

# Navigating the Regulatory Landmines

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## Overview

- ◆ Prohibitions against discrimination
  - Americans with Disabilities Act
  - Age discrimination
- ◆ CMS regulatory requirements: facilities
  - CMS Interpretive Guidelines
    - Hospitals
    - ASCs

## Overview

- ◆ CMS payment issues
  - Recovery audit contractors
- ◆ Patient privacy
  - HIPAA & HITECH breach notification
- ◆ Payment & compensation
  - Gainsharing & quality incentives

## Focus of Presentation



## Overview

- ◆ Many other "landmines" beyond scope of this presentation
  - Antitrust
  - Kickbacks (demands from facilities)
  - HIPAA basics
  - Red flags rule

Discrimination



## **Bans on Discrimination**

- ◆ **In dealing with employees - whether senior or junior**
  - Must consider potential for the faculty member to claim illegal discrimination
- ◆ **Federal law bars discrimination on many grounds**
  - Race, color, religion, sex, national origin, disability, genetic information, or age

## **Bans on Discrimination**

- ◆ **All actions covered:**
  - Hiring & firing
  - Compensation, assignment, & leave
  - Transfer, promotion, layoff, or recall
  - Recruitment
  - Training
  - Fringe benefits
  - Other terms & conditions

## **Americans w/Disabilities Act**

- ◆ **Prohibits discrimination on basis of disability in employment**
- ◆ **Protects “*qualified individuals with disabilities*” -**
  - Physical or mental impairment that substantially limits one or more major life activities
  - Record of such an impairment, or
  - Is regarded as having such an impairment

## **Age Discrimination**

- ◆ **ADEA protects individuals who are 40 years of age or older from employment discrimination based on age**
  - ADEA permits employers to favor older workers based on age even when doing so adversely affects a younger worker who is 40 or older

## **Age Discrimination**

- ◆ **Are actions to deal with increasingly incompetent anesthesiologist**
  - Based upon a documented record of inability to perform, or
  - Seemingly sudden decision to terminate
    - Without documentation
    - Without fair process

**CMS  
Interpretive  
Guidelines**



## CMS Interpretive Guidelines

- ◆ Clarify conditions of participation (for facilities) in Medicare program
- ◆ New IGs issued in December 2009
  - Hospitals (updated in May 2010)
  - ASCs
- ◆ Updated provisions regarding Anesthesia Services

## CMS IGs: Hospitals

- ◆ Supervision & immediate availability
  - In discussing supervision of CRNAs/AAs:
    - » Hospitals must establish policies for supervision
      - An anesthesiologist is considered “immediately available” only if he/she is physically located within the same area as the CRNA or AA

## CMS IGs: Hospitals

- ◆ CMS on “same area” – *e.g.*
  - In the same operative/procedural suite, or
  - In the same L&D suite, **AND**
- ◆ “Not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed”

## CMS IGs: Hospitals

- ◆ Preanesthesia evaluation
  - Within 48 hrs prior to any inpatient or outpatient surgery/procedure
  - Six elements listed – similar to ASA stds
    1. Review medical history
    2. Interview, examine patient
    3. Note anesthesia risk
    4. I.D. potential anesthesia problems
    5. Additional evaluation as needed
    6. Develop plan of care

## CMS IGs: Hospitals

- ◆ Postanesthesia evaluation
  - Within 48 hrs after surgery/procedure
  - Seven elements listed
    1. Respiratory function
    2. CV function
    3. Mental status
    4. Temperature
    5. Pain
    6. N&V
    7. Postop hydration

Originally, IGs req'd completion prior to discharge of outpatients; this req't deleted in May 2010 update

## CMS IGs: Hospitals

- ◆ Timing of postanesthesia evaluation
  - Except when postop sedation is required:
    - » “The evaluation generally would not be performed immediately at the point of movement” from the OR to the PACU
  - Can occur in the PACU

## **CMS IGs: ASCs**

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- ◆ **Similar requirements on**
    - **Supervision & immediate availability**
      - ▶ Physically present in the ASC and
      - ▶ “Prepared to immediately conduct hands-on intervention if needed”
    - **Pre- anesthesia evaluation**
      - ▶ Is ASC an appropriate setting, given risks associated w/ anesthesia
    - **Post- anesthesia evaluation pre- discharge**
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## **IGs on Patient Selection**

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- ◆ **From CMS Interpretive Guidelines for ASCs (revised Dec. 2009):**
    - (After noting that ASCs should consider whether to accept ASA IV pts . . . )
    - “For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.”
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## **CMS Interpretive Guidelines**

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- ◆ **Implications of the IGs for *billing* uncertain**
    - They do, however, reflect CMS thinking
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## **Recovery Audit Contractors**

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- ◆ **Recovery audit contractors (RACs)**
    - **Paid on a contingency fee basis to identify & recoup Medicare overpayments**
      - ▶ RACs collect money from providers (that's you)
      - ▶ Also identify underpayments
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## **Recovery Audit Contractors**

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- ◆ **Started with a demonstration program (Medicare Modernization Act of 2003)**
    - **In CA, FL, & NY (the 3 states w/ highest Medicare expenditure):**
      - ▶ Collected > \$1.03 billion in improper payments
      - ▶ Cost (est.): \$0.20 for each \$1 returned to Medicare Trust Fund
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## **Recovery Audit Contractors**

- ◆ **Tax Relief and Health Care Act of 2006** made RAC program permanent
  - Requires expansion of RAC program to all 50 states by 2010
- ◆ **Authority to pay RACs on a contingency fee basis**
  - From 9% - 12.5%

## **RAC Review Process**

- ◆ **Post payment review**
  - Use FI, carrier, MAC Medicare policies (NCDs, LCDs & CMS manuals)
- ◆ **Two types of review:**
  - Automated (no medical record)
    - Certainty service incorrectly coded or not covered
  - Complex (medical record required)

## **RAC Review Process**

- ◆ **RACs can go back 3 yrs from date claim paid**
  - Cannot review claims paid prior to October 1, 2007
- ◆ **CMS approves issues for review prior to widespread RAC review**
- ◆ **Approved issues are posted to RAC websites**

## **RAC Collection Process**

- ◆ **RAC issues a demand letter**
- ◆ **Medicare (via the MAC) recoups by offset unless provider has**
  - Submitted a check, or
  - Submitted a valid (& timely) appeal
    - Must file within 30 days of receipt of the overpayment letter to stop recoupment

## **Preparing for RACs**

- ◆ **Internal review of compliance**
- ◆ **Review RAC websites for areas of persistent improper payments**
  - Also review OIG reports
- ◆ **Implement procedures to respond promptly to RAC requests for medical records**
  - Make sure RAC has correct address

## **Preparing for RACs**

- ◆ **Keep track of denied claims**
  - Correct these previous errors
- ◆ **Determine corrective actions needed to ensure compliance & avoid submitting incorrect claims**
- ◆ **Bottom line: RAC program produces huge returns - compliance more important than ever**

## HIPAA, HITECH, Breach Notification



## HIPAA & HITECH

- ◆ In past, HIPAA privacy & security enforcement largely focused on obtaining voluntary compliance
  - Through technical assistance
- ◆ HITECH Act (Health Information Technology for Economic and Clinical Health Act)
  - Major changes

## HITECH Privacy & Security

- ◆ Establishes **mandatory breach reporting** for covered entities & their business associates (BAs)
- ◆ Applies most HIPAA privacy & security rules directly to BAs
- ◆ Creates new HIPAA privacy requirements
- ◆ Establishes new civil & criminal penalties for noncompliance
- ◆ Expands enforcement authority to states

## HITECH Breach Notification

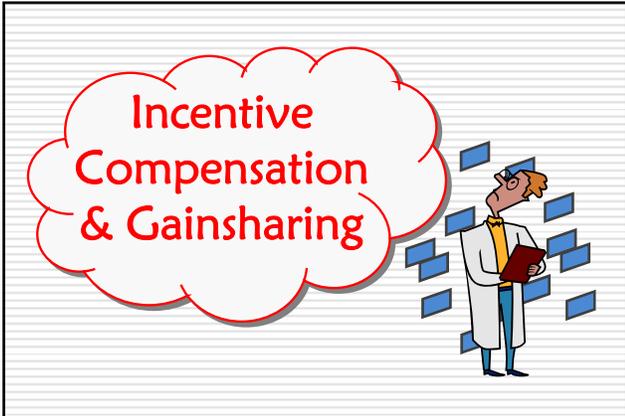
- ◆ Mandates covered entities & BAs to notify affected individuals, HHS, & media outlets
  - If unsecured PHI is accessed, acquired, or disclosed by or to an unauthorized person
- ◆ Must notify the media if more than 500 individuals of a particular state are affected

## HITECH Breach Notification

- ◆ More important than ever to identify where PHI (protected health information) is maintained
  - Do your Dep't members have PHI on
    - Handheld devices?
    - Thumb drives?
    - PCs?

## HITECH Compliance

- ◆ To limit exposure
  - Limit the types of PHI faculty members may download
  - Require encryption of all devices
    - Encryption per HHS/NIST standards
  - Retrain staff on HIPAA & HITECH requirements



### Gainsharing & Quality Incentives

- ◆ Continued talk of performance-based compensation
  - Including incentive compensation and gainsharing
- ◆ Need to be sensitive to regulation of how these arrangements are structured
  - CMS proposed rule (2008) on incentive compensation not finalized

### Gainsharing Defined

**An arrangement under which a hospital gives physicians a share of the reduction of the hospital's cost savings attributable in part to the physicians' efforts**

### Concerns

- ◆ CMS & OIG have expressed deep concern
  - Potential for gainsharing & incentive payment program to have **adverse effect on patient care**

### Concerns

- ◆ May be hard to define the line between
  - A gainsharing or incentive compensation payment, versus
  - A payment to induce a physician to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries

Reduce budget deficits

Reduce turnover time

Reduce ALOS in PACU

### OIG & CMS Views

- ◆ OIG has issued advisory opinions providing guidance on how to structure arrangements
- ◆ In three 2008 rules, CMS addressed concerns with gainsharing & incentive-based compensation
  - CMS issued very detailed proposed rule on the topic - not yet finalized

## **Incentive- Based Compensation**

- ◆ **Given very clear OIG and CMS regulatory concerns with gainsharing and incentive- based compensation**
- **Take OIG and CMS guidance into account in structuring any programs**
  - ▶ **Proper protections to ensure no adverse effect on patient care**
  - ▶ **Notice to patients**

## **Conclusion**

- ◆ **As businesses, your Dep'ts must comply with many federal regulations**
- ◆ **In addition, many different federal agencies regulate health care**
- ◆ **With technological advances, even more need to protect against abuse**
- ◆ **Regulation of health care is inevitable**
- **And is likely to increase**