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

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
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)

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
Key CCA Elements Related to Research Billing

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

Policies & Procedures

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

Auditing & Monitoring

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

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
**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

“In Compliance with all other Federal laws…”
• DISCLOSURES:
  - Errors
  - Deficiencies
  - Violations

• REPORTED TO:
  - OIG
  - DOJ

• RESULTS IN:
  - Settlement
  - C.I.A.
  - C.C.A.
Elements Required and Addressed in Agreement

All other Federal Laws

Institutional Compliance

Clinical Trials Billing

Program

All Other Laws =

• Stark III (Physician Self-Referral)

• Anti-Kickback Statute (AKS)

• Tax Exemption –
  - charitable purpose
  - bond compliance
Stark III

- Preparedness assessment
- Implementation plan
- Monitoring plan

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
Stark & Clinical Trials Billing

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

Scenario 1

Sponsor ←→ RUMC
P.I. is private practice (Faculty)

Risk

Private MD signs
Private Group signs

? who signs  ? how does the money flow
Scenario 2

Sponsor (1 contract)

$    $  

RUMC    Practice (private)

Scenario 3

Sponsor

$  

RUMC

Private Practice  
(for services)
Scenario 4

Sponsor
$
RUMC \text{ and } RUMC \text{ has contract with }
Private Practice
(\text{Intellectual Property})

Scenario 5

Sponsor
$
Private Practice
$
RUMC
(\text{contract for services})
Questions