The Art of Self-Disclosures

Robert Hussar
Of Counsel
Barclay Damon LLP

A little about me …

Robert Hussar
Of Counsel
Barclay Damon LLP
518.429.4278
rhussar@barclaydamon.com

- Memberships and Activities
  - Former Chair – NYS Bar Association Health Law Section
  - HCCA – Past Board Member, Certified in Compliance (CHC)
  - Frequent speaker/author on compliance-related topics
- Experience
  - First Deputy - NYS OMIG
  - Chief Compliance Officer - Essen Health
  - Interim Chief Compliance/Privacy Officer – Yale New Haven Health
  - Chief Compliance Officer – Northeast Health
- Focus Areas
  - Compliance program assessment and assistance
  - Internal investigations
  - OIG/CMS/OMIG/MFCU/NYS Justice Center – audit/investigation/exclusion defense, negotiation, and settlements
  - Self-disclosures
  - Board of directors, senior management, and staff training

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Agenda

- Background/History
- Relevant Laws and Regulations
- Disclosure Options
- Benefits and Risks
- Considerations and Tips for Success
- Questions and Answers

hfma
ma-ri chapter

NEW ENGLAND HEALTHCARE INTERNAL AUDITORS INC.

History of Compliance and Self-Disclosures

- Corporate Integrity Agreements and Voluntary Guidance (US HHS-OIG)—early 1990s
- Mandated Compliance Disclosures for Non-Profits on IRS 990 (2008) (not required to have compliance standards on conflicts, disclosure, etc.—only to report whether you do)
- Compliance Programs for Medicare Advantage and Part D (CMS-2009) (72 FR 68700 and program memos)
- Compliance Programs for Federal Contractors (2009) (FAR 52.203-13) (reporting of “significant overpayment(s)” on the contract)
- “Effective” Compliance Programs for NY Medicaid Providers (New York OMIG 2009) (18 NYCRR 521)
- Repayment of Medicare and Medicaid Overpayments (PPACA Section 6402 (2010))
- Compliance Programs for Nursing Homes and Some Other Health Providers—Patient Protection and Affordable Care Act Sections 6102, 6401 (2013 for nursing homes)
- Compliance Programs for ACOs, FIDAs, and DSRIP PPSs (2011–Present)

Element Seven: Responding to Identified Issues

Issues:

- Investigate issues/causes
- Address problems (including refunding overpayments)
- Implementing sustainable corrective actions

Recommendations:

- Shared responsibility and accountability
- Issue tracking and management
- Timely resolution

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Duty to Disclose Overpayment

- Social Security Act § 1128B (42 U.S.C. 1320a-7b[a][3])
  - Makes it a felony for "[h]aving knowledge of the occurrence of any event affecting (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 behalf 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…"
- Imposes criminal penalties on providers who knowingly keep overpayments from federal health care programs.
- Govt. has argued that failing to repay overpayments within a reasonable time could be seen as intentionally concealing the funds.

Expansion of Refund Obligations

- **2009:** FERA (Fraud Enforcement and Recovery Act) clarified the obligation to refund overpayments.
- **2010:** ACA (Affordable Care Act) reinforced the requirement.
- Expanded penalties under:
  - False Claims Act (FCA)
  - Civil Monetary Penalties Law (CMPL)

Fraud Enforcement and Recovery Act

- FERA introduced two key provisions:
  - Liability for knowingly concealing or improperly avoiding payments to the government.
  - “Obligation” includes the retention of overpayments.
- Key terms “knowing” and “knowingly” defined broadly:
  - Includes actual knowledge, deliberate ignorance, or reckless disregard.
  - No proof of specific intent to defraud required.
- Health care providers’ responsibilities:
  - Stay current on Medicare/Medicaid rules and documentation requirements.
  - Implement processes to monitor payments, identify overpayments, and refund promptly.

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Affordable Care Act

- Affordable Care Act (ACA) introduced a 60-day rule for health care providers to report and return overpayments to Medicare/Medicaid.
  - Time limit triggered once an overpayment is “identified.”
  - Overpayments must be reported and refunded within 60 days or by the cost report due date. A written explanation for the overpayment is required.
- Consequences of noncompliance:
  - Failure to report/refund within 60 days results in FCA liability.
  - Overpayments treated as false claims.
  - Treble damages and fines may be imposed under the Civil Monetary Penalties Law (CMPL).

Overpayments

- Affordable Care Act Section 6402(a) (42 U.S.C. 1320a-7k) established a requirement that overpayments must be reported, explained, and returned by the later of:
  - 60 days after the date on which the overpayment was identified; or
  - The date any corresponding cost report is due, if applicable.

Section 6402(a) Requirements

The term “overpayment” means any funds that a person receives or retains to which the person, after applicable reconciliation, is not entitled to.

- Overpayments must be reported and returned to the appropriate party (i.e., DHHS, the state, an intermediary, a carrier, or a contractor), at the correct address, and
- Must include a written explanation of the reason for the overpayment.
- Any overpayment retained after the deadline for reporting/returning is an “obligation” for purposes of the Federal False Claims Act.

42 C.F.R. 401.301-305

Regulatory provisions interpreting the overpayment statute

Lookback period:

- Six years from the date the overpayment was received

How to report and return:

- Use the “most appropriate mechanism” based on the “nature of the overpayment”

Meaning of identified:

- When a provider or supplier “has determined, or should have determined through the exercise of reasonable diligence, that [it] received an overpayment and quantified the amount of the overpayment”
- “Should have determined” means the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

CMS Comments

“We choose 6 months as the benchmark for timely investigation because we believe that providers and suppliers should prioritize these investigations and also to recognize that completing these investigations may require the devotion of resources and time.”

Extraordinary Circumstances

May include:

- unusually complex investigations (i.e., physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP))
- natural disasters or a state of emergency

Theories Giving Rise to Liability Under the False Claims Act

1. **Factually False Claims** – Where the claimant supplies "an incorrect description of goods or services provided, or a request for reimbursement for goods or services never provided."
2. **Legally False Claims (including below)**
   - **Express False Certification:** Where the claimant expressly certifies compliance with a regulation or other condition when submitting claim for payment.
   - **Implied False Certification:** Where the claimant impliedly certifies compliance with regulation or other condition simply by submitting claim for payment.

U.S. Supreme Court's 2016 Ruling in *Universal Health v. Escobar*

- Defendant sought reimbursement from Medicaid for certain mental health services. *Escobar*, 136 S. Ct. 1989 (2016).
- Because the employees who provided the mental health services allegedly did not meet qualification and licensing requirements under Medicaid regulations, the reimbursement requests were alleged to be false claims on the theory that the claims impliedly certified that the employees met the relevant regulatory requirements.

U.S. Supreme Court's 2016 Ruling in *Universal Health v. Escobar* (Cont.)

Holding

- The Supreme Court unanimously held that "implied certification" can present a viable theory for liability under the False Claims Act, but also stressed the heightened materiality requirement.
- By not disclosing the violations of qualifications and licensing requirements, the defendant's Medicaid reimbursement claims constituted misrepresentations.

- Implied certification could apply where:
  1. the claim does not merely request payment, but also makes specific representations about the goods or services provided, and
  2. the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.
  - A regulation need not be labeled a "condition of payment" to trigger implied certification.

Overpayments From Referral Violations

- Referral violations under AKS and Stark Law can lead to overpayments:
  - Even if services are properly rendered, coded, and billed.
- Anti-Kickback Statute (AKS):
  - Prohibits remuneration in exchange for referrals. Violations result in potential FCA liability for false claims.
- Stark Law:
  - Restricts certain financial relationships between providers.
  - Requires refunds for prohibited referrals.
  - Penalties: Up to $15,000 per service for improper claims.

So, you found an overpayment . . .

Now what?

Common Questions

- Are you sure it is an overpayment?
- When should you do a deep dive?
- How do you handle small-dollar issues where cost of investigation exceeds exposure?
- How far back should you go?
- Do you extrapolate?
- If so, how do you select a sample?
- What is the claims have been audited
- How to handle a subsequent audit that includes claims included in a self-disclosure?

hfma
ma-ri chapter

NEW ENGLAND HEALTHCARE INTERNAL AUDITORS INC.

The “Inquiry”

- Identify the team, roles, responsibilities.
- Define scope – issue, time period, providers, vendors, etc.
- Identify “subjects” or “targets.”
- Thorough review of laws, regulations, guidance, etc.
- Identify changes within review period.
- Access to:
  - Records
  - IT systems
- Be mindful of timing.
- **Be prepared to defend.**

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Disclose and Repay?

- How?

AND

- To whom?

It depends!!!*

***Lawyers' favorite answer**

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Making a Disclosure and Refund

- Civil and criminal liabilities for failing to disclose and refund overpayments are significant.
- Overpayments can be refunded through:
  - Medicare Administrative Contractor (MAC)
  - Self-disclosure to OIG or other agencies (DOJ, U.S. Attorney's Office)
  - Routine electronic billing adjustments
- Deciding between a simple refund and a formal disclosure can be complex.

Benefits of Self-Disclosure

- Self-disclosing may help avoid or reduce:
  - Significant fines for false claims or overbilling
  - Potential civil liability for fraud
  - Fines or imprisonment for knowingly submitting false claims
  - Risk of being barred from participating in government health care programs like Medicare and Medicaid

Benefits of Self-Disclosing

- Own the narrative
- Possible waiving of interest
- Good-faith participation in the self-disclosure program may be considered a mitigating factor in the determination of an administrative enforcement action
- Preempt whistleblower actions
- Avoid negative press
- Evidence of an effective compliance program
- Positive reputation

Compliance Effectiveness

] Self-Disclosures

hfma
ma-ri chapter

New England Healthcare Internal Auditors Inc.

Deciding Where to Disclose

Many options, many factors . . .

- Voids/adjustments
- CMS contractor
- CMS SRDP (Stark only)
- OIG SDP
- DOJ
- OMIG
- AG MFCU
- MCO

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Common Examples

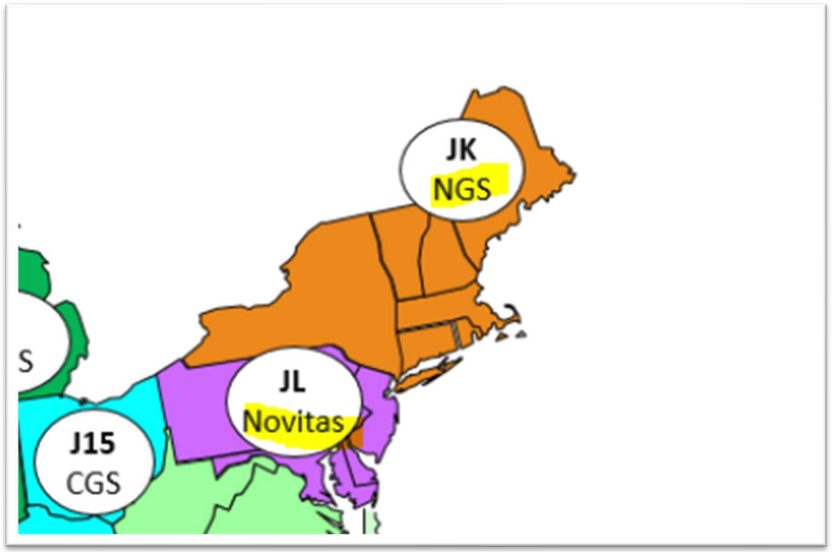
- Services not provided
- Exclusions
- Stark/Kickback violations
- Documentation issues
  - Timely and signed certs/Tx plans
  - Units of service
  - OPRA requirements
  - Qualified staff

Refunds to the MAC

- MAC refunds: For small overpayments from inadvertent billing errors, a direct refund to the MAC may suffice.
  - No formal threshold exists for the amount requiring disclosure vs. simple refund.
  - Use CMS-provided refund forms with specific “reason codes” for overpayments.
- Refunds do not protect against further investigations; MACs may refer cases to the OIG for further review.

MACs in Tristate Area for Part A and Part B Providers

- Jurisdiction K: National Government Services, Inc.
  - Includes: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont
- Jurisdiction L: Novitas Solutions, Inc.
  - Includes: Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania

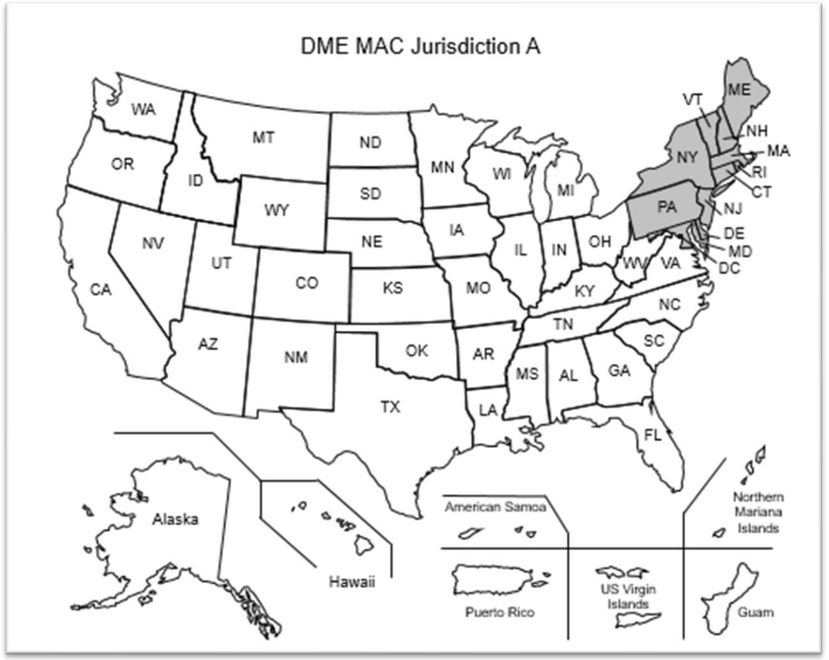


hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

MACs in Tristate Area for DME Providers

- Jurisdiction A: Noridian Healthcare Solutions, LLC
  - Includes: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont



hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

Novitas Self-Disclosures: Procedures

- Novitas on its website requires the following forms for the following situations:

Notifying Medicare of an overpayment

If you believe that an overpayment has been made, you can notify Medicare by:

- Medicare redetermination and clerical error reopening request form (Part A) (Part B):
  - Do **not** include a check when sending redetermination and clerical error reopening request form.
- Novitasphere **(Part B only)** billed in error (JH) (JL)
- Reopening Gateway (**Part B only**) billed in error
- Unsolicited return of monies form (Part A) (Part B):
  - Include a check when sending unsolicited return of monies form.
  - If refunding a high volume (100 or more) of claims, please use our Voluntary refunds spreadsheet.

Novitas Self-Disclosures: Requirements

Voluntary Disclosures

Voluntary Disclosures are voluntary refunds received in relation to internal compliance investigations. When notifying Medicare of a voluntary disclosure, answer the following questions. If any information below is missing, we will contact you.

- Why was the voluntary refund made?
- How was it identified?
- What sampling techniques were used to identify the refund?
- What steps were taken to assure that the issue leading to the overpayment was corrected?
- The date the corrective action was implemented.
- Claims information involved in the inappropriate payments.
- The methodology used to arrive at the amount of the refund.
- Was a full assessment performed to determine the entire time frame and total amount of refund for the period during which the problem existed?

Please include the following when notifying us of a voluntary disclosure. If any of the information below is missing will contact you.

- Provider name and number
- Beneficiary's Medicare Beneficiary ID Number(s)
- Claim number(s)
- Reason for overpayment
- Amount of overpayment
- Method of repayment
- Copy of the primary insurance Explanation of Benefits (Medicare Secondary Payer situations only)
- If you do or do not have a Corporate Integrity Agreement with the Office Inspector General (OIG)
- If you are or are not participating in an OIG Self-Disclosure Protocol

National Government Services Refund Process

Complete a Voluntary Refund

A voluntary refund is when you have self-identified you have been overpaid and you need to refund the excess funds to Medicare. All checks are made payable to National Government Services.

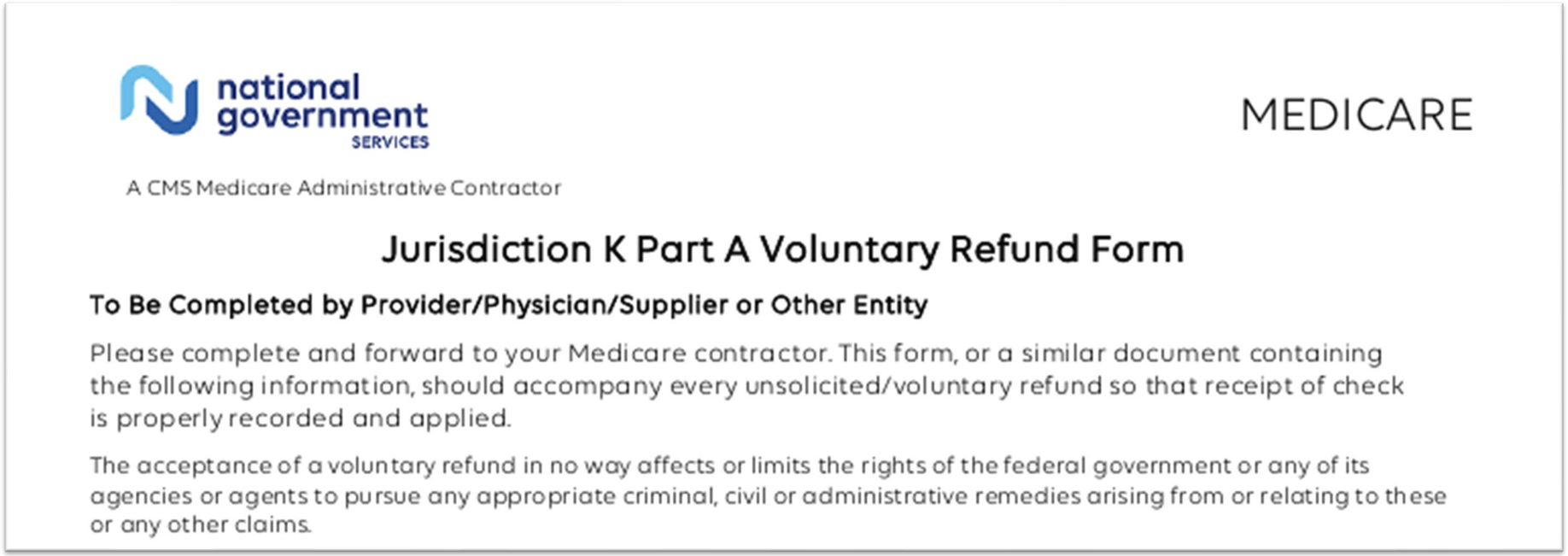
Whenever possible, the refund to Medicare should be completed through the claims system by initiating an adjustment. Customer Care should be contacted if you are unsure whether or not you are able to initiate the claim adjustment as well as if you have questions about how to adjust a claim. If initiating the adjustment is not possible, the voluntary refund form should be completed.

You have two options:

1. Submit a check with the voluntary refund form. When the claim(s) is adjusted, Medicare will apply the monies to the overpayment.
2. Submit the voluntary refund form without a check and when the claim(s) is adjusted, Medicare will take back the overpayments through the offset process.

National Government Services: Forms

- NGS requires the following form for Part A providers:



national government SERVICES

A CMS Medicare Administrative Contractor

MEDICARE

Jurisdiction K Part A Voluntary Refund Form

To Be Completed by Provider/Physician/Supplier or Other Entity

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

The acceptance of a voluntary refund in no way affects or limits the rights of the federal government or any of its agencies or agents to pursue any appropriate criminal, civil or administrative remedies arising from or relating to these or any other claims.

Noridian Disclosure Procedures

- There are two different forms:
  - Medicare Secondary Payer (MSP) Overpayment Refund Form:

DME JA Medicare Secondary Payer Overpayment Refund Form

Supplier or other entity:
This form should accompany every unsolicited/MSP Voluntary refund check. Complete and mail this form along with a check and EOB(s) to the address listed on the bottom of this form. If you have discovered an MSP clerical error or omission and do not wish to submit a check, please fill out the MSP form located at https://med.noridianmedicare.com/web/jadme/forms.

  - Non-MSP Refund Form

DME JA Non-MSP Voluntary Refund Checks Form (Check Enclosed)

Note: Do not use this form for MSP refunds.
This form should accompany every unsolicited/voluntary refund check. Complete and mail this form along with a check to the address listed on the bottom of this form. To request an adjustment without submitting a check, select the Non-MSP Overpayment Request option on the Forms page at https://med.noridianmedicare.com/web/jadme/forms.

Noridian Disclosure General Requirements

Check Number: _____ Check Date: _____

Reason for Refund (For OIG Reporting Requirements)
☐ Corporate Integrity Program ☐ OIG Self Disclosure Protocol ☐ Voluntary Refund

Required Information: Please provide the following refund information for each claim.

Claim Control Number (CCN)	Beneficiary Name	Medicare Number	Date of Service	Dollar Amount to be refunded	HCPCS Code to be refunded	Reason Code
			Total	0.00		

For additional claims please use the spreadsheet located at https://med.noridianmedicare.com/web/jadme/forms.

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.

OIG Self-Disclosure Protocol

- OIG's Health Care Fraud Self-Disclosure Protocol (SDP)
  - Allows health care providers to voluntarily identify, disclose, and resolve potential fraud.
  - Applies to health care providers and suppliers under OIG's CMP authority.
  - Must involve violations of federal criminal, civil, or administrative laws (e.g., AKS, Stark Law).
  - Does not apply for overpayments or errors without legal violations.
- Risk:
  - No guarantees on resolution; OIG may refer cases to DOJ for prosecution.

OIG Self-Disclosure Protocol (Cont.)

- Benefits of Using the SDP
  - Lower penalties compared to government-initiated investigations.
  - Potential to avoid exclusion from federal health care programs.
  - Timely resolution within 12 months, on average.
- Steps for Submitting to the SDP
  - Conduct internal investigation.
  - Provide concise, detailed disclosure, including but not limited to:
    - Federal laws violated
    - Estimated damages
    - Corrective actions taken
  - Submit online through OIG's website.

CMS Self-Referral Disclosure Protocol (SRDP)

- Allows health care providers to self-disclose potential violations of the physician self-referral law (Stark Law).
- Key Features:
  - ACA Section 6409: Established the SRDP, allowing providers to resolve violations of the physician self-referral law.
  - Disclosures suspend the 60-day overpayment refund obligation until a settlement is reached.

CMS Self-Referral Disclosure Protocol (Cont.)

CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL: CHECKLIST

CHECKLIST OF REQUIRED ITEMS FOR A COMPLETE SUBMISSION:

- ☐ SRDP Disclosure Form
  - ☐ Physician Information Form(s) (unless the disclosure qualifies for the special rule for physicians who stand in the shoes of their physician organization noted above at Section IV.A.2.c, the disclosing party must submit one Physician Information Form for each physician included in the disclosure who made referrals in violation of section 1877 of the Act)

    OR

  - ☐ The Group Practice Information Form
- ☐ Financial Analysis Worksheet, submitted in Microsoft Excel®-compatible format
- ☐ Certification

The disclosing party may also submit an optional cover letter. All the items listed above (and the optional cover letter, if included) must be submitted electronically to **1877SRDP@cms.hhs.gov**.

Obligation to update

Disclosing parties are reminded of the obligation to update the disclosure if the disclosing party files for bankruptcy, undergoes a change of ownership, or changes its designated representative. The update must be submitted electronically to **1877SRDP@cms.hhs.gov** within 30 days of the change. Include the word "UPDATE" in the subject line of the e-mail.

General Disclosure Issues

hfma
ma-ri chapter

New England Healthcare Internal Auditors Inc.

The Refund Letter

- Who is it from?
- Who is it to?
- How much detail do you provide?
- Do you ever send a “placeholder” letter?
- What do and don’t you say?

hfma
ma-ri chapter

New England Healthcare Internal Auditors Inc.

The Refund Letter (Cont.)

- “As part of our ongoing compliance process.”
- “Possible issues”
- “More appropriate” is a great phrase.
- “Level we are confident defending...”
- “Refund” vs. “overpayment”
- Beware of “our attorney has told us . . . ”
- “Steps to improve....”
- Reserve the right to recant.

A few final thoughts ....

- Compliance is a journey.
- Must be proactive.
- React and respond!
  - Thoroughness and timeliness are key!
- Document progress and activity.

hfma
ma-ri chapter

New England Healthcare Internal Auditors Inc.

Questions? Comments?

hfma
ma-ri chapter

New England Healthcare Internal Auditors Inc.

Contact Information

Robert Hussar
Of Counsel
Barclay Damon LLP
518.429.4278
rhussar@barclaydamon.com

- Memberships and Activities
  - Former Chair – NYS Bar Association Health Law Section
  - HCCA – Past Board Member, Certified in Compliance (CHC)
  - Frequent speaker/author on compliance-related topics
- Experience
  - First Deputy - NYS OMIG
  - Chief Compliance Officer - Essen Health
  - Interim Chief Compliance/Privacy Officer – Yale New Haven Health
  - Chief Compliance Officer – Northeast Health
- Focus Areas
  - Compliance program assessment and assistance
  - Internal investigations
  - OIG/CMS/OMIG/MFCU/NYS Justice Center – audit/investigation/exclusion defense, negotiation, and settlements
  - Self-disclosures
  - Board of directors, senior management, and staff training

hfma ma-ri chapter

New England Healthcare Internal Auditors Inc.