
Repayments and Self-Disclosure

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Institute on Medicare and Medicaid Payment Issues

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NOTE

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Outline

- A. Legal Obligations to Disclose and Refund**
 - B. Recent Enforcement Actions
 - C. Benefits and Incentives to Disclose
 - D. Risks of Disclosure
 - E. Considerations as to Where to Make a Disclosure
 - F. OIG Provider Self-Disclosure Protocol
 - G. Other Disclosure Issues
 - H. AHLA'S Self-Disclosure Task Force
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Overview

- ◆ **“Voluntary Disclosure” a misnomer**
- ◆ **Repayment of funds may be legally compelled when Medicare statutes have been violated**
- ◆ **Assuming past problems that are not continuing**

Legal Obligations to Disclose and Refund

Are refunds mandatory?

Federal law makes it a felony for whoever--

having knowledge of the occurrence of any event effecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose benefit he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in greater amount or quantity than is due or when no such benefit or payment is authorized. . .

42 U.S.C. § 1320a-7b(a)(3); Social Security Act § 1128B(a)(3)

Legal Obligations to Disclose and Refund

- **This provision obligates the return of funds if an individual or entity becomes aware that she is retaining federal funds to which she is not entitled**
- **Knowingly retaining such funds in this context, even if the receipt of such funds was through a billing mistake or the error of the fiscal intermediary, constitutes a felony**

Legal Obligations to Disclose and Refund

Can be very difficult to determine whether a known overpayment exists

- Medicare laws permit overpayment to be waived in certain instances generally where a provider is “without fault”
- Where counsel finds a good-faith basis to believe that no overpayment exists, a refund to the government is not compelled

Legal Obligations to Disclose and Refund

Retention of Overpayments

- **Several Medicare authorities to consider**
 - CMS 855 provider/supplier enrollment form -- overpayments may be recouped through withholding
 - Medicare requires accurate reporting of financial information
 - Knowing reporting of materially inaccurate or false information may constitute a false statement
 - Similar state laws may also apply

Legal Obligations to Disclose and Refund

- **When a refund is required to be made to Medicare, a good faith effort may need to be made to refund co-payment amounts to beneficiaries**
- **HCFA Program Memorandum (“PM”) HCFA Pub. 60AB, Transmittal No. AB-00-41 (May 1, 2000) *Procedures for the Benefit Integrity (BI) and Medical Review (MR) Units on Unsolicited/Voluntary Refund Checks***

Legal Obligations to Disclose and Refund

The PM Outlines procedures for the fiscal intermediaries (“FIs”) including determining:

- Why the refund is being made;
- How the problem was identified
- What sampling techniques were used
- What steps were taken to assure that the problem will not reoccur

Legal Obligations to Disclose and Refund

Continued:

- **The dates of the corrective action**
- **Claims information related to the inappropriate payments**
- **Methodology used to determine the amount of the overpayment**
- **Whether a full assessment was performed to determine the entire time-frame of the inappropriate action and the total amount of the over payment**

Legal Obligations to Disclose and Refund

HCFA Transmittal No. AB-33 (June 1, 1999) “Overpayment Refund” form

- **Identify all related claims information**
- **17 reason codes are provided, including:**
 - **Services not rendered (Code 15),**
 - **Medical necessity (Code 16),**
 - **Billed in error (Code 6), and**
 - **Secondary payor problems (Codes 8-11)**

**Overpayment Refund
Form -- HCFA
Transmittal No. AB-33
(June 1, 1999) Tracking
and Reporting Procedures
for Unsolicited/Voluntary
Refund Checks from
Providers/Suppliers**

EXHIBIT 1

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)
(Please list all claim numbers involved. Attach separate sheet, if necessary)
Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? _____ Yes _____ No

Reason Codes:

Billing/Clerical Error MSP/Other Payer Involvement Miscellaneous

- 01 - Corrected Date of Service 08 - MSP Group Health Plan Insurance 13 - Insufficient Documentation
- 02 - Duplicate 09 - MSP No Fault Insurance 14 - Patient Enrolled in an HMO
- 03 - Corrected CPT Code 10 - MSP Liability Insurance 15 - Services Not Rendered
- 04 - Not Our Patient(s) 11 - MSP, Workers Comp.(Including 16 - Medical Necessity
- 05 - Modifier Added/Removed Black Lung 17 - Other (Please Specify)
- 06 - Billed in Error 12 - Veterans Administration _____
- 07 - Corrected CPT Code

Legal Obligations to Disclose and Refund

This form raises potential

- **APA issues (failure to issue rulemaking), and**
- **Constitutional self-incrimination issues**

Legal Obligations to Disclose and Refund

January 2002 CMS Proposed Rule – Reporting Overpayments

- **Defines “overpayment” as Medicare funds a provider, supplier, individual or other entity has received in excess of amounts payable under the Medicare statute and regulations**
- **Requires providers, suppliers and individuals to report and return overpayments, within 60 days of identifying the overpayment**

Legal Obligations to Disclose and Refund

- **Indicates that submission of a corrected bill within 60 days fulfills the reporting requirement for providers, suppliers and individuals**
- **Also requires “other entities” to report and return overpayments, within 60 days in accordance with applicable cost settlement procedures**

Legal Obligations to Disclose and Refund

- **Defines “other entities” as entities contracting with CMS, including managed care organizations, that are not a provider, supplier or individual and that provide Medicare services to Medicare beneficiaries**
- **Proposed rule takes appropriate interpretation that an overpayment does not necessarily exist if the claim or payment is merely inconsistent with program guidance**
- **NPRM never enacted in final form -- withdrawn**

Legal Obligations to Disclose and Refund

The Stark Law

- **Prohibits the submission of a claim when a Medicare or Medicaid referral has taken place pursuant to a prohibited financial relationship**
- **When a provider concludes that a clear violation of the Stark law exists, a refund may be compelled**

Legal Obligations to Disclose and Refund

Anti-Kickback Statute

- **Involves somewhat different issues than statutorily mandated repayments**
- **CMS 855 provider/supplier enrollment form -- a claim for payment "is conditioned on the claim and underlying transaction complying with [Medicare] laws, regulations and program instructions (including the anti-kickback statute and the Stark law). . ."**

Legal Obligations to Disclose and Refund

- **Significant question exists whether the CMS 855 form can create a legal obligation not otherwise authorized in the absence of notice and comment rulemaking**
- **The anti-kickback statute is an intent-based statute, the analysis of which is highly fact-based -- it is often difficult for counsel to form a judgment that the anti-kickback statute has clearly been violated**

Legal Obligations to Disclose and Refund

- **Counsel should nevertheless consider the appropriateness of making a disclosure in light of the other considerations**

Legal Obligations to Disclose and Refund

Implied False Claim Theory

- **Some courts have held that a violation of the anti-kickback statute or the Stark law may also constitute a violation of the False Claims Act**

Legal Obligations to Disclose and Refund

Private Payors

- **The Social Security Act provision cited above is not applicable to private payors**
- **For the most part any obligation a provider may have to repay funds to which it is not entitled lies with the payor's provider contract**
- **Other state laws may require disclosure and/or refunds**

Legal Obligations to Disclose and Refund

Other Authorities

- **Various federal and state laws require reporting professional misconduct and adverse professional actions**
- **Under Corporate Integrity Agreements (“CIA’s”) with the OIG, providers typically agree to report and refund overpayments, and “Reportable Events.”**

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Recent Enforcement Actions

- **Add as potential authorities, HIPAA health care crimes --**
 - **18 U.S.C. § 669 (theft or embezzlement in connection with a health care benefit program)**
 - **§ 1347 (health care fraud)**
- **As applied in US Attorney for the Eastern District of Tennessee settlement with East Tennessee Heart Consultants (“ETHC”), January 4, 2007**

Recent Enforcement Actions

Background And Allegations

- **ETHC is a medical practice of 42 cardiologists that employs more than 250 people in Knoxville, Tennessee.**
- **Two former employees of ETHC filed a *qui tam* action under the False Claims Act on November 6, 2003. These employees had worked as ETHC's Patient Financial Services Representatives ("PSRs").**

Recent Enforcement Actions

Background And Allegations (cont.)

- **Allegations:** ETHC had a number of credit balance practices which amounted to a “policy” of avoiding repaying credit balances or making refunds difficult for payors and patients seeking money owed them
- The vast amounts of credit balances that the practice owed related to patients, not Medicare, Medicaid or other payors
- **Important:** there were no allegations of false claims or poor quality of care.

Recent Enforcement Actions

Background And Allegations (cont.)

- **ETHC's year-end books did not reflect credit balances as accounts payable, allowing these monies to be treated as year-end profits to physicians.**
- **When the practice converted to a new billing system, a large portion of the credit balances at that time did not move over into the new system and were thus removed from the practice's books.**

Recent Enforcement Actions

The Settlements

- **ETHC agreed to --**
 - a criminal pretrial diversion agreement (“PDA”),
 - separate civil settlements with the federal and state governments,
 - a five-year Corporate Integrity Agreement with the Office of the Inspector General (“CIA”).
- **Financial Terms -- \$2.9 million in civil penalties and restitution to private payors and 11,220 patients.**

Recent Enforcement Actions

The Settlements (cont.)

- Government Programs:
 - \$1.5 million to DOJ for settling civil claims under the FCA related to federal health care programs;
 - \$200,000 to the state for settling state laws claims;
 - (Relators' share came to over \$330,000)
- Restitution:
 - \$1 million to 11,220 patients;
 - \$200,000 to private health plans.
- **ETHC paid \$71,868 for Relators' attorney's fees.**

Recent Enforcement Actions

Criminal Pretrial Diversion Agreement

A Criminal Pretrial Diversion Agreement (“PDA”) is a process by which a prosecutor agrees to waive criminal charges for a defined period of time during which the target agrees to undertake certain activities, either under the oversight of the probation department or a court-appointed monitor.

Recent Enforcement Actions

Pretrial Diversion Agreement (cont.)

The PDA has the following conditions:

- 18 month supervision by U.S. Probation Office;
- The payment of restitution for all overpayments which ETHC received since January 1, 1995 from all parties, including both individual patients and health care benefit programs;
- \$167,449 to private health plans, including commercial insurance
- \$1,043,629 to 11,220 patients.

Recent Enforcement Actions

Pretrial Diversion Agreement (cont.)

- 18 month supervision by U.S. Probation Office;
- the PDA does not permit ETHC to waive refunds for amounts below a dollar threshold.
- All unpaid credit balances as identified in the PDA at the end of this 18 month process must be paid to the Government's Crime Victim Fund.

Recent Enforcement Actions

Civil Settlements:

ETHC entered into separate civil settlement agreements with the federal government and the state of Tennessee.

The Government Alleged:

- Claims for payments were false claims because ETHC had a legal obligation to pay the government previously received overpayments on prior claims.
- ETHC submitted duplicate claims to both primary and secondary payers resulting in overpayments, despite the knowledge that it had a legal obligation to promptly refund such overpayments.

Recent Enforcement Actions

Corporate Integrity Agreement:

The CIA requires:

- **ETCH to develop and implement specific policies and procedures to encourage full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements.**
- **This policy must be reflected in ETHC's Code of Conduct.**

Recent Enforcement Actions

Corporate Integrity Agreement (cont.)

- **ETHC employees with responsibilities for submitting claims are required to attend to five (5) hours of specific training annually.**
- **The CIA also requires that ETHC engage an Independent Review Organization to perform reviews to assist ETHC in assessing and evaluating its billing and coding practices**

Recent Enforcement Actions

Significance:

- **First enforcement action against providers for failing to repay overpayments.**
- **Sets new ground in the use of government fraud authorities related to provider conduct affecting private payors and patients, not just Medicare and Medicaid programs.**
- **Government used the criminal process to break this new legal ground to effectuate a result it felt was needed.**

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Benefits and Incentives to Disclose

Benefits

- **May reduce exposure to criminal fines**
- **Reasonable prospect that a prosecutor will not pursue a criminal action**
- **Reduction in penalties under the civil FCA**
- **Decreased risk of prosecution**
- **Settlement**

Benefits and Incentives to Disclose

Additional benefits:

- **Ability to more fully frame the issues and disclosure,**
- **Ability to demonstrate that the organization is ready and willing to behave responsibly,**
- **Likelihood of avoiding subpoenas or search warrants**

Benefits and Incentives to Disclose

- **Ability to complete a thorough internal investigation, and**
- **Opportunity to develop and improve relationships with enforcement officials that are less adversarial, and may prove useful in the future**

Benefits and Incentives to Disclose

Federal Sentencing Guidelines

- **United States Sentencing Guidelines provide substantial incentives for organizations that identify criminal conduct to self-disclose**
- **A voluntary disclosure coupled with cooperation and acceptance of responsibility should -- at a minimum -- halve the organization's fine**

Benefits and Incentives to Disclose

False Claims Act

- **In the civil context, the False Claims Act (“FCA”) provides for treble damages and penalties of \$5,000 to \$10,000 for each false claim**
- **A voluntary disclosure may reduce damages to an amount not less than two times the amount of damages**
- **Disclosure must be made to the person “responsible for investigating FCA violations” within 30 days**

Benefits and Incentives to Disclose

- **Person must fully cooperate and must not “have actual knowledge” of the existence of an investigation**
- **If criminal exposure may exist, consideration could be given to proceeding under a proffer agreement**

Benefits and Incentives to Disclose

March 9, 2000 Open Letter to Health Care Providers from DHHS OIG

- ▶ **Health care providers that promptly self-disclose improper conduct may receive favorable treatment**
 - **OIG's "best evidence" is where a provider, through its compliance program –**
 - identifies problematic conduct
 - remedies the conduct and prevents it from recurring, and
 - makes a full and timely disclosure

Benefits and Incentives to Disclose

- **Where a provider has demonstrated that its compliance program is effective and agrees to maintain it, OIG may not even require a CIA**
- **Potential for less rigorous CIAs, e.g., require the provider to make only limited changes to its existing policies and procedures**

Benefits and Incentives to Disclose

- **Recent OIG informal survey of CIA negotiations since issuance of the “Open Letter to Health Care Providers” indicates OIG willing to impose no CIA or less onerous CIA where provider has established compliance program and voluntarily reports misconduct**

Benefits and Incentives to Disclose

- **CIA modifications most often agreed to by OIG include:**
 - **Reduction in CIA term from 5 years to 3 years**
 - **Reduction in role of Independent Review Organization (“IRO”) where provider has established system of internal audits**

Benefits and Incentives to Disclose

Voluntary Disclosure Protocols

- **OIG has provided no guarantee or formula by which to calculate a reduction in penalties -- however it has promised to consider voluntary disclosure in assessing penalties**

Benefits and Incentives to Disclose

Whistleblowers

- *Qui tam* lawsuits have substantially increased the odds that improper conduct will eventually be disclosed
- Voluntary disclosure gives the organization a greater opportunity to manage the process and mitigate the impact of a whistleblower claim
- Voluntary disclosure by a provider may not bar whistleblower lawsuits on the same matter

Benefits and Incentives to Disclose

Prosecutorial Discretion

- **DOJ's *Principles of Federal Prosecution* are guidelines designed to assist federal prosecutors in deciding whether to indict a potential defendant**
 - **Voluntary disclosure will be a substantial mitigating factor and may well mean the difference between a criminal prosecution and a civil action against the *entity***
 - **In all likelihood, the prosecutor will still proceed against culpable *individuals***

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Risks of Disclosure

- ▶ **Will inevitably lead to repayments**
- ▶ **Always a chance that the government would never find out about the problem**
- ▶ **May also require the provider to be more forthcoming**
- ▶ **May result in the issue becoming more expensive and may identify other issues that may never have been raised otherwise**

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Considerations as to Where to Make a Disclosure

Options

- ▲ **Providers have a variety of choices**
 - **Fiscal intermediaries or carriers,**
 - **CMS,**
 - **OIG,**
 - **A local U.S. Attorney's office (DOJ), and**
 - **States Attorneys General**

Considerations as to Where to Make a Disclosure

General Rules

- **Matters that involve billing errors can generally be disclosed to the fiscal intermediary and/or the carrier as appropriate**
- **When possible civil or criminal exposure has been identified, counsel must determine whether or not to bring the matter to the attention of the OIG or the DOJ**

Considerations as to Where to Make a Disclosure

Selecting the Option

- ▶ **The second most difficult task facing healthcare counsel is the determination where to disclose among the options identified above**
- ▶ **Few clearly right or wrong answers**
- ▶ **Many factors to be considered in advising clients**

Considerations as to Where to Make a Disclosure

- ▶ **Is this merely a negligent billing error?**
- ▶ **Does the provider need the certainty of a formal settlement or closing letter?**
- ▶ **Are there indicia of wrongdoing?**
- ▶ **Is the matter criminal or civil in nature, and what is the potential exposure for the client?**

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OIG Provider Self-Disclosure Protocol

When to Use the OIG Protocol

- ▶ **It is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, are potential violations of federal, criminal, civil or administrative laws**

OIG Provider Self-Disclosure Protocol

- ▲ **Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity that processes claims and issues payment on behalf of the government agency responsible for the particular Federal healthcare program**

OIG Provider Self-Disclosure Protocol

- ▶ **If the contractor concludes that the overpayment raises concerns about the integrity of the provider, the matter may be referred to OIG**
- ▶ **OIG still refuses to go on record that it will limit its recovery to double damages**

OIG Provider Self-Disclosure Protocol

Format for Disclosure

- ▲ **Must be written and mailed and delivered to the OIG in Washington and provide:**
 - **The name, address, PIN, tax I.D. number, disclosure of “pertinent relationships” and names and addresses of any related entities;**
 - **Whether the provider had knowledge of a current government inquiry;**
 - **A “full description” of the problem;**
 - **The identity of the provider, type and provider billing number;**

OIG Provider Self-Disclosure Protocol

- **The reason the provider believes a violation of federal, criminal, civil or administrative laws has occurred; and**
- **A certification that the disclosure is truthful.**

OIG Provider Self-Disclosure Protocol

- ◆ **Internal Investigation Requirements**
 - ▲ **The Self-Disclosure Protocol requires the provider to conduct an internal investigation demonstrating “that a full examination of the practice has been conducted”**
 - ▲ **The two principal categories of the written report address the nature and extent of the problem and the organization’s discovery in response to the problem**

OIG Provider Self-Disclosure Protocol

◆ **Self-Assessment**

- ▲ **Estimate the financial impact of the problem on the Medicare, Medicaid or other government programs**
- ▲ **The Self-Disclosure Protocol contains detailed guidance relating to developing the self-assessment workplan**

OIG Provider Self-Disclosure Protocol

◆ **OIG Follow-Up**

- ▲ **OIG retains the right to review documents, interview witnesses, review records and otherwise test the validity of the provider's assertions and conclusions**

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Other Disclosure Issues

◆ **Negotiating Voluntary Disclosure Agreements**

- ▲ **Set forth the details and process and may:**
 - **Present an opportunity for counsel to address critical issues**
 - **Limit the scope and extent of the disclosure**
 - **Include processes that are designed to:**
 - **Minimize disruption of the organization's business activities,**
 - **Control access to employees, and**
 - **Define acceptable use of the disclosed information**

Other Disclosure Issues

Key Provisions

- **Voluntary disclosure agreement should set forth in reasonable detail:**
 - **The nature and extent of the information to be disclosed,**
 - **The timetable for disclosure, and**
 - **The format for disclosure**

Other Disclosure Issues

Understanding Legal Impact

- **Disclosure of information in this context may eliminate entirely the organization's ability to protect or maintain the privilege and confidentiality of the information in the context of other civil litigation or proceedings**

Other Disclosure Issues

Importance of Pre-Disclosure Investigation

- **Counsel has an enormous advantage in a voluntary disclosure when she is in full command of all relevant facts based upon a thorough internal investigation**
- **Research fully applicable law in order to marshal appropriate legal defenses**

Other Disclosure Issues

Possible Simultaneous Actions to Consider

- **To the extent possible, it is important to be able to demonstrate that the provider has:**
 - Investigated the practice and identified the cause,
 - Taken steps to correct the problem through systems changes and appropriate employee education,
 - A process in place to ensure that the problem will not recur (e.g. corporate compliance program), and
 - Appropriately disciplined employees or agents responsible for the problem.

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AHLA's Self Disclosure Task Force

In early 2005, AHLA's Fraud and Abuse, Self-Referrals, and False Claims Practice Group formed a task force on self-disclosure.

As described on the Practice Group's website:

"The Voluntary Disclosure Task Force will study voluntary disclosures to the government by persons or entities in the healthcare industry. The goal is to examine whether the various methods of voluntary disclosure are achieving their purpose, including encouraging compliance and voluntarily bringing forward problems for prompt, fair resolution. The Task Force hopes to gather data on the overall frequency of voluntary disclosures, to which government entity the disclosures were made (the Fiscal Intermediary, Carrier, OIG, local US Attorney, or Justice Department), and the result or effect of disclosure on the resolution of the matter."

AHLA's Self Disclosure Task Force

- ◆ **The Task Force will be developing a Self-Disclosure survey to be distributed to AHLA members and on its website.**
- ◆ **The Task Force intends to create and maintain a self-disclosure data base.**
- ◆ **The Task Force hopes to complete a report to the Practice Group this year.**

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