

Research billing audits: It's (almost) all in the planning?

A site perspective

HCCA Research Compliance Conference, Austin, 3 June 2018

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

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

Karen Mottola, MA, CHRC, CPC, CCRC

Research Compliance Officer
Ethics and Compliance Services
Sutter Health

mottolk@sutterhealth.org

415-385-5916



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