

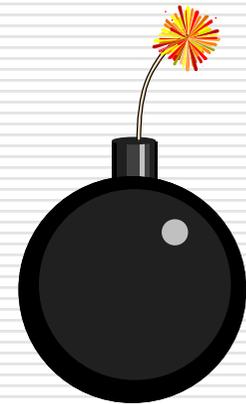
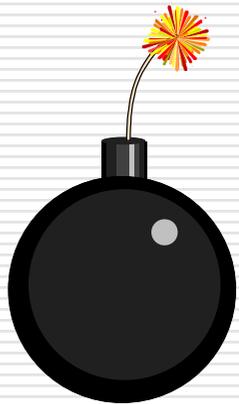
Navigating the Regulatory Landmines

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Disclosures

- ◆ **In private law practice**
 - **Advise clients on potential liability issues**
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Overview

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

- ◆ **CMS payment issues**

 - **Recovery audit contractors**

- ◆ **Patient privacy**

 - **HIPAA & HITECH breach notification**

- ◆ **Payment & compensation**

 - **Gainsharing & quality incentives**

 - **PQRS**

Focus of Presentation

CMS

OCR

OIG

EEOC

IRS

State
Agencies



Overview

- ◆ Many other “landmines” beyond scope of this presentation
 - Anesthesia billing compliance
 - Antitrust
 - Kickbacks (demands from facilities)
 - HIPAA basics
 - Labor/unionization
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Discrimination



Bans on Discrimination

- ◆ In dealing with employees whether senior or junior
 - Race**
 - Sex**
 - Disability**
 - Must consider potential for the faculty member to claim discrimination
 - ◆ Federal law bars discrimination on many grounds
 - Color**
 - Nat'l Origin**
 - Age**
 - Religion**
 - Genetic Info**
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Bans on Discrimination

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

- ◆ Weaker member of Dep' t
 - Clinically not as strong
 - ▶ Reassignment?
 - ▶ Termination?
 - ▶ How has Dept dealt w/others?
 - ◆ Attending w/behavioral issues
 - ◆ Off-color jokes in the OR
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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
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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
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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
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CMS Interpretive Guidelines



CMS Interpretive Guidelines

- ◆ **Clarify conditions of participation (for facilities) in Medicare program**
 - ◆ **New IGs issued in December 2009**
 - ➔ **Hospitals (updated in 2011)**
 - ➔ **ASCs (updated in 2011)**
 - ◆ **Updated provisions regarding Anesthesia Services**
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CMS IGs: Hospitals (2009-2010)

- ◆ **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 (2009-2010)

- ◆ 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”
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CMS Interpretive Guidelines - Anesthesia Services (2011)

◆ 2011 IGs:

- All discussion of what constitutes “immediate availability” has been deleted**
 - Regulation identifies supervision
 - ▶ Up to each Hospital to implement
 - In practical terms, what constitutes immediate availability******
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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
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Preanesthesia Evaluation

◆ Scenario:

- Patient has had EKG 1 month ago
- Comes into PAT
- Seen by RN - medical history taken
- Comes in one week later for surgery
- Anesthesiologist reviews medical history

◆ Any issues?

CMS Interpretive Guidelines – Preanesthesia Evaluation

◆ Loosening of time frame for preanesthesia evaluation

→ *“Some individual elements contributing to the pre-anesthesia evaluation may be performed prior to the 48-hour timeframe.”*

→ *These elements cannot be performed > 30 days prior to surgery or a procedure requiring anesthesia services.”*

CMS Interpretive Guidelines – Preanesthesia Evaluation

- ◆ *Must review any elements performed prior to 48-hour timeframe*
 - ◆ *Must document any appropriate updates documented*
 - ➔ *Within the 48-hour timeframe*
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Postanesthesia Evaluation

◆ Scenario

- Patient undergoes relatively minor procedure
- Transferred to PACU; no complications
- PACU staff assesses patient per protocol developed by Anesthesiology
- Patient discharged

◆ Any issues?

CMS Interpretive Guidelines - Postanesthesia Evaluation

- ◆ A postanesthesia evaluation must be completed & documented no later than 48 hours after surgery or a procedure requiring anesthesia services.
 - By any practitioner who administered anesthesia.
 - *“This need not be the practitioner who administered the anesthesia to the patient.”*
- Not
PACU nurse**

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

Postanesthesia Evaluation

- ◆ Patient undergoes minor procedure
 - ◆ Patient slightly groggy upon transfer to PACU, but seemingly doing well
 - ◆ Anesthesiologist knows he/she must assess & next case will be prolonged
 - ◆ Performs postanesthesia evaluation before leaving PACU
 - Any issues?
-

CMS Interpretive Guidelines - Postanesthesia Evaluation

- ◆ Calculation of 48-hour timeframe begins at point patient is moved into the designated recovery area
 - ◆ *The evaluation generally should not be performed immediately at the point of movement from the operative area to the designated recovery area.*
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CMS Interpretive Guidelines - Postanesthesia Evaluation

- ◆ **Accepted standards of anesthesia care indicate that the evaluation should not begin until the patient is sufficiently recovered from anesthesia so as to participate in the evaluation, *e.g.***
 - ➔ **Answer questions appropriately**
 - ➔ **Perform simple tasks**
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CMS Interpretive Guidelines - Postanesthesia Evaluation

- ◆ **Does your postanesthesia evaluation document all seven elements?**
 - ◆ **Must be completed by “individual qualified to administer anesthesia”**
 - ➔ **Not by PACU nurse**
 - ◆ **ASA has documentation templates to assist anesthesiologists in complying with the IGs**
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CMS IGS: ASCs

- ◆ **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: Patient Selection in ASCs

- ◆ **From CMS Interpretive Guidelines for ASCs:**
 - ➔ (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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**Recovery
Audit
Contractors
(& others)**



Recovery Audit Contractors

◆ 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



RAC

Your Dep't

Recovery Audit Contractors

- ◆ Started with a demonstration program (Medicare Modernization Act of 2003)
 - ◆ Tax Relief and Health Care Act of 2006 made RAC program permanent
 - Expansion of RAC program to all 50 states by 2010
 - ◆ RACs paid on a contingency fee basis
 - From 9% - 12.5%
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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
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“Anesthesia Care Package”

- ◆ Anesthesiologist performs post-op pain procedure
 - In addition to anesthesia for primary procedure (*e.g.*, orthopedic)
 - ◆ Rounds on patient to follow up
 - Day after the procedure
 - Charges E&M code for location/level of service
 - ◆ Any issues?
-

“Anesthesia Care Package”

◆ HDI (RAC- Region D*) – Jan. 2010

→ “Anesthesia care package”

▶ Attempted automated review to recoup payments where anesthesia & E&M codes reported w/in specified date range

▶ Did not identify circumstances where E&M an appropriate service

■ *E.g.*, post-op pain follow up

◆ Successful ASA intervention to stop

* AK, AZ, CA, HI, IA, ID, KS, MO, MT, ND, NE, NV, OR, SD, UT, WA, WY

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
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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
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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**
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Others Reviewing Claims

- ◆ **MACs – Medicare Administrative Contractors**
 - ◆ **ZPICs – Zone Program Integrity Contractors**
 - Conduct investigations
 - Support law enforcement
 - Some to focus on Medicare billing "hot" targets
 - ◆ **MICs – Medicaid Integrity Contractors**
 - ◆ **Private payor audits, as well**
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**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
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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
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HIPAA & Data Breaches

◆ Scenario:

- Dep' t sends next day' s schedule via e-mail
 - ▶ Identifies patient & surgeon
 - Someone loses smart phone w/e-mail
 - Issues?
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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
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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?
 - Smart phones?
 - ▶▶ Thumb drives?
 - ▶▶ PCs?
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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
 - ▶ Particularly minimum necessary req' t
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Incentive Compensation & Gainsharing



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**
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Concerns

**Reduce
anesthesia
budget
deficits**

**Reduce
ALOS
in
PACU**

**Reduce
turnover
time**

to define the l
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beneficiarie
services
Medicaid

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**
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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**
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PQRS



PQRS

◆ Physician Quality Reporting System

→ No longer an initiative

◆ Money available:

→ 2011 1.0%

→ 2012-2014 0.5%

→ 2015 -1.5%

→ 2016 on -2.0%

PQRS: Anesthesiology Msrs

- ◆ #30, Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics
 - ◆ #76, Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol
 - ◆ #193, Perioperative Temperature Management (Normothermia)
-

PQRS

◆ In 2011

→ **Threshold to qualify for bonus dropped**

▶ **From valid PQRS Quality Data Codes (QDCs) submitted for 80% of eligible cases**

▶ **To 50% of QDCs**

Conclusion

- ◆ As businesses, your Dep'ts must
Appreciation of risks any federal regulations by different federal agencies regulate
 - ◆ With technological
Documentation need to protect against abuse
 - ◆ Regulation of health care is inevitable
→ And is likely to increase
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