

**Research billing audits:  
It's (almost) all in the  
planning?**  
*A site perspective*

HCCA Research Compliance Conference, Austin, 3 June 2018

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**Disclaimer, thanks**

- I have **no financial conflict** of interest
- The **opinions** presented here are **my own** and constitute neither legal nor compliance advice; nor are they representative of Sutter Health; please consult your own compliance and/or legal departments
- Thank you for joining us on a **Sunday!**

*Karen Mottola  
3 June 2018*

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**Objectives**

Awareness or increased awareness of:

- **Preliminaries** to consider prior to any audit design and planning
- Importance of **pre-estimation** of audit results, including **risk assessment**
- Relation of **process maturity** to audit and/or process development needs

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## A little background

- In research operations and compliance, my experience is site-specific
- In conducting audits, I have always done so as a compliance officer.
- My site perspective includes agreement with the billing compliance opinions of my co-presenters
- I add to their presentation: **preliminary assessments** to support a site's audit specificities

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## General audit considerations

*Before planning any audit*

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## Which degree(s) of separation?

- Operations: **internal monitoring** (aka quality assurance (QA) and/or quality improvement (QI))
- **Compliance** department
  - Relative development of research compliance program?
  - Often: significant billing experience, ties to revenue cycle
  - Further removed than QA/QI but process design role?
- **Internal audit (IA)** department
  - How does it partner with compliance?
- **External consultants**
  - Experience across institutions, furthest removed
  - Doesn't know institution, have access

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## How will the audit fit the program?

Compliance Tool = "Element"	
1. Standards & Procedures	Implement written policies and procedures and standards of conduct
2. Oversight	Designate a compliance officer and committee
3. Training & Education	Provide regular and relevant training and education
4. Reporting	Develop communication resource for complaint/incident reporting that protects anonymity, prevents retaliation
5. Enforcement & Discipline	Enforce standards through well-publicized and utilized disciplinary guidelines
6. Auditing & Monitoring	Conduct internal monitoring and auditing
7. Investigation & Remediation	Respond promptly to detected offenses and undertaking corrective action

\* From Office of the Inspector General; see Federal Register, v63, n35 (1998)

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## Status of the elements inform audit design

- The relative strength of the **seven elements** –as well as risk assessment – **reflect the relative strength of the compliance-assurance process**
- Already have comprehensive, validated training; robust policies, oversight, enforcement?: do research staff and administrators report incidents and feel protected in doing so? ...
- The greater the integrity of the compliance program, the:
  - **readier for audit** the risk area is
  - the **greater the potential range of audit features**, including scope, mix of scheduled and for-cause, ratio of monitoring to audit

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## *In the absence of audit results, how does one know what is needed?*

- Accept:
- One doesn't know (but has some idea)
  - Compliance assurance is never 100%
  - Institutional culture is unique
  - Seek out only what you are prepared to find
  - (Try to) leave judgment out of it
- Recognition of the foregoing **pragmatic principles** maximizes compliance assurance

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The planning before the planning  
*Divining audit needs and preparing for audit results before designing the audit*

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Before initiating audit design:

- **Estimate type and degree of findings** to project optimal scope and cost of corrective action
  - Garner preliminary leadership or supervisor support to support your estimation efforts
  - Calculate, prioritize sub-risks: **topic risk assessment**
  - Identify current state as thoroughly as possible
    - *Relative maturity informs approach*
  - Determine institutional risk tolerance
- Confirm that **leadership is ready to respond** to audit results
- Gather your audit **design team**: research, rev cycle, counsel, compliance, IA, consultants?

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Weigh the relative risks applicable to the research portfolio, among them:

- Billing **patients** for services:
  - that are **not medically necessary** (are for data collection purposes only)
  - **promised** by the sponsor contract or the consent form (regardless of medical necessity)
- Billing **federally insured patients** for services:
  - without appending the requisite claims modifications
  - provided free-of-charge to non-federally insured patients
- Billing appropriately for **non-protocol-specified**, study-related services (care related to adverse events)
- **Failing to bill the sponsor** for services for which the sponsor was responsible to provide
- Billing the study for services that were **billable to insurance**

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## Process maturation informs mix of audit and process development

Match your audit plans to current state

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### Assess the current state

Degrees of process maturation	Assessment
QA/QI provides a continual feedback loop that confirms our process works	<b>Wow!</b>
We've established a front-to-back-end compliance assurance process	<b>QA, please</b>
Our front-end process includes document concordance; what else beside bill review would back-end need?	<b>Test the front; explore, meet end needs</b>
Every study is analyzed for billing needs and we use the analysis to review bills	<b>Focus on process development</b>
The rules are known, applied to identified research, but unsure we capture all	<b>Process &amp; communication!!!</b>
We have an inkling about Q's; what is charge segregation again?	<b>Long, deep breaths; begin where you are</b>

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### Matching current state and audit

Audit to meet degree of maturation	
<i>Compliance or internal audit (IA) develops a periodic scheduled audit plan, external to ops, for assurance</i>	<input type="radio"/>
<i>Compliance/IA conducts a broad audit; operations institutes internal monitoring</i>	<input type="radio"/>
<i>Audit the front end; deliberate for back-end process development prior to audit</i>	<input type="radio"/>
<i>Deliberate for comprehensive process development, expand leadership champions; targeted audit?*</i>	<input type="radio"/>
<i>Identify research and billing champions; conduct billing reqs research, initiate process design*</i>	<input type="radio"/>
<i>Consult experts; consider bill hold; assess importance of research to institution; commence process design</i>	<input type="radio"/>

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## Contact

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