Overpayments: If, When and How to Self-Disclose

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Self-Disclosure of “Overpayments”

- What are overpayments?
- Laws and other guidance impacting the decision whether to self-disclose
- Risks of non-disclosure
- Risks of self-disclosure
- Benefits of self-disclosure
- The OIG’s Provider Self-Disclosure Protocol
Laws Impacting the Decision Whether to Self-Disclose

- No statute or regulation explicitly requires refund of overpayment to the government
  - Except for Stark Law regulations, 42 CFR 411.353(d)
- However, some laws can be interpreted as prohibiting the retention of funds to which the provider is not entitled
  - 42 USC §1320a-7b(a)(3)
  - 42 CFR §405.371
  - 18 USC §1001
  - 42 USC §1395u(b)(3)(B)(ii)
  - 31 USC §§3729(a)(1), (a)(7)
  - 42 USC §1395nn(g)(2)
  - 18 USC §§669, 1347
Other Guidance Influencing the Decision Whether to Self-Disclose

- CMS Forms 855
- CMS’ “Overpayment Refund Form”
- CMS’ January, 2002 Proposed Rule
- State laws
The Stark Law and Overpayments

- Prohibits a physician from referring a patient for “designated health services” to an entity with which the physician (or an immediate family member) has a financial relationship.
- Prohibits the entity from billing Medicare for services rendered pursuant to such a patient.
- Numerous statutory and regulatory exceptions permit certain financial relationships.
- Unexpected financial relationship + bills to Medicare = potentially large overpayments.
- Statutory refund obligation: runs to the beneficiary.
- Regulatory refund obligation: runs to Medicare.
- Stark Law carries its own penalties.
The False Claims Act, “Implied Certification,” and Overpayments

- The Reverse False Claim, 31 USC §3729(a)(7)
- The “Implied Certification Theory” under 31 USC §3729(a)(1)
  - May apply when a claimant receives reimbursement while in violation of a law and, if the government had known of the violation, it would not have paid the claim
  - Courts: underlying law must expressly condition payment on compliance with the law
  - Stark Law: explicit refund provisions mentioned above
  - Anti-Kickback Statute: no explicit refund provisions
    - But see CMS Forms 855: claims while in violation of Anti-Kickback Statute could constitute overpayments / “false claims”
Potential Risks of Retaining Overpayments

- Potential violation of law(s)
- Knowing retention of an overpayment, even a minor one, can blossom into a big problem
- Government perceptions subsequent to decision not to disclose
- Maximum penalties and fines can be grave
  - Civil monetary penalties
  - Corporate Integrity Agreement
  - False Claims Act
  - Program exclusion
  - Criminal laws at issue
East Tennessee Heart Consultants Settlement (January 2007)

- First enforcement action against physicians for failure to refund overpayments
- Allegations: ETHC improperly retained credit balances (i.e., amounts due to payors and patients as a result of overpayments)
- Alleged violations of 18 USC §§669, 1347
- Charges waived for 18 month probationary period
- 12 years of overpayments ($1.2m) to be refunded – to Medicare, Medicare, private payors, and to patients
- If ETHC can’t find the individual/payor, refund goes to government
- Also: 5 year CIA, $2.9m in civil penalties and restitution
Potential Risks of Self-Disclosure

- Repayments will be made
- Cost of pre-disclosure investigation
- Provider’s “buyer’s remorse”
- Government may not agree that self-disclosure and proffered repayment is sufficient
- Compliance plans and efforts subject to scrutiny
- Government *not* bound to anything: may decide to further investigate, impose discipline
- Cost of post-disclosure efforts to resolve situation
Potential Benefits of Self-Disclosure

- Criminal exposure may be eradicated
- Reduced penalties
  - US Sentencing Guidelines
  - False Claims Act: double damages, rather than treble
- CIA may be more lenient, if not avoided
- Opportunity to cast story in proper light
- Reduce chance / scope of government investigation
Risk – Benefit Analysis

- In absence of legal obligation to refund overpayments, decision whether to refund may be a risk – benefit analysis:
  - Investigate, understand, consider FACTS
  - Consider applicability of laws to facts
  - Consider potential resultant damages
  - Consider amount of potential repayments
  - Consider results of compliance plan
  - Consider propriety of other business operations
OIG Provider Self-Disclosure Protocol

- Released in October, 1998
- Open to all providers and suppliers
- Protocol intended to resolve matters that potentially violate Federal criminal, civil or administrative laws
  - Not intended for resolution of simple billing errors
  - Other than the Stark Law, these laws typically require at least some form of intentional or reckless conduct
- OIG report:
  - In 10 years, 379 disclosures accepted into protocol
  - 165 resolved for $118 million
    - Of first 136, 27 required CIA
  - CY 2007: 53 disclosures submitted
OIG Provider Self-Disclosure Protocol

Requirements of 1998 Protocol:
- Although providers under government scrutiny are not necessarily ineligible, self-disclosure must be made “in good faith” (and must reveal any knowledge of such scrutiny)
- Full cooperation throughout process
- In writing
- Description of organizational complexities, if any
- Full description of matter (type of claims, entities/individuals involved, their roles, time period at issue, provider number(s), programs affected)
- Reason why provider believes a law may have been violated
- Certification that submission is truthful
OIG Provider Self-Disclosure Protocol

- OIG expects that provider will have conducted (or is in process of completing) thorough internal investigation and self-assessment prior to self-disclosure.
- OIG will forego its own investigation if, upon self-disclosure, provider agrees to complete its investigation and self-assessment in adherence to OIG’s Internal Investigation Guidelines and Self-Assessment Guidelines.
OIG’s Internal Investigation Guidelines

- In addition to prescribed detail for original submission (above), Internal Investigation Guidelines require:
  - Identification of potential causes of incident / practice
  - Description of impact on health, safety, quality of care
  - Identification of corporate officials who knew of, but failed to detect, the incident
  - Estimate of monetary impact on Federal programs
  - Description of response to matter:
    - Steps taken to prevent future incidents
    - Thorough explanation of investigative steps
    - Disciplinary actions taken
OIG’s Self-Assessment Guidelines

- Designed to calculate potential program losses
- Review of either all claims or statistically valid sample of claims
- Provider must divulge to OIG:
  - Review objective and procedures
  - Review population
  - Sources of data
  - Qualifications of reviewers
  - If review based on sample, detail pertaining to sampling
Then What?

- Refunds will not be accepted at this point, but are encouraged to be placed in escrow
- OIG begins its review
- Scope of OIG review should be based on completeness of self-disclosure
- OIG will likely request access to audit work papers and supporting documentation
  - Attorney-client privilege?
- OIG and DOJ not bound to any concessions
  - Particularly DOJ with respect to attorney-client privilege
2000 and 2001 OIG Guidance

- 2000 Open Letter: OIG may “be more flexible in considering the terms of a CIA” or “not even require a CIA” for providers that self-disclose
- 2001 Open Letter: self-disclosure would be the “first factor” the OIG would consider when determining whether to waive program authorities without imposing a CIA
- 2001 OIG report: describes concessions resulting from self-disclosure
  - Reduced length of CIA
  - Reduce role of Independent Review Organization
  - CIA requirements tailored to meet providers’ compliance programs
April, 2006 Open Letter to Providers

- Seeks to promote use of Protocol for hospital-physician financial relationships that lead to violations of Stark Law and/or Anti-Kickback Statute
- Indicates OIG will waive exclusionary authority for “trustworthy” providers and those who have, or will put in place, an effective compliance program
- Indicates OIG will seek monetary restitution at multiplier of “lower end” of damages continuum
  - Stark Law: damages based on claims for tainted referrals
  - Anti-Kickback Statute: damages based on amounts paid under financial relationship(s)
- Indicates OIG will review compliance program when determining whether to impose CIA or CCA
April, 2008 Open Letter to Providers

- Reiterates commitment to resolve self-disclosures at “lower end” of damages continuum
- Commits to resolving self-disclosures speedily
- Elements of Internal Investigation Guidelines now required as part of initial submission:
  - Complete description of conduct being disclosed
  - Description of internal investigation, or commitment to completion date within 3 months
  - Estimate of program damages, and methodology used to calculate it… or commitment to calculation within 3 months
  - Statement of laws potentially violated
April, 2008 Open Letter to Providers, cont.

- Reiterates that SDP is not intended for mere billing errors (report these directly to contractors)
- Concession: OIG will generally NOT require a CIA or CCA in exchange for a monetary payment
  - “Recognizes the provider’s commitment to integrity and also advances [the] goal of expediting the resolution of self-disclosures”
- Coincidence?: Open Letter released contemporaneously with CMS proposal to audit approximately 10% of Medicare-participating hospitals for Stark Law compliance
Provider Self-Disclosure

- In absence of legal obligation to refund overpayments, decision whether to refund may continue to be a risk – benefit analysis
- However, consider whether…
- Risks are being reduced
- Benefits are being increased
Questions?

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