **Compliance Program Efforts and Best Practices**
- **Discussion and Questions**

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WHAT IS AN OVERPAYMENT?

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WHAT IS AN OVERPAYMENT?

- An overpayment is any funds that a person has receives or retained under the Medicare program to which the person, after applicable reconciliation, is not entitled to such.
  - Any funds not received in conformance to the payment rules, whether inadvertently or due to fraudulent activity, are funds to which the recipient is not entitled.
  - Overpayment amount is the difference between the amount that was paid, and amount that should have been paid.

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OVERVIEW OF THE LAW

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OVERVIEW OF THE LAW

- False Claims Act (FCA)
- Affordable Care Act (ACA)
- Final Medicare Overpayment Rule (60-Day Rule)

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THE FALSE CLAIMS ACT
31 U.S.C. § 3729

- **Prohibitions include:**
  - Knowingly submitting or causing to be submitted false or fraudulent claims
  - Knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim
- **"Reverse" False Claims Prohibition**
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government

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THE FALSE CLAIMS ACT
31 U.S.C. § 3729

- **PENALTIES**
  - Treble damages
  - Penalties currently $11,181 - $22,363 per false claim
- Many cases brought by *qui tam* relators who receive a percentage of the recovery
- Number of cases and recovery amounts increasing

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OVERPAYMENT STATUTE – ACA SECTION 1128J(D); 42 U.S.C. § 1320A-7K(D)

- **In general, if a person has received an overpayment, the person shall:**
  - Report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  - Notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- **What is an overpayment?**
  - The term "overpayment" means any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after applicable reconciliation, is not entitled under such subchapter.

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CREATION OF THE 60-DAY REPAYMENT REQUIREMENT

- The Affordable Care Act (ACA) requires providers to report and return any overpayment within 60 days after identification (or the date any corresponding cost report is due), whichever is later – Section 1128 J(d) of the Social Security Act
- "Overpayment" is defined as any funds that a person receives or retains from Medicare or Medicaid to which the person, after any applicable reconciliation, is not entitled
- Overpayments include payments received for claims submitted in violation of the Stark Law or the Anti-Kickback Statute
- Any overpayment retained after the repayment deadline is considered an obligation for purposes of the False Claims Act

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THE 60-DAY RULE
(Medicare Parts A & B)

Final regulations for the 60-Day Rule (Medicare Parts A & B) became effective on March 14, 2016 (the final rule was published on February 12, 2016, 81 Fed. Reg. 7654)

- The final regulations:
  - Clarify when an overpayment is identified
  - Establish a six-year lookback period
  - Describe options for reporting and returning identified overpayments
- There is no minimum monetary threshold; all identified overpayments must be returned

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THE 60-DAY RULE
(Medicare Parts A & B)

Key Concepts:

- Identification of an Overpayment
- The Reasonable Diligence Standard
- Credible Information
- Time Within Which to Exercise Reasonable Diligence
- Lookback Period

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THE 60-DAY RULE
(Medicare Parts A & B)

Identification of an Overpayment:

- "[A] person has **identified** an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that **the person has received an overpayment** ***and quantified*** **the amount of the overpayment."** (emphasis added)

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THE 60-DAY RULE
(Medicare Parts A & B)

Reasonable Diligence Standard:

- **"Reasonable Diligence" includes both (1) proactive compliance activities and (2) reactive investigations conducted** in a timely manner in response to credible information of a potential overpayment
  - "Minimal compliance activities to monitor the appropriateness and accuracy of claims would be a failure to exercise reasonable diligence"
  - Identification of a single overpaid claim requires further investigation
  - "Part of identification is quantifying the amount, which requires a reasonably diligent investigation."

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THE 60-DAY RULE
(Medicare Parts A & B)

How Long is Reasonable Diligence?

The Final Rule states:

A good faith investigation should occur within six months from receipt of the credible information, absent "extraordinary circumstances"

- Following the six month period to investigate, you have 60 days to report and return the overpayment
- A total of eight months, absent extraordinary circumstances, is presumptively reasonable

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THE 60-DAY RULE
(Medicare Parts A & B)

What does CMS consider to be **"Extraordinary Circumstances"**?

Extraordinary circumstances may include:

- "Unusually complex" investigations
- Stark Law violations
- Natural disasters or state of emergency

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THE 60-DAY RULE
(Medicare Parts A & B)

Credible Information:

- "Credible information" is information that supports a reasonable belief that an overpayment may have been received.
- Potential sources of credible information:
  - Government of contractor audits
  - Government request for information (subpoenas, CIDs)
  - Internal compliance reviews
  - Exit interviews
  - *Qui Tam*
  - Hotline complaints
  - Unexplained revenue increases
  - Unusually high profits or wRVUs
  - A single overpaid claim

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THE 60-DAY RULE
(Medicare Parts A & B)

- The 60-day time period for reporting / returning begins when either:
  - The reasonable diligence is completed (including proactive compliance activities conducted in good faith in a timely manner); or
  - On the day the provider received credible information of a potential overpayment (if the provider fails to conduct reasonable diligence)
- For an investigation to be conducted in a "timely" manner, providers typically must <u>complete the investigation within 6 months</u> from receipt of credible information indicating there may be an overpayment
  - 6-month timeframe may potentially be extended under "extraordinary circumstances"
  - 8 *months generally the maximum total time to return overpayments.*
- The government recommends that providers maintain records documenting "reasonable diligence"

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THE 60-DAY RULE
(Medicare Parts A & B)

What is the Lookback Period?

- The final rule states the lookback period is six (6) years from the receipt of an overpayment.
- Providers need to review audit findings and determine whether there are overpayments going back the full six- years.

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60-DAY RULE LIMITATIONS

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WHAT THE 60-DAY RULE LEAVES UNANSWERED

- Medicaid
- Provider report and return obligations to Part C and D plans or sponsors
- What types of non-compliance result in overpayments
  - Some "overpayments" are easily identifiable (e.g., routine billing errors, claims submitted in violation of the Stark Law)
  - What about non-compliance with certain regulatory requirements?

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MEDICAID

- ACA requirement encompasses Medicaid
- Regulations do not apply to Medicaid
- BUT… explicitly states providers are required to report and return overpayments to Medicaid within 60 days of identification, despite lack of regulatory guidance from CMS

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MEDICARE PARTS C & D

- Part C & D regulations are generally similar to those for Parts A and B
  - An overpayment is "identified" when the MA organization / Part D sponsor "has determined, or should have determined through the exercise of reasonable diligence" that it had received an overpayment
  - Overpayment must be reported and returned within 60 days after the date it was identified
- BUT … due to structural differences, the overpayment return concepts and methodologies are implemented differently in Parts C and D
  - E.g., lookback period = six most recent completed payment years.
- At least one court has found that failing to report / return in the Medicare Advantage context could create FCA liability
- Providers may have a contractual obligation to report / return.

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ENFORCEMENT AND RELEVANT CASES

U.S. EX REL. KANE V. HEALTH FIRST, INC. CHRONOLOGY

Jan. 2009	Software glitch
Sep 2010	Comptroller contacts Continuum
Dec 2010	Software patch
Jan 2011	Comptroller notifies of additional claims
Feb 4, 2011	Kane email
Feb 8, 2011	Kane terminated
Feb 2011	Continuum repays five claims
Mar 11 – Feb 12	Comptroller notifies of additional tranches of claims; Continuum slowly repays
Apr 2011	Kane files *qui tam* under seal
June 2012	DOJ issues CID
Mar 2013	Continuum completes repayment of all claims

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U.S. EX REL. KANE V. HEALTH FIRST, INC. KNOWING RETENTION OF OVERPAYMENTS

United States' Argument:

- "Identified" means the provider has determined, or should have determined through reasonable diligence, that it received an overpayment.
- Reasonable diligence might require an investigation conducted in good faith and in a timely manner by qualified individuals in response to credible information of potential overpayment.
- Cannot avoid obligation simply by deciding not to investigate.

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U.S. EX REL. KANE V. HEALTH FIRST, INC. KNOWING RETENTION OF OVERPAYMENTS

From: Robert Kane
Sent: Friday, February 04, 2011 5:51 PM
To: Kathryn Dakis; Toni Jones; Allise Williams; Cristobal Barriuso; Howard Lindenauer
Subject: RE: AG's office on the Healthfirst/Medicaid Coins problem.
Attachments: HF ERA Analysis.xls

Adding Howard

Allise,
As we discussed at yesterday's meeting attached is the spreadsheet that used our available ERA files that dated back to May of '09 to report on the CAS CO 2 Segments that were problematic from HF. This does not replace the need for IS to continue their efforts to produce the complete report from the Remit Database.
Nothing on these sheets shows the effect the posting had on Eagle, but most likely was problematic. This gives some insight to the magnitude of the issue. The secondary FC was obtained by cross referencing to Eagle.

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U.S. EX REL. KANE V. HEALTH FIRST, INC. KNOWING RETENTION OF OVERPAYMENTS

Continuum's Argument:

- Overpayment is not "identified" by mere notice of a potential but unconfirmed overpayment
- 60-day timeframe is impossible to satisfy unless an overpayment has been confirmed and quantified

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U.S. EX REL. KANE V. HEALTH FIRST, INC. KNOWING RETENTION OF OVERPAYMENTS

Court:

- The sixty day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained
- BUT. . . just because a claim might qualify as an obligation does not establish a violation of the FCA

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U.S. EX REL. KELTNER V. LAKESHORE MED. CLIN. LTD., KNOWING RETENTION OF OVERPAYMENTS

- ***U.S. ex rel. Keltner v. Lakeshore Med. Clin. Ltd.,* 2013 U.S. Dist. LEXIS 44640(E.D. Wis.)**
  - Former audit employee alleged violations of 3729(a)(1)(G)
  - Court denied motion to dismiss – practice "ignored audits disclosing a high rate of upcoding"
  - Allegations "plausibly suggest that defendants acted with disregard for the truth and submitted some false claims"

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LIABILITY FOR RETAINING OVERPAYMENTS

- ***U.S. ex rel. Hernandez-Gil v. Dental Dreams, LLC*** (D.N.M. 2018)
  - Relator, former employee, alleged defendant dental practice retained overpayments in violation of FCA
    - Management informed of billing practices but refused to allow investigation or audit
    - "[I]t would cost too much money"
  - District court denied summary judgment motion
    - Reasonable jury could infer defendant "*knew* it received overpayments and took no steps to investigate, quantify, report, or return overpayments"
- Reasonably investigate potential overpayments even when no overpayments specifically identified

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OPTIONS FOR HANDLING AN OVERPAYMENT

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WHAT IF I CHOOSE NOT TO REPORT AND REFUND?

- Retention may create an "obligation" for purposes of False Claims Act.
- Reverse false claim if "knowingly concealing" or "knowingly and improperly avoiding or decreasing" an obligation to pay back to federal government. 31 U.S.C. §3729(a)(1)(G).
- Potential Civil Monetary Penalty (CMP) liability of not more than $20,000 for each knowing unpaid refund/overpayment, and an assessment of not more than threes times the amount of each unpaid refund/overpayment (*also*, risk of Federal health care program exclusion). 42 USC § 1320a-7a(a)(10).

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CHALLENGES AND CONSIDERATIONS IN CHOOSING TO REPORT/DISCLOSE

- ❑ Have any laws been violated? If so, which ones?
- ❑ Was this provider-identified or externally identified (e.g., through government or contractor audit)?
- ❑ What steps should be taken to remedy the situation?
- ❑ What payors are impacted? What are the rules for each?
- ❑ Are all records electronic? Paper? Note: will this present a problem with a six-year lookback?
- ❑ Sample versus all claims?
- ❑ Who should be involved in the decision?
- ❑ What is the scope of potential disclosure?
- ❑ How would the scope change if violation is reported?
- ❑ What was the root cause?
- ❑ What can be done to prevent violation from happening again?
- ❑ Should we disclose or just refund?
- ❑ What is the right place to disclose?

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OPTIONS FOR WHERE TO REPORT AND RETURN AN OVERPAYMENT

If you decide there is an overpayment or potential liability, there are options on where to report and return:

- Contractor Refund (Medicare Administrative Contractor, MAC)
- Contracted Payor Refund (Parts C and D)
- State Agency
- OIG Self-Disclosure Protocol (SDP)
- CMS Self-Referral Disclosure Protocol (SRDP)
- Department of Justice (DOJ) / U.S. Attorney's Office (USAO)

Tip: Use the most appropriate mechanism based on the nature of the overpayment.

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OPTIONS FOR REPORTING / RETURNING OVERPAYMENTS

- **Medicare Administrative Contractor (MAC) reporting process**
  - Provider-identified overpayments to the MAC:
    - Use the MAC process generally for: simple overpayments, claim corrections, claim adjustments, credit balance, self-reported refund, or other reporting process set forth by the Medicare contractor.
    - Familiarize yourself with the MAC's process for reporting and returning overpayments.
    - Be transparent when reporting to the MAC.
    - Follow their process (if one is provided).

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CONTRACTOR (MAC) DISCLOSURE/REFUND: PROS AND CONS

Pros

- Typically least costly option
- Best for simple overpayment matters (e.g., improper coding)
- Simple process
- Somewhat predictable process, though varies by MAC
- Often faster than OIG/DOJ/SRDP
- Low to no reputational harm
- Six-year lookback period
- Satisfies legal obligation to report and return overpayment

Cons

- No release

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POTENTIAL BENEFITS OF SELF-DISCLOSURE

- The amount to be re-paid to the government likely will be lower than if the government identifies the issue
- The government is unlikely to impose a costly Corporate Integrity Agreement (CIA)
- Depending on the disclosure, the provider likely will receive one or more releases, protecting against certain types of liability
- If a self-disclosure is well-structured, the government is less likely to conduct its own, more intrusive investigation that could expand to other types of issues as well
- May provide better protection for individuals

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POTENTIAL RISKS OF SELF-DISCLOSURE

- The government may not limit its review to the facts and issues disclosed, which could lead to expanded exposure
  - If the government identifies overpayments or issues not identified in the self-disclosure, questions could be raised about the provider's intent
- Protocols provide no guarantees of leniency, immunity, or specific benefits
- Providers may not be accepted into the OIG or CMS protocols
- Self-disclosure to one agency may not resolve potential liability to another
- Impact of self-disclosures on *qui tam* complaints filed under the federal FCA also is unclear
- Certain types of self-disclosure may take a significant amount of time to resolve
- Complexity of the fraud and abuse laws may lead to unnecessary disclosure and liability

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OIG SDP: THE BASICS

- **OIG: Self-Disclosure Protocol (SDP)**
  - Created in 1998, updated in 2013
  - Receives approximately 100 submissions a year
  - Disclose for:
    - Potential violations of federal criminal, civil, or administrative law for which Civil Monetary Penalties are authorized. Examples include:
      - Conduct involving false billing; Conduct involving excluded persons.
      - Conduct involving the Anti-Kickback Statute (including conduct that violates <u>both</u> the AKS and Stark Law). Not for Stark-only conduct.
  - Not for:
    - Error on overpayments, requests for opinion on whether there is a potential violation, Stark-only conduct

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OIG SDP: PROS AND CONS

Pros

- Lower settlement multiplier on single damages (often 1.5x) and other potential damages likely reduced
- False Claims Calculation: All claims or statistical sample of 100 claims minimum; Use point estimate
- AKS: Remuneration Based
- Excluded individuals: Salary and benefits based
- Presumption of no CIA (Corporate Integrity Agreement)
- The OIG can provide a release from exposure under the CMP law and permissive exclusion
- 6-year statute of limitations
- Tolls 60-day period after submission
- May help limit FCA exposure
- More predictable process, clear framework provided
- Often faster than DOJ/SRDP
- Expedited resolution
- Low reputational harm
- Possibly indicative of a good compliance program

Cons

- Can make referrals to other agencies
- Cannot provide release for potential FCA liability (without DOJ involvement), though may help limit exposure
- DOJ participation often results in higher settlement amounts
- May cost more and can be a longer process than returning money to the MAC
- May result in public reporting
- Not eligible for overpayments where there is no potential violation of CMPL
- Not eligible for Stark-only conduct
- Not eligible for settlements less than $10,000 ($50,000 AKS)
- Not for opinion requests on whether there is a potential violation

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TIPS AND COMMON MISTAKES FOR DISCLOSURES (OIG SDP)

MISTAKES

- Does not follow the revised SDP
- Lack of cooperation
- Statement of no fraud liability
- Not identifying laws potentially violated
- Disclosing conduct too early or too late
- No plan to quantify damages or correct issue
- Conduct violates only Stark
- Refusal to pay multiplier
- Argues damages should be calculated in a manner contrary to the SDP

TIPS

- Review the revised SDP and use as a roadmap. Include and address all parts.
- Do not admit guilt or make definitive statements of no fraud
- Review, address, and state all potential violations of law
- Provide initial letter with deadline to submit final SDP

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CMS SELF-REFERRAL DISCLOSURE PROTOCOL (SRDP): PROS AND CONS

Pros

- CMS has discretion in determining settlement amounts (often based on excess remuneration paid; not reimbursement received)
- CMS may release disclosing party from certain limited administrative liabilities and claims
- Tolls the 60-day report/return obligation after submission
- Six-year lookback period
- Form available for SRDP complete disclosure submission, specific requirements provided

Cons

- Disclosure can involve *only* actual or potential violations of the Stark Law (Stark overpayment release)
- Limited scope release – CMS only releases overpayment liability under Section 1877(g)(1) of the Social Security Act
- CMS may coordinate with the OIG and/or DOJ for additional releases, although the settlement amount likely would increase
- No FCA release, but can help limit exposure
- SRDP process can be extremely slow

CMS SELF-REFERRAL DISCLOSURE PROTOCOL (SRDP): TIPS

Factors considered in reducing amounts owed:

- Nature and extent of improper or illegal practice;
- The timeliness of self-disclosure;
- Cooperation in providing additional information related to the disclosure;
- Litigation risk; and
- Financial position of the disclosing party

DEPARTMENT OF JUSTICE (DOJ) / U.S. ATTORNEY'S OFFICE (USAO)

Pros

- Beneficial to providers who require an FCA release
- Broadest release, including FCA
- Six-year lookback period
- *Note: typically through local U.S. Attorney's Office (USAO). Experience varies by jurisdiction.*

Cons

- No guaranteed settlement formula, and anecdotal reports that some USAOs will not settle for less than double damages
- Does not toll 60-day report/return requirement
- No formal guidance or protocol
- *Note: typically through local U.S. Attorney's Office (USAO). Experience varies by jurisdiction.*

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STATE AGENCY DISCLOSURE/REFUND: PROS AND CONS

Pros

- Release of State authorities
- *Note: experience may vary*
- *Note: posture and penalty may vary by state*

Cons

- No federal release
- *Note: experience may vary*
- *Note: posture and penalty may vary by state*

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PARTS C & D: PROS AND CONS

Pros	Cons
❑ Typically least costly option, if any repayment	❑ May or may not be required by agreement
❑ Potentially resolve with notification letter or discussion	❑ No clear process
❑ Transparency and positive relationship with Payor	❑ Payor may not know how to process and could either return, or elect to treat as untimely filing and take back the payment for the full visit
❑ Compliance with Contract (if covered)	

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6 COMPLIANCE PROGRAM EFFORTS AND BEST PRACTICES

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COMPLIANCE PROGRAMS: EVALUATION & EFFECTIVENESS

Measuring compliance program effectiveness has long been recommended by several authorities. There has been a recent increase in government focus on measuring effectiveness and evaluating compliance programs, as seen with the release of several new guidance documents:

- OIG Measuring Compliance Program Effectiveness (2017)
- DOJ Evaluation of Corporate Compliance Programs (2017 and 2019 update; 2019 Criminal Antitrust Investigations)
- *OIG Compliance Program Guidance and Supplemental Guidance Documents; ACA; Federal Sentencing Guidelines; CMS Guidelines for Part C and D (Fraud, Waste, and Abuse); Justice Manual; FCPA Guide; Department of Treasury Office of Foreign Asset Control (OFAC) New Framework for Effective Sanctions Compliance (2019)*

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COMPLIANCE EFFORTS: THE OIG'S "7 ELEMENTS"

1. Designating a Compliance Officer and Compliance Committee
2. Implementing written policies, procedures and standards of conduct
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal auditing and monitoring
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected offenses and implementing corrective actions
8. ***"8th Element" – Compliance Program Effectiveness***

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COMPLIANCE PROGRAMS: EVALUATION & EFFECTIVENESS

- The new guidance documents contain similar elements to the well known "7 elements", however, go further in providing specific areas and suggestions to providers. Many of these relate to matters of possible self-disclosure to various agencies (e.g., Exclusion, Stark and Anti-kickback). **Compliance should look to these for tips to comply with the 60-day overpayments rule.**
- The documents are designed to help organizations with possible approaches to move beyond basic compliance program development, and address the government approach to measuring effectiveness in detecting, deterring and remediating fraud and abuse.
- **Release of these documents demonstrated that compliance program effectiveness is critical for maintaining compliant operations on an ongoing basis, and could also lead to consideration for more favorable settlements, especially in the event of an investigation.**
- **With any disclosure, the government will review submission and facts. It is important for organizations to showcase their compliance proactive and reactive efforts.** In DOJ cases of criminal investigations they are required to review to determine its existence, effectiveness, and remedial efforts to implement or improve its program.

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COMPLIANCE PROGRAMS: MEASURING EFFECTIVENESS (HCCA/OIG 2017)

<u>OIG's 2017 Compliance Program Elements</u>
(7 elements, covering 400 compliance program metrics with 700 questions):

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

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COMPLIANCE PROGRAMS: MEASURING EFFECTIVENESS (HCCA/OIG 2017)

- Verify that appropriate overpayment policies and procedures exist.
- Verify that appropriate coding policies and procedures exist.
- Maintain policies and procedures for internal and external compliance audits.
- Verify appropriate policies and procedures to address regulatory requirements (e.g., Anti-Kickback, Stark).
- Verify background/sanction checks are conducted in accordance with applicable rules and laws (e.g., employment, promotions, credentialing).
- Monitor government sanction lists for excluded individuals/entities (e.g., OIG, GSA).
- Recommend action for individuals and entities that have been excluded from government programs.
- Assure corrective action is taken based on background/sanction check findings.
- Assure risk-specific training is conducted for targeted employees.
- Assure monitoring occurs for violations of laws and regulations.
- Complete risk assessments. Develop work plan based on risk assessment.

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COMPLIANCE PROGRAMS: MEASURING EFFECTIVENESS (HCCA/OIG 2017)

- Maintain reporting system(s) to enable employees to report any noncompliance (e.g., hotline).
- Respond to compliance concerns expressed by employees through internal reporting.
- Verify that disciplinary action is reported to regulatory body when required.
- Participate in negotiation with regulatory agencies.
- Cooperate with government inquiries and investigations.
- Assure remedial efforts are implemented to reduce risk.
- Assure that overpayments to payers are refunded in a timely manner.
- Recognize need for subject matter experts.
- Collaborate with legal counsel regarding voluntary disclosures.
- Coordinate investigations to preserve privileges, as applicable.
- Verify due diligence is conducted on third parties (e.g., consultants, vendors, acquisitions).

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COMPLIANCE PROGRAMS: EVALUATING COMPLIANCE (DOJ 2017/2019)

DOJ's 2019 Compliance Program Elements
(3 main questions, 11 elements, several sample topics and questions):

1. Risk assessment
2. Policies and procedures
3. Training and communications
4. Confidential reporting structure and investigation process
5. Third-party management
6. Mergers and acquisitions (M&A)
7. Commitment by Senior and middle management
8. Autonomy and resources
9. Incentives and disciplinary measures
10. Continuous improvement, periodic testing, and review
11. Analysis and remediation of any underlying misconduct

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COMPLIANCE PROGRAMS: EVALUATING COMPLIANCE (DOJ 2019)

Based on 2019 DOJ Guidance, Compliance Programs must:

1. Be properly resourced
2. Have independent access to the Board of Directors or Audit Committee
3. Be integrated with other functions
4. Adopt a risk-based approach
5. Implement metrics that matter
6. Train managers and gatekeepers differently
7. Adopt stringent third-party controls, continuously monitor third parties
8. Communicate policies and procedures to third-parties
9. Maintain a robust whistle-blowing process
10. Have Compliance Program Evaluations performed

Credit: Kristy Grant-Hart

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COMPLIANCE PROGRAMS: EVALUATING COMPLIANCE (DOJ 2019)

Recurrent focus areas in the new DOJ Guidance:

- Responsibility, accountability, consistency, and leadership commitment
- Misconduct: root cause, prior indications, remediation, information gathering and analysis, manifested risks, communication, real actions and consequences
- Effective, risk-based training and availability of guidance
- Effective reporting mechanisms, appropriate response, proper scope of investigations by qualified personnel
- Effective testing and controls
- Internal audit, HR processes, vendor management and management of relationships, payment systems

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PROACTIVE COMPLIANCE EFFORTS

- Ensure appropriate and dedicated compliance committees, including those for certain high risk areas such as overpayments. Involve outside experts or counsel when needed.
- Conduct effective compliance training, including training for high-risk regulatory areas and billing compliance. Provide re-training when needed. Educate personnel to spot overpayments.
- Ensure policies and procedures are well designed, accessible, communicated, and followed. Distribute guidance and regulatory/industry materials to personnel.
- Ensure employees have multiple avenues to report compliance concerns. Treat hotline calls and all reported concerns seriously, including those which may identify a potential overpayment. Communicate whistle-blower policies to personnel and protect against retaliation.
- Ensure proper screening processes to detect excluded individuals and entities.
- Monitor third-parties for compliance purposes.

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PROACTIVE COMPLIANCE EFFORTS

- Conduct auditing and monitoring as part of an established work plan, including high-risk areas that may result in a potential overpayment. Conduct both proactive and reactive risk-based reviews. Properly scope and execute audits and investigations.
- Be aware of and monitor credible information sources for potential overpayments (e.g., denial and recoupment trends, payor/agency/contractor requests).
- Appropriately respond to external contractor audits and demand letters. Self-audit to identify risks and determine obligations. Note: This is considered "credible information".
- Respond timely and appropriately to potential or known issues. Adhere to the timeframes under the 60-day rule (note the investigation period to quantify potential overpayments).
- Maintain documentation of progress and issues throughout.
- Considerations for applying privilege and work with legal counsel.

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COMPLIANCE EFFORTS FOR PROVIDER IDENTIFIED OVERPAYMENTS (MAC)

- Look to guidance documents for compliance proactive efforts.
- Understand the applicable rules and legal authority related to overpayments.
- Understand the duty to report/refund a provider-identified overpayment, deadlines, lookback periods, and any other facts specific to each payor.
- Understand the requirements for simple refunds/rebills as per your local Administrative Contractor (MAC). Contact your MAC to ensure understanding of their overpayment handling and reporting process.
- Review third-party payor agreements to understand report/refund obligations.
- Develop a policy to address provider-identified overpayments and those identified through external audits or investigations.
- Draft a template letter to accompany simple refunds/reporting and audits for your local MAC and/or Payors. Include all required elements per the payor.

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COMPLIANCE EFFORTS FOR PROVIDER IDENTIFIED OVERPAYMENTS (MAC)

All known or potential overpayments should be analyzed to determine the scope, actions needed, volume and estimated refund or adjustments, and potential reporting. Determine root cause and other impacts. Upon completion of the analysis, refunds/corrections should be timely initiated as per payor guidelines.

1. Issue identification
2. Analysis
3. Issue correction (process and system corrections / enhancements)
4. Review and decision making
5. Charge correction and refund
6. Follow-up

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COMPLIANCE EFFORTS FOR PROVIDER IDENTIFIED OVERPAYMENTS (MAC)

Steps to consider to remedy an overpayment with the MAC:

- Identify potential overpayment, consider claims hold, 'stop the bleed'
- Notify appropriate parties (e.g., compliance, revenue cycle, IT, departments)
- Identify impacted accounts/patients
- Analyze charges, CDM, systems; Determine Root Cause Analysis (RCA)
- Calculate reimbursement and financial information
- Address charges, CDM, system issues, note accounts and make corrections
- Address root cause and look for similar issues (note lookback period)
- Review by appropriate parties (including committee(s))
- Consider remedy options and decide actions based on facts
- Prepare files for disclosure to MAC (notification letter, spreadsheet of accounts, refund check)
- Follow-up: Enhanced workflows and processes, re-educate, monitor)

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COMPLIANCE EFFORTS FOR PROVIDER IDENTIFIED OVERPAYMENTS: PARTS C & D

Steps to consider to remedy Parts C & D Provider-identified overpayments:

- Parts C & D regulations are generally similar to those for Parts A & B, but not addressed in the final rule.
- Review relevant State laws.
- Review payor contracts (consult with counsel and managed care).
- Many contracts have requirements on reporting and returning of overpayments, others are silent. If contract is silent, best practice is to notify and/or return an identified overpayment.
- Recommend discussing with counsel, managed care, and payors to determine an acceptable process.
- Consider documenting your policy to remedy third-party payor overpayments.

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TAKEAWAYS: FACILITATING COMPLIANCE WITH THE 60-DAY RULE

- Take proactive steps in Compliance Programs
- Identify the laws that were potentially violated, the timeframes during which the potential violation occurred, and acknowledge the potential violation
- Engage legal/outside counsel and other experts when necessary to complete a thorough investigation (including quantification)
- Ensure understanding of risks, benefits, and methods for reporting and returning overpayments, including which method is appropriate for which type of overpayment
- Take corrective action to end the non-compliant practice, arrangement, etc., and prevent recurrence
- Determine whether self-disclosure is appropriate, and decide most appropriate option
- Cooperate fully during the process and/or with the agency's investigation

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DISCUSSION & QUESTIONS

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