



## Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices

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University of Southern California

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### USC Health System

- 1,300 faculty physicians and scientists
- Three USC-owned private hospitals
- 9,000 patients enrolled in clinical trials and more than \$300M in research funding
- 900 medical residents – one of the largest residency programs in the U.S.
- 200 fellows and interns
- 670 medical students, 292 Ph.D. students, 300 master's students



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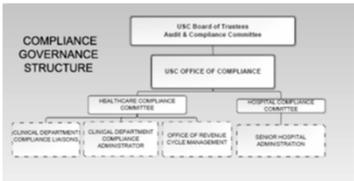
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### Compliance Governance Structure



The Keck Medicine of USC Compliance Program develops and maintains hospital and clinical compliance programs for:

- Keck Hospital of USC
- USC Norris Cancer Hospital
- USC Eye Institute – Keck Medical Center of USC in Ophthalmology
- USC Verdugo Hills Hospital
- USC Care Medical Group
- USC School of Dentistry
- USC School of Pharmacy

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## Key Issues in Academic Medical Centers

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### Key Initiative: Overlapping Surgery



**Clash in the Name of Care**

When key or critical elements of the first operation have been completed and attending surgeon is performing key or critical components of a second operation in another room.



**United States Senate**

February 17, 2016

VIA ELECTRONIC TRANSMISSION

David F. Tomlinson, MD  
President and Chief Executive Officer  
Partners Healthcare, 600 North Dearborn Street, Suite 1100  
Chicago, IL 60610-3000

Dear Dr. Tomlinson:

Recent news reports have revealed that physicians at some hospitals that participate in federal health care programs are engaging in concurrent surgery. Such behavior can compromise patient safety, compromise quality of care, and create other problems by affecting operating rooms at the same time.

Overlapping Surgery



**AAMC**

National call of Academic Medical Centers led by USC/Massachusetts General Hospital

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### Key Initiative: Overlapping Surgery




**American College of Surgeons Recommendations**

- Intraoperative Responsibility of the Primary Surgeon
- Definition of Backup Surgeon
- Definition of "Immediately Available"
- Communication to Patients
- Pre-incision Timeout, Name of Backup Surgeon
- Documentation & Coding Guidelines

**Senate Finance Committee Concluding Concerns**

- Patient Safety
- Improper Payment

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**What is Overlapping/Concurrent Surgery?**

- Concurrent Surgery:
  - When critical or key components of surgeries occur all or in part at the same time.
- Overlapping surgery:
  - When key or critical elements of the first operation have been completed and attending surgeon is performing key or critical components of a second operation in another room.
  - A surgeon cannot have a third case started until the first case is completed in its entirety
    - **"OPEN TO CLOSE"**

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**Overlapping/Concurrent Surgery**

- A December 2015 Boston Globe "Spotlight" article focused on concurrent surgery practice at Massachusetts General Hospital
- Topic came to the attention of the American College of Surgeons (ACS), the Association of American Medical Colleges (AAMC) as well as the US Senate Finance Committee
- Nationwide focus on the practice of overlapping/concurrent surgery and its impact on patient safety during the perioperative process
- Keck Medical Center of USC created a workgroup to study the issue

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**Policy Highlights**

- Intraoperative Responsibility of the Primary Surgeon\*
  - Primary attending surgeon personally responsible for the patient's welfare during entire operation
  - Generally, the primary attending surgeon should be immediately available
  - When primary attending surgeon not present or immediately available, another qualified surgeon should be assigned to the patient (backup)

\* Corresponds to ACS Guidelines

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<p><b>Policy Highlights</b></p> <ul style="list-style-type: none"> <li>• Definition of backup surgeon*             <ul style="list-style-type: none"> <li>• Attending surgeon credentialed in the same surgical specialty</li> <li>• Surgeon credentialed in the same surgical specialty and holds a Category A independent privilege</li> </ul> </li> <li>• Definition of "Immediately Available"             <ul style="list-style-type: none"> <li>• Able to return to the OR immediately</li> <li>• Reachable through a paging system or other electronic means</li> <li>• Not involved in anything that cannot be interrupted</li> <li>• Keck Hospital                 <ul style="list-style-type: none"> <li>• Within the hospital and HCC 1-4 and Norris Cancer Hospital</li> </ul> </li> <li>• Norris Cancer Hospital                 <ul style="list-style-type: none"> <li>• Within the hospital and HCC1-4 and Keck Hospital</li> </ul> </li> </ul> </li> </ul> <p>* Corresponds to ACS Guidelines</p> <p>Keck Medicine of USC</p>
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<p><b>Policy Highlights</b></p> <ul style="list-style-type: none"> <li>• Documentation &amp; Billing Guidelines:             <ul style="list-style-type: none"> <li>• Primary attending surgeon must personally document on each overlapping case, "I was present for the key and critical portions of the case"</li> <li>• If Fellow/Resident/NPP documenting the case, the attending must personally addend the record to note their presence during key/critical of overlapping procedures.</li> <li>• 3 overlapping or concurrent cases considered a supervisory service by the teaching physician                 <ul style="list-style-type: none"> <li>• Cannot bill 3 overlapping cases</li> </ul> </li> </ul> </li> </ul> <p>Keck Medicine of USC</p>
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<p><b>Importance of Documentation</b></p> <p>Focused Review of Overlapping records-</p> <ul style="list-style-type: none"> <li>• OR Schedule of overlapping cases</li> <li>• OR record in Powerchart shows IN/OUT times of attending</li> <li>• Notes for overlapping procedures             <ul style="list-style-type: none"> <li>• Did the attending personally document their presence during key/critical</li> <li>• If missing, the assumption is the attending is present for entire case, which conflicts with OR records</li> </ul> </li> </ul> <p>Conflicting documentation may not support billing</p> <p>Keck Medicine of USC</p>
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<h2>Clinical Trials Research Billing at USC</h2>


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<b>Overview</b>
<ul style="list-style-type: none"><li>• Compliant clinical trial billing requires<ul style="list-style-type: none"><li>• Substantive knowledge of complex coverage and coding rules</li><li>• Coordination across USC providers and functions</li></ul></li><li>• USC policies, procedures and processes are designed to ensure actions are consistent with coverage rules<ul style="list-style-type: none"><li>• Critical to avoid potential liability</li></ul></li></ul>


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<b>Clinical Trial Billing Challenges:</b>
<b>Complexity</b>
<ul style="list-style-type: none"><li>• Compliant billing for even routine medical care presents ongoing challenges for healthcare providers</li><li>• Clinical trial billing adds complexity and increases the challenge<ul style="list-style-type: none"><li>• Coverage and coding</li></ul></li><li>• No consistency among third party payors on clinical trial coverage<ul style="list-style-type: none"><li>• Medicare coverage principles may influence private health insurance</li><li>• New federal clinical trial coverage mandate applies to private health insurance but has limited applicability</li></ul></li><li>• Multiple coverage rules therefore apply to a clinical trial if subjects will be covered by multiple third party payors</li></ul>


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**Clinical Trial Billing Challenges:  
Coordination**

- Compliant billing requires coordination by multiple individuals, departments and entities
  - Research team
  - Other treating practitioners and providers
  - Patient registration
  - Finance
  - USC Clinical Research Organization
- Compliant billing requires coordination throughout clinical trial
  - Clinical trial agreement negotiation/budgeting
  - Subject enrollment/informed consent
  - Patient registration/scheduling
  - Clinical services ordering
  - Billing for services

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**Clinical Trial Billing Challenges:  
Coordination**

- Research team contribution is critical to compliant billing
  - Unique understanding of protocol and services provided under protocol
  - Often primary point of contact for patients enrolled in clinical trial
    - Notice of adverse events or complaints about billing
  - Responsible for scheduling/coordination of specific clinical trial services

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**Relationships with Industry**

Tom Bates, RN BSN MBA CPHRM LNCC  
Office of Integrated Risk Management

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<b>Fundamental USC Position</b>
<ul style="list-style-type: none"> <li>• USC supports meaningful interactions with Industry.</li> <li>• USC recognizes that these collaborations have led to the discovery of new knowledge which has directly benefited patients/public health.</li> <li>• USC seeks to maintain a culture of ethics in its business relations and to minimize conflicts of interest or even the appearance of conflicts of interest.</li> </ul>


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<b>USC Policy</b>
<p><b>Gifts</b></p> <ul style="list-style-type: none"> <li>• No gifts of any kind from Industry even if gifts are nominal</li> <li>• Food is as a gift</li> <li>• No branded items such as pens and notepads</li> <li>• No gifts to family members of Healthcare Professionals</li> </ul> <p><b>Education Grants and Trainee Scholarships</b></p> <ul style="list-style-type: none"> <li>• Education grants received from Industry must be clearly documented, signed by authorized signer for USC, and deposited in USC restricted accounts</li> <li>• Education events must comply with ACCME Standards for Commercial Support. <small>Key Questions: Budget? , Educational Objectives? , Target audience?</small></li> <li>• Education funding should not originate from company's sales/ marketing.</li> <li>• Industry can not influence educational event / content.</li> </ul>


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<b>Consulting Criteria for Chair Approval</b>
<ul style="list-style-type: none"> <li>• Is there a detailed Scope of Work?</li> <li>• Fair Market Value review</li> <li>• Is there a "quid pro quo"</li> <li>• When are services provided?</li> <li>• Conflict of Interest and Commitment Review</li> <li>• Is the faculty member involved in research with the company requesting services?</li> <li>• Paid Promotional Speaking Review</li> </ul>


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### Industry Payments Continue to be Scrutinized in the News

- ProPublica has updated the "Dollars for Docs" website to include the reported Open Payments data from 2013-2015. The application now also includes lists of the highest-earning physicians, physicians paid the most often, and teaching hospitals paid the most.  
<https://www.propublica.org/article/updated-dollars-for-docs-heres-whats-new>
- Time magazine published an article in early October discussing over \$34 million from industry to Dermatology physicians in 2014. The article discusses studies showing an increase in prescribing of brand-name prescriptions linked to receiving industry payments and meals.  
<http://time.com/4519504/dermatologists-skin-pharmaceutical-companies/>
- Modern Healthcare released a story in January of this year regarding a study on physicians tweeting about drugs or other commercial products and the lack of conflict disclosure. The researchers used the Open Payments database and the Dollars for Docs website to discover the conflicts physicians had.  
<http://www.modernhealthcare.com/article/20170117/NEWS/170119925>

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### Example of Payment Information

Summary Information for Program Year 2014 Change Program Year (2014 x)

\$354,083.10	398	N/A	0
Total General Payments	Total General Transactions	Total Amount Invested	Total Invested Transactions
N/A	0	N/A	0
Total Research Payments	Total Research Transactions	Total Value of Interest	Total Interest Transactions
\$29,358.70	4	0	402
Total Approved Research Funding	Total Approved Research Transactions	Total Disposed Payments	Total Undisposed Payments

General Payments Received<sup>®</sup>

Company Making Payment	Nature of Payment	Date	Amount	Third Party Payment	Disputed	Comment
Acorda Therapeutics, Inc.	Compensation for services: 2014-2015 consulting, including speaking at faculty and a 2014-2015 research education program	02/05/2014	\$2,000.00	No Third Party Payment	No	
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$60.00	No Third Party Payment	No	
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$300.00	No Third Party Payment	No	
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$702.00	No Third Party Payment	No	

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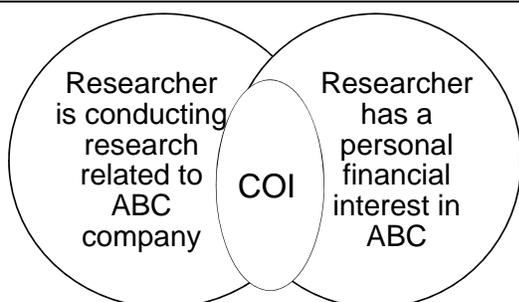
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### What is a conflict of interest in research?



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<b>Conflicts of Interest in Research</b>
<ul style="list-style-type: none"><li>• Conflict of Interest in Research (COI) is a situation where financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research.</li><li>• <u>Example</u>: You own 10% of a start-up company called ABC Medical Devices. You are conducting research at USC on an ABC prototype or a prototype licensed to ABC.</li></ul>
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<b>Institutional Conflict of Interest (ICOI)</b>
<ul style="list-style-type: none"><li>• An institutional conflict of interest occurs when a financial interest of the university has the potential to bias research conducted by its employees or students.</li><li>• Such financial interests include, but are not limited to, receipt of licensing payments or royalties from the outside entity, or an ownership interest in the outside entity.</li></ul>
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<b>Institutional Conflict of Interest (ICOI) cont.</b>
<p>An ICOI is deemed a "Significant Conflict" when a research project includes human subjects and any of the following conditions applies:</p> <ul style="list-style-type: none"><li>• The university holds any private equity in the outside entity,</li><li>• The university has the potential to receive cash payments from existing licensing arrangements with the outside entity;</li><li>• The university maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subject research as a result of technology licensing activities.</li></ul>
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## Lawmaker Probes Payments to Doctors by Medical Device Companies

by Marian Wang  
ProPublica, Nov. 1, 2010, 11:30 a.m.

7 Comments | Republish | Email | Print

1:30 pm: This post has been updated.

Payments to doctors by medical device company Medtronic could pose conflicts of interest, especially when the compensation is significant or when doctors could benefit financially from the success of a specific product, according to a letter by Sen. Charles Grassley, R-Iowa.

Medical devices, just like drugs, must be approved by the FDA for use on patients. This often occurs through clinical trials conducted by doctors. Both pharmaceutical companies and medical device companies pay doctors for speaking, consulting, and research

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Tweet Share +1



Sen. Charles Grassley, R-Iowa, left, at a hearing on Capitol Hill in June 2010. Grassley called out medical

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## HIPAA, Keck Medical Center & University of Southern California

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### Compliance Strategies

- Why identify covered entities, hybrid entities and covered components?
  - Entities/components subject to HIPAA compliance requirements
  - Workforce of entities/components subject to HIPAA compliance training
- Status of University and Keck Medical Center
  - University is a "hybrid entity"
    - Primary purpose is education

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### HIPAA for Hybrid Entities -University of Massachusetts Amherst (UMass)

- November 22, 2016 the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") reported a settlement for a malware infection that penetrated a covered entity's entire system.
- Infection started in a system that was not designated as a "health care component" in a hybrid entity which means there were no HIPAA Privacy and Security policies in place to prevent the breach.
- The settlement included a \$650k monetary penalty and corrective action.
- Of note is the designation of the organization as a "hybrid entity," a single entity with both covered and non-covered business activities.
- A health care component would be any component or combination of components that are involved in covered business practices.
- Hybrid entities must ensure that there are policies and procedures to ensure a separation between the health care and non-health care components.

Source: [https://www.hhs.gov/ohrt/default/files/umass\\_ra\\_cop.pdf](https://www.hhs.gov/ohrt/default/files/umass_ra_cop.pdf)

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### HIPAA for Hybrid Entities

- Covered entities that perform covered and non-covered functions that have not elected the hybrid entity designation should consider whether the designation is appropriate for the organization. The designation may help focus its HIPAA compliance efforts and reduce HIPAA compliance costs.

Source: <http://www.hallrender.com/2016/12/02/ocr-settlement-announced-hybrid-entity-hipaa-breach-2/>

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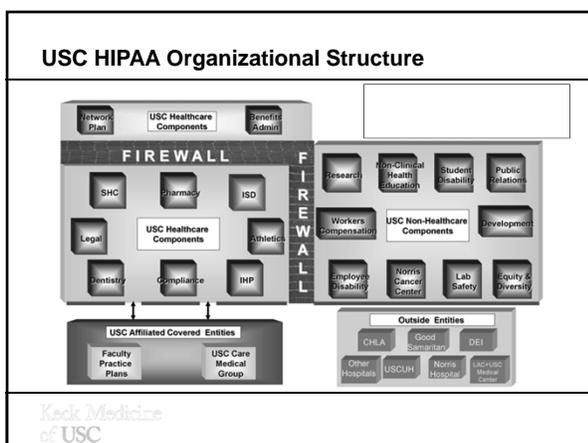
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Questions?
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