

## How Does It Really Work?

*Case Studies and Internal Reviews, Repayments and Self-Disclosure*

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## Session Objectives

- Internal review process
- Self-disclosure options
- Strategies for repayments and self disclosures
- Post disclosure – What happens next?



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## CHI Background

- Nonprofit, faith-based health system
- One of the nation's largest nonprofit health systems in 17 states with 100 hospitals, including three academic health centers and major teaching hospitals and 30 critical-access facilities; community health-services organizations; accredited nursing colleges; home-health agencies; living communities; and other facilities
- In FY2017, CHI provided more than \$1.2 billion in financial assistance and community benefit for programs and services for the poor, free clinics, education and research
- FY17 operating revenues = \$15.5 billion, assets = \$22 billion



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### Why is an Internal Review Process Important?

- Integral to support an organization’s internal controls and self-assessment/risk mitigation processes
- Key element of an effective compliance program - promotes compliance with regulations, laws, policies and procedures
- Response to hotline complaint, inquiry, audit/review finding, or identified risk
- Solid business process - fosters an ethical culture
- Provides opportunities to strengthen internal controls, policies and procedures, improve training and communication
- Provides basis for disciplinary action



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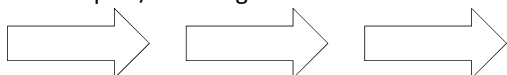
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### Internal Review Process Steps

- Issue identification
- Planning and coordination
- Fieldwork
- Reporting/resolution
- Action plan/risk mitigation



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### Issue Identification Avenues

- Risk assessment
- Data mining
- “In the News”
- Internal or hotline report/inquiry/complaint
- Exit Interview and/or disciplinary action
- Audit/review finding
- Third-party inquiry or audit notice



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### Planning and Coordination

- Determine need for privilege
- Define scope, objectives and time period to be covered (review plan)
- Identify documents to be reviewed
- Identify resources and parties involved
  - Knowledge and expertise
  - Conflicts of interest?
  - Will interviews be conducted?
  - Data requests and sampling technique
- Define notification process and timeline
- Make assignments
- Arrange update meetings/de-briefs



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### Internal Review Process

- Key decisions
  - Attorney client privilege (ACP)
  - Notifications – internal and external
    - Leadership
    - Compliance governance
    - Intermediary – heads up
  - Scope of review
  - Time period under review
  - Type of review – probe, statistical sample, etc.
  - Resources



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### Attorney Client Privilege

- Why invoke ACP?
- When do you invoke ACP?
- How do you invoke and preserve ACP?
- How do you “release” an investigation from ACP?



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### Why Invoke ACP?

- Protects legal advice not acts
- Protects discussions concerning potential compliance Issues (those that *might* have occurred)
- Allows for the free exploration of the larger picture prior to focusing on the facts
- Allows for a roadmap to be developed regarding how a particular compliance issue occurred



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### When Do You Invoke ACP?

- Known or potentially serious violations of law, regulation or policy
- Potential of material overpayment/refund
- Potential of systemic (far reaching or long term) problem
- If potential to lose focus in early analysis
- Public relations concern



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### How Do You Invoke and Preserve ACP?

- Invoke
  - Legal counsel must initiate and sustain the review – engagement letter, work product, report, etc.
- Preserve
  - Files, documents, and e-mails must be clearly marked and segregated
  - Mark correspondence “Confidential Attorney Client Privileged Communication”
  - Label storage “Privileged and Confidential: Attorney Work Product”
  - Limit discussions with those who “need to know”
  - Do not distribute ACP documents, reports, e-mails, etc.
  - Report findings with attorney present/on phone



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### How and When Do You “Release” an Investigation from ACP?

- Discuss with attorney
- Recommendation may be to keep certain aspects of investigation under ACP, while releasing other aspects
- However, once legal advice is under ACP, it’s always under ACP until ACP is breached
  - Just because an investigation has been “released” from ACP – does not mean that the issue can be freely discussed
  - As used here “release from ACP” merely means going forward non-lawyers adhere to legal advice and remain focused on issue identified while investigation was under ACP



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### Fieldwork

- Execute audit/review plan
- Obtain required documentation
- Track audit/review findings
- Adjust plan as needed based on findings
  - Additional expertise?
  - ACP?
  - Reduced/expanded scope?
  - Additional notifications/reporting needed?
- Recommendation: Complete fieldwork in less than 6 months

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### Reporting/Resolution

- Report Objectives
  - Thorough
  - Accurate
  - Objective
  - Logical
  - Concise
  - Timely (60 days)
- Reporting Format
  - Full Report/Executive Summary
  - Recommendations
- Audience
  - Senior management
  - Internal committee/subcommittee
  - Board and/or board oversight
  - External
    - o Government agency
    - o Other payors, patients, others



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### Action Plan/Risk Mitigation

- Action Plan
  - Priority/timing
  - Tracking
  - Assignment and accountability
  - Disclosure/resolution - coordination with legal, revenue cycle, etc.
  - Corrective action/discipline
- Risk Mitigation
  - Cease billing until correction made
  - Root cause analysis to close identified gaps
  - Policy/process changes
  - Education
  - Conduct follow-up reviews/audits



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### Caplan and Earnest/My Background

- Caplan and Earnest is a full-service law firm located in Boulder, CO
  - Specializes in health care, education, and litigation
  - My practice – health care fraud and abuse and regulatory compliance; Medicare reimbursement and privilege issues
- Prior to entering private practice:
  - Associate Counsel in the U.S. Department of Health and Human Services Office of Counsel to the Inspector General (OIG) Administrative and Civil Remedies Branch
    - Most relevant for today: Resolved self-disclosures submitted through the OIG's self-disclosure protocol



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### Self-Disclosure Options

Threshold question: What did your internal investigation reveal?

#### Fraud Continuum



100% Compliance (Hal)      Mistake(s)      Systemic Fraud

Depending on where your matter falls on this continuum, your "options" may not be so optional...let's discuss....



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### Best Case? Simple Overpayment

(Sure – true best case is the investigation reveals nothing or that you were even underpaid), but realistically...

*investigation reveals a simple mistake that can be repaid through fiscal intermediary/contractor, like Novitas Solutions for Medicare claims. Easiest and least expensive resolution – return the overpaid amount, 1-1.*

How do you know if you have a simple overpayment?

- Error that resulted in an overpayment (money to which “not entitled”)...aka “billed in error”
- Routine reimbursement issue
- No evidence of fraud (FCA, AKS, Stark, etc.)
- Does not rise to the level of deliberate indifference or reckless disregard, which is the standard of proof for an FCA violation




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### Considerations for Overpayment Return to a Contractor

- ACA requirement to report and return an overpayment within 60 days of identification **OR** the date any corresponding cost report is due
  - Failure to meet this obligation is ground for False Claims Act liability, and yes, DOJ is pursuing these types of cases
- When making your return, be truthful and be ready to answer questions...checking the box for “billed in error” may not cut it
  - Contractor and/or government can use this to conduct own investigation, expand the scope of liability, find other issues, question why those additional issues were not disclosed, etc.




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### Moving along the Continuum....

Not a simple overpayment. We have an overpayment that involves potential violations of the AKS, Stark Law, and/or FCA.

Now we are getting into the true self-disclosure discussion.

Purpose of self-disclosing to the government: to offer organizations reduced liability as an incentive to come clean about possible misconduct that perhaps the government would never have identified itself, and then they can fix things going forward.

- OIG Provider Self-Disclosure Protocol
- CMS Self-Referral Disclosure Protocol
- Direct referral to DOJ




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### OIG Provider Self-Disclosure Protocol (SDP)

- The SDP is available to resolve matters that in the disclosing party's reasonable assessment, "potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized."
- The disclosing party must:
  - explicitly identify the laws that were potentially violated and acknowledge there is a potential violation;
  - take corrective action and end the potential conduct at issue within 90 days of submission to the SDP;
  - perform an initial investigation and damages audit within three months of acceptance into the SDP by the OIG; and
  - submit a disclosure including all other information stipulated in the SDP.



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### Benefits of OIG SDP

1. OIG CMP and exclusion release
  - OIG has the authority to release a provider from any claims or causes of action the OIG may have against the provider under the Civil Monetary Penalties law, including release for permissive exclusion based on fraud, kickbacks, and other prohibited activities
  - Potentially no CIA
2. Potential lower multiplier
  - If you cooperate, 1.5x damages, but this is not guaranteed...
3. Quicker resolution?
  - Goal resolution within 12 months of acceptance
4. Acceptance = no ongoing investigation? (DOJ or otherwise)
5. Publicity?



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### Drawbacks for OIG SDP?

- OIG does not have the authority to release False Claims Act liability (DOJ only)
  - But practically speaking...
- OIG will not accept Stark-only matters
- OIG will not issue opinions through the SDP (Advisory Opinions)
- OIG will not guarantee entry into SDP
- Cooperation is paramount
- No promise that OIG won't ask for more information....



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### CMS Voluntary Self-Referral Disclosure Protocol

- CMS SRDP is for *Stark-only* violations
  - Also an additional expedited process for non-compliance with Stark Law requirement that physician-owned hospitals must disclose its ownership on any public website or advertisement (the "Abbreviated Protocol").
- Open to all health care providers and suppliers
- Disclosing parties must:
  - make a submission to the SRDP with the intention of resolving its overpayment liability exposure for the conduct identified; and
  - fully cooperate throughout the SRDP process, including providing documents and information requested by CMS, without CMS having to resort to compulsory methods.



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### Benefits of CMS SRDP

- Very likely the settlement amount will be drastically reduced
  - Under the SRDP, CMS may consider the following factors in reducing the amounts that may otherwise be owed by the provider:
    - the nature and extent of the improper or illegal practice;
    - the timeliness of the self-disclosure;
    - the cooperation in providing additional information related to the disclosure;
    - the litigation risk associated with the matter disclosed; and
    - the financial position of the disclosing party.
  - Will get a release under Section 1877(g)(1) of the Social Security Act
- Tolls 60-day overpayment period?



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### Drawbacks to CMS SRDP?

- Limited release
  - No FCA, AKS, CMP releases.
  - No administrative releases (exclusion)
- Lengthy resolution timeline
  - Years...SEVERAL years...
  - Improving?
- Must be Stark-only
  - If AKS potentially implicated, consider OIG SDP





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## Disclosure to DOJ?

No formal self-disclosure process...BUT it could be the right call based on your particular relationships, facts, or circumstances.

**Pro:** Buddies/married/you are the local AUSA? Good start....

**Con:** AUSA is unpredictable / is not knowledgeable about health care?

**Pro:** DOJ has the authority to release the FCA.

**Con:** Can't release administrative authorities. CIA?

**Pro:** Some rogue AUSAs don't notify CMS and OIG of resolution

**Con:** Trick question - that's bad.

**Con:** DOJ loves 2x damages...sometimes to a frustrating degree?

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## Wrapping it all up

Depending on what your internal investigation reveals, your self-disclosure options will vary.

But if you do determine a self-disclosure is appropriate:

1. Work efficiently, but quickly (60-day rule)
2. Determine what laws are potentially implicated (Stark-only)
3. Analyze appropriate route for self-disclosure (if at all????)
4. Know what releases are wanted/needed
5. Be open and honest (but focused on the issue)
6. Cooperate - be ready to answer questions
7. Be ready to wait...and sometimes wait and wait and wait...

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## Q&A

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