



HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

APRIL 13-16, 2008 | NEW ORLEANS, LA | HILTON RIVERSIDE NEW ORLEANS

Enforcement of Research Compliance From the Stark and CCA Perspectives

Kimberly Zajczenko, Executive Director, Corporate Compliance, Rush
University Medical Center

Janis Anfossi, JD, MPH, RN, Associate General Counsel, Rush University
Medical Center



www.hcca-info.org | 888-580-8373



Objectives

- How to audit & monitor research compliance under a CCA
- What it's like to prepare an annual CCA report
- Implementing Stark compliance into clinical research trials



www.hcca-info.org | 888-580-8373

2

What is a CCA?

- CCA = Certification of Compliance Agreement
- Negotiated between the OIG and the provider as part of a settlement of a Federal health care program investigation
- In lieu of a comprehensive Corporate Integrity Agreement (CIA)



www.hcca-info.org | 888-580-8373

3

Main Elements of a CCA

- Provider is required to maintain its existing compliance program
- Provider must make annual reports to the OIG regarding its compliance program activities during the term of the CCA, which include:
 - Reporting overpayments
 - Reportable events
 - Ongoing investigations and legal proceedings



www.hcca-info.org | 888-580-8373

4

Key CCA Elements Related to Research Billing

- Policies & procedures
- Education & training
- Auditing & monitoring



www.hcca-info.org | 888-580-8373

5

Policies & Procedures

- Developed 2 policies related to research billing:
 - Device trials
 - Non-device trials



www.hcca-info.org | 888-580-8373

6

Education & Training

- Developed an annual education & training program specific to research billing
- Research billing education is in addition to annual compliance & HIPAA training
- Research billing education includes:
 - The federal requirements for billing services associated with clinical trials and the impact of improper billing
 - RUMC's coverage analysis process
 - RUMC's research billing policies and process



www.hcca-info.org | 888-580-8373

7

Auditing & Monitoring

- RUMC's research billing audit process consists of 2 parts:
 - Auditing the coverage analysis process
 - Auditing the accuracy of research billing



www.hcca-info.org | 888-580-8373

8

Auditing the Coverage Analysis Process

- Coverage Analysis = a “billing plan” for each clinical trial, outlining the services required by the trial’s protocol the billing status for each required service
- Audit objective = assess the accuracy of the coverage analysis
- Audit scope & techniques
 - Sampling by coverage analyst
 - Shadowing technique
 - Random or judgmental sampling



www.hcca-info.org | 888-580-8373

9

Auditing the Accuracy of Research Billing

- Audit Objective: to assess the accuracy of the clinicians’ interpretation and implementation of the coverage analysis
- Audit scope & techniques
 - Sampling each principal investigator
 - Sampling by clinical section/department



www.hcca-info.org | 888-580-8373

10

Tips For Preparing an Annual CCA Report

- Don't procrastinate
- Outline needs & expectations at the beginning of each reporting period
- Get quarterly progress reports/updates
- Verify that processes are occurring as intended
- Put the report together as the year goes on
- Anticipate what the OIG might ask questions about, get the answers and put them in the report



www.hcca-info.org | 888-580-8373

11

“In Compliance with all other Federal laws...”



www.hcca-info.org | 888-580-8373

12

- DISCLOSURES:
 - Errors
 - Deficiencies
 - Violations

- REPORTED TO:
 - OIG
 - DOJ



www.hcca-info.org | 888-580-8373

13

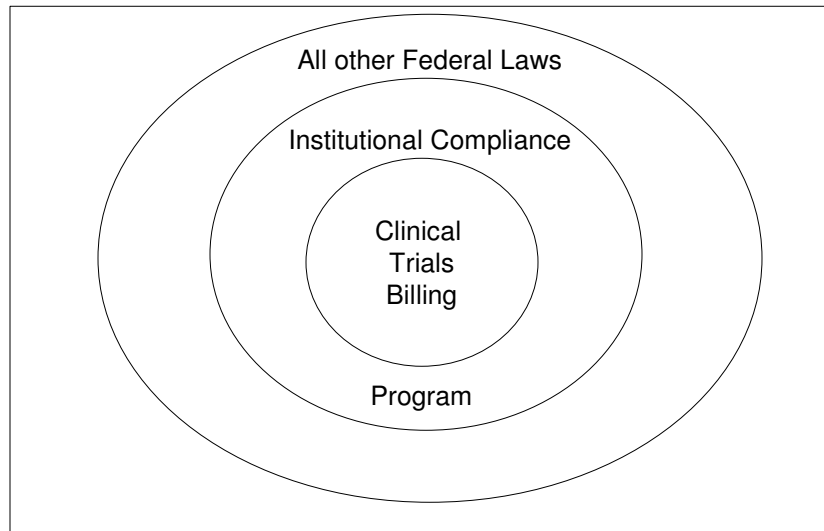
- RESULTS IN:
 - Settlement
 - C.I.A.
 - C.C.A.



www.hcca-info.org | 888-580-8373

14

Elements Required and Addressed in Agreement



www.hcca-info.org | 888-580-8373

15

All Other Laws =

- Stark III (Physician Self-Referral)
- Anti-Kickback Statute (AKS)
- Tax Exemption –
 - charitable purpose
 - bond compliance



www.hcca-info.org | 888-580-8373

16

Stark III

- Preparedness assessment
- Implementation plan
- Monitoring plan



www.hcca-info.org | 888-580-8373

17

Stark Review

- Contracts:
 - Call for Contracts/written agreements
 - Review of Arrangements/Transactions – unwritten or never reviewed
 - Contract Review Policy/process
 - Contract Database
 - Legal sufficiency analysis/reformation
- Leases:
 - leases/subleases/timeshares
 - equipment/administrative services
- NonMonetary Compensation - tracking



www.hcca-info.org | 888-580-8373

18

Stark & Clinical Trials Billing

- Key principles =
 - Follow the money
 - Follow the payments
 - Follow the relationships



www.hcca-info.org | 888-580-8373

19

Scenario 1

Sponsor ↔ RUMC
P.I. is private practice (Faculty)

Risk

Private MD signs
Private Group signs

? who signs

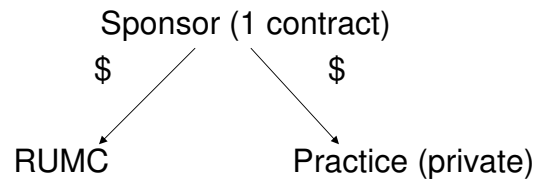
? how does the money flow



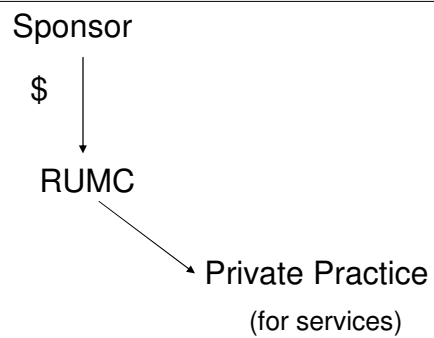
www.hcca-info.org | 888-580-8373

20

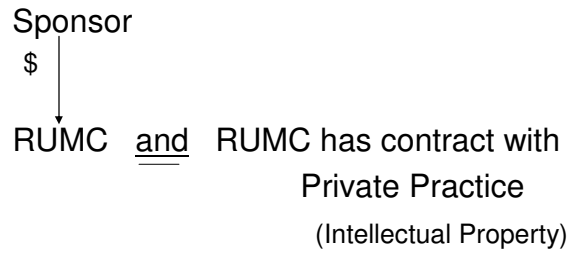
Scenario 2



Scenario 3



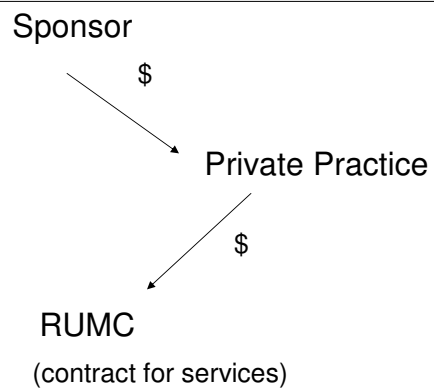
Scenario 4



www.hcca-info.org | 888-580-8373

23

Scenario 5



www.hcca-info.org | 888-580-8373

24

Questions



www.hcca-info.org | 888-580-8373

25