RESPONDING TO NON-COMPLIANCE

Repaying Overpayments and Self-Reporting





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AFFORDABLE CARE ACT: OVERPAYMENT

- If a provider receives or retains an "overpayment," the provider must:
 - Return the overpayment to the federal agency, the state, an intermediary, a carrier, or a contractor, and
 - Notify the entity of the reason for the overpayment.
- What is an "overpayment"?
 - Any funds that a person receives or retains from Medicare or Medicaid to which the person, after applicable reconciliation, is not entitled



AFFORDABLE CARE ACT: OVERPAYMENT

Examples

- Includes payments received for claims submitted in violation of the Stark Law or the Anti-Kickback Statute
- Payments for non-covered services
- Payments in excess of the allowable amount
- Errors and non-reimbursable expenses in cost reports
- Duplicate payments
- Receipt of Medicare payment when another payor has primary responsibility for payment
- Conditions of payment vs. participation
- Lookback period: Overpayments must be reported and returned if identified within 6 years of the date the overpayment was received



PENALTIES: THE FALSE CLAIMS ACT

- The statute imposes liability on people who defraud government programs
- Relevant prohibitions:
 - 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
 - So-called "reverse" false claims
 - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
 - An "overpayment" retained after the repayment deadline is considered an obligation for purposes of the False Claims Act



PENALTIES: THE FALSE CLAIMS ACT

- Penalties
 - Treble damages
 - Penalties of approximately \$11,000 to \$22,000 per violation
 - Qui Tam lawsuit relators file suit and receive a percentage of the ultimate recovery



PENALTIES: THE CIVIL MONETARY PENALTY LAW

- Violation of the Civil Monetary Penalty Law
 - \$10,000 penalty
 - Treble damages
 - Exclusion from Medicare or Medicaid



PENALTIES

The number of cases and recovery amounts are rising





THE 60 DAY RULE

- A provider must report and return an overpayment within the later of:
 - 60 days after the overpayment is *identified* or
 - The date a corresponding cost report is due





THE 60 DAY RULE: IDENTIFYING THE OVERPAYMENT

- A "person has identified an overpayment when the person [1] has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and [2] quantified the amount of the overpayment"
- "Reasonable diligence" includes both proactive compliance monitoring and reactive investigations in response to credible information of a potential overpayment
 - Taking only "[m]inimal compliance activities to monitor the appropriateness and accuracy of claims would be a failure to exercise reasonable diligence"



THE 60 DAY RULE: IDENTIFYING THE OVERPAYMENT

- Identification of a single overpaid claim requires further investigation
- For example, you have a duty to investigate if you receive information of
 - Significant and unexplained increase in Medicare revenue
 - Review of bills showing incorrect codes
 - Discovery of services rendered by unlicensed provider
 - Internal or external audit that discloses overpayments
 - Discovery of a violation of Anti-Kickback Statute, Stark, or Civil Monetary Penalty Law



THE 60 DAY RULE: IDENTIFYING THE OVERPAYMENT

 "Part of identification is quantifying the amount, which requires a reasonably diligent investigation."





THE 60 DAY RULE: STARTING THE CLOCK

- The 60 day time period for reporting and returning an overpayment begins when:
 - The reasonably diligence investigation is completed (confirming the receipt or retention of a quantified overpayment); or
 - If the provider failed to exercise "reasonable diligence," the day the provider received credible information of a potential overpayment
- Providers typically must complete their investigation within <u>6</u> months from receipt of credible information of an overpayment
 - This may be extended under "extraordinary circumstances," but 8 months generally the maximum total time to return overpayments.
- DO THIS: maintain records documenting "reasonable diligence"



THE 60 DAY RULE: STARTING THE CLOCK

- The repayment deadline is suspended by:
 - OIG Self-Disclosure Protocol
 - CMS Stark Self-Referral Disclosure Protocol
 - Request for an extended repayment schedule



OVERPAYMENTS: RETURNING AND REPORTING

- MAC reporting process
 - For reporting overpayments such as a claims adjustment, credit balance, or self-reported refund
 - If Medicare contractor believes repayment involves violation of federal law, contractor may report repayment to the OIG, CMS, or other federal agency.





OVERPAYMENTS: RETURNING AND REPORTING

- Self-disclosure protocols
 - OIG's Self-Disclosure Protocol
 - CMS Voluntary Self-Referral Disclosure Protocol
- Submit for overpayments requiring a settlement agreement
- Submission to the OIG or CMS protocols suspends the 60 day requirement for returning overpayments until a settlement agreement is executed
 - Self-disclosures to other agencies do not suspend the repayment deadline
- Repayment does not resolve violations or penalties under other laws



Medicaid

- While the regulations do not apply to Medicaid, the Affordable Care Act requirement does
- Providers must report and return overpayments to Medicaid within 60 days of identification notwithstanding the lack of CMS guidance
- Penalties include (1) exclusion from state health programs, e.g., Medicaid; (2) a civil penalty per violation; and (3) referral to the Medicaid fraud unit
- Medicare Parts C & D
 - At least one court has found that failing to return and report overpayments in the Medicare Advantage creates liability under the False Claims Act



- Non-compliance with regulatory requirements: *Escobar* and the "implied certification" theory
- What happened in *Escobar*?
 - The defendant submitted billing codes to Medicaid corresponding to specific counseling services along with NPI numbers corresponding to specific job titles
 - This was a representation by to Medicaid that it provided the services through professionals with certain qualifications
 - The qualifications of the defendant's professional staff did not meet Medicaid requirements
 - The Government would not have paid the claims but for the misrepresentation
- Result?
 - False Claims Act liability can be founded on non-compliance with requirements that are not express conditions of payment
 - BUT, not all non-compliance creates False Claims Act liability



- *Escobar* set a framework for implied certification:
 - A claim makes a specific representation about the goods/services provided;
 - The defendant knowingly failed to disclose noncompliance with material statutory, regulatory, or contractual requirements, turning representations into "misleading half-truths"; and
 - The misrepresentation is material to the decision to pay the claim.
- What is material?
 - Evidence that the defendant knows the government has consistently refused to pay the claim
 - Did the government have actual knowledge of the noncompliance yet continue to pay the claim?



Where does that leave the analysis for purposes of the 60 day rule?



- Escobar provides no examples or what would satisfy the "implied certification" theory beyond the facts of the case
- The framework does help to analyze noncompliance with regulatory requirements for potential overpayment liability
- Other cases are fleshing out *Escobar*



60 DAY RULE: ENFORCEMENT

- Court decisions have turned on procedural issues rather than the merits
- Settlements
 - A number of providers have entered into settlement agreements, e.g.,
 - Genesis Medical Center paid \$1.88 million to resolve allegations that it improperly retained Medicare overpayments for hospital admission claims that should have been billed as either outpatient or observation services, services that would have resulted in lower reimbursement
 - The University of Rochester paid \$113,722 to resolve allegations that it improperly used an ophthalmologic modifier to receive increased reimbursement
 - The University of Rochester also self-disclosed to learning about a related, previously filed *qui tam* complaint



SELF-DISCLOSURE

- When is self-disclosure appropriate?
 - Ask: Does the issue involve a potential violation of law?
 - Matters exclusively involving overpayments that do not involve violations of law should be brought to the attention of the MAC
 - Ask: Is the provider operating under a Corporate Integrity Agreement?
- Benefits of self-disclosure
 - Repayment amount will likely be lower
 - Less likely to lead to a Corporate Integrity Agreement
 - Likely to receive releases, protecting against certain types of liability
 - Less likely that the government conducts its own, more intrusive investigation
 - Better protection for individuals



SELF-DISCLOSURE

- The risks of self-disclosure:
 - The agency may not limit its review to the issues disclosed
 - This is especially true of OIG disclosures
 - Complex fraud and abuse laws may lead to unnecessary disclosure and liability
 - 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 liability to another agency
 - Some types of self-disclosure may take a long time to resolve



BEFORE YOU SELF-DISCLOSE

- Identify:
 - all laws potentially violated and
 - the relevant timeframe(s) when the potential violation(s) occurred
- Take action to correct the non-compliant practice and to prevent it from happening again
- Understand that you will need to (1) acknowledge the potential violation and (2) cooperate fully with the agency investigation



BEFORE YOU SELF-DISCLOSE

- Familiarize yourself with disclosure protocols
 - OIG Self-Disclosure Protocol: <u>https://oig.hhs.gov/compliance/self-disclosure-info/index.asp</u>
 - Stark Self-Referral Disclosure Protocol: <u>https://www.cms.gov/medicare/fraud-and-</u> <u>abuse/physicianselfreferral/self_referral_disclosure_p_rotocol.html</u>
- Contact compliance officer
- Consider contacting a knowledgeable attorney



WHERE TO SELF-DISCLOSE

- OIG Self-Disclosure Protocol
 - Conduct involving false billing
 - Conduct involving excluded persons
 - Conduct involving the Anti-Kickback Statute (including conduct that violates both the Anti-Kickback Statute and Stark Law)
- CMS Self-Referral Disclosure Protocol
 - Conduct involving only violations of the Stark Law
- DOJ
 - May be appropriate when provider believes a FCA release is necessary
- Other (*e.g.*, the MAC)
 - Usually best for relatively simple overpayment returns
 - No release, but generally the least expensive route



OIG – SELF-DISCLOSURE PROTOCOL

Benefits

- Tolls the 60 day deadline to report and repay
- Release from exposure under the Civil Monetary Penalty Law and from permissive exclusion
- Lower multiplier on single damages (often 1.5)
 - Other potential damages likely reduced
- Expedited resolution
- Limitations
 - OIG cannot provide a release for False Claims Act liability without DOJ involvement
 - DOJ participation often results in higher settlement amounts
 - Costs more than returning money to the MAC



OIG – SELF-DISCLOSURE PROTOCOL

Conduct	Settlement
Care center employed excluded individual.	\$162,171
Hospital paid physicians in excess of FMV for services not performed	\$79,167
Hospital paid submitted claims to Medicaid without preauthorization	\$196,013
Hospital received services by home health agency to induce referrals	\$1,923,993
Health care company employed two excluded individuals	\$359,388
Hospital submitted unsupported claims for home health services	\$3,757,615
Hospital submitted claims for services that were not provided as claimed	\$872,925
Physician group upcoded claims	\$259,746
Physician group submitted claims for services that were not	\$422,741



CMS – SELF-REFERRAL DISCLOSURE PROTOCOL

- Benefits
 - Tolls the 60 day deadline to report and repay
 - CMS has discretion in determining settlement amounts
 - These amounts are often based on the amount of the overpayment
 - Potential release
- Limitations
 - Only violations of the Stark Law
 - Limited scope release CMS only releases overpayment liability under Section 1877(g)(1) of the Social Security Act
 - May coordinate with OIG and DOJ for additional releases, but the settlement amount likely would increase
 - Can be extremely slow
 - Costs more than returning money to the MAC



CMS – SELF-REFERRAL DISCLOSURE PROTOCOL



ferral > Self-Referral Disclosure Protocol Settlements

Self-Referral Disclosure Protocol Settlements

The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) enables providers of services and suppliers to selfdisclose actual or potential violations of the physician self-referral statute. The following table displays settlements to date and will be updated on a yearly basis.

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60 - \$579,000	\$709,060
2012	14	\$1,600 - \$584,700	\$1,236,200
2013	24	\$760 - \$317,620	\$2,468,348
2014	41	\$3,322 - \$463,473	\$5,175,168
2015	49	\$5,081 - \$815,405	\$6,706,458
Totals	131	\$60 - \$815,405	\$16,295,234

Notes:

As of December 31, 2015, an additional 56 disclosures to the SRDP were withdrawn or settled by CMS' law enforcement partners.

Because disclosures of actual or potential violations of the physician self-referral law include proprietary, confidential, or



BETTER TO COMPLY IN THE FIRST PLACE!





COMPLIANCE PROGRAM

- A compliance program should include:
 - Appropriate policies and procedures
 - Periodic billing and coding audits to identify overpayments proactively
 - Focus on high-risk areas
 - Use of government resources to guide audit efforts
 - Investigation of any suspected incidents of non-compliance with federal health care program requirements
- Engage outside counsel and other experts as needed to complete a thorough investigation, including quantification of any overpayment
- Understand the methods for reporting and returning overpayments with their accompanying risks and benefits
- Document the diligence exercised in any overpayment investigation



IF YOU THINK YOU HAVE A PROBLEM

Don't do this!





IF YOU THINK YOU HAVE A PROBLEM

- Suspend payments or claims until resolved
- Investigate the problem under your compliance plan
 - Consider involving a knowledgeable attorney to maintain privilege
- Implement appropriate corrective action
 - Remember that prospective compliance may not be enough
- If repayment is due:
 - Report and repay
 - Self-disclosure



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Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in 1 minds of many of our clients. We are here to guide our clients through the challenges a opportunities that arise in this dynamic industry.

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Cory A. Talbot office 801-799-5917

catalbot@hollandhart.com

