

**– Privacy in Perspective –
Dealing with Hybrids & Other
Unique Collaborations**

**Thursday, September 8, 2005
Washington, DC**

Thomas E. Jeffry, Jr., Esq.

Partner, Davis Wright Tremaine LLP, Los Angeles, CA

Austin M. O’Flynn, Esq.

Senior Counsel, Catholic Healthcare West, San Francisco, CA

Catholic Healthcare West



CHW

Davis Wright Tremaine LLP



Issues Addressed

- Legal vs. Operational Relationships
- Hybrids
- ACE – Regulatory Enforcement
- Basic Organizational Structures and Strategies
- Enforcement Table
- Collaboration Types involving PHI
- CHW HIPAA Org Chart
- Customizing Authorizations
- NPP in terms of ACE and Websites postings



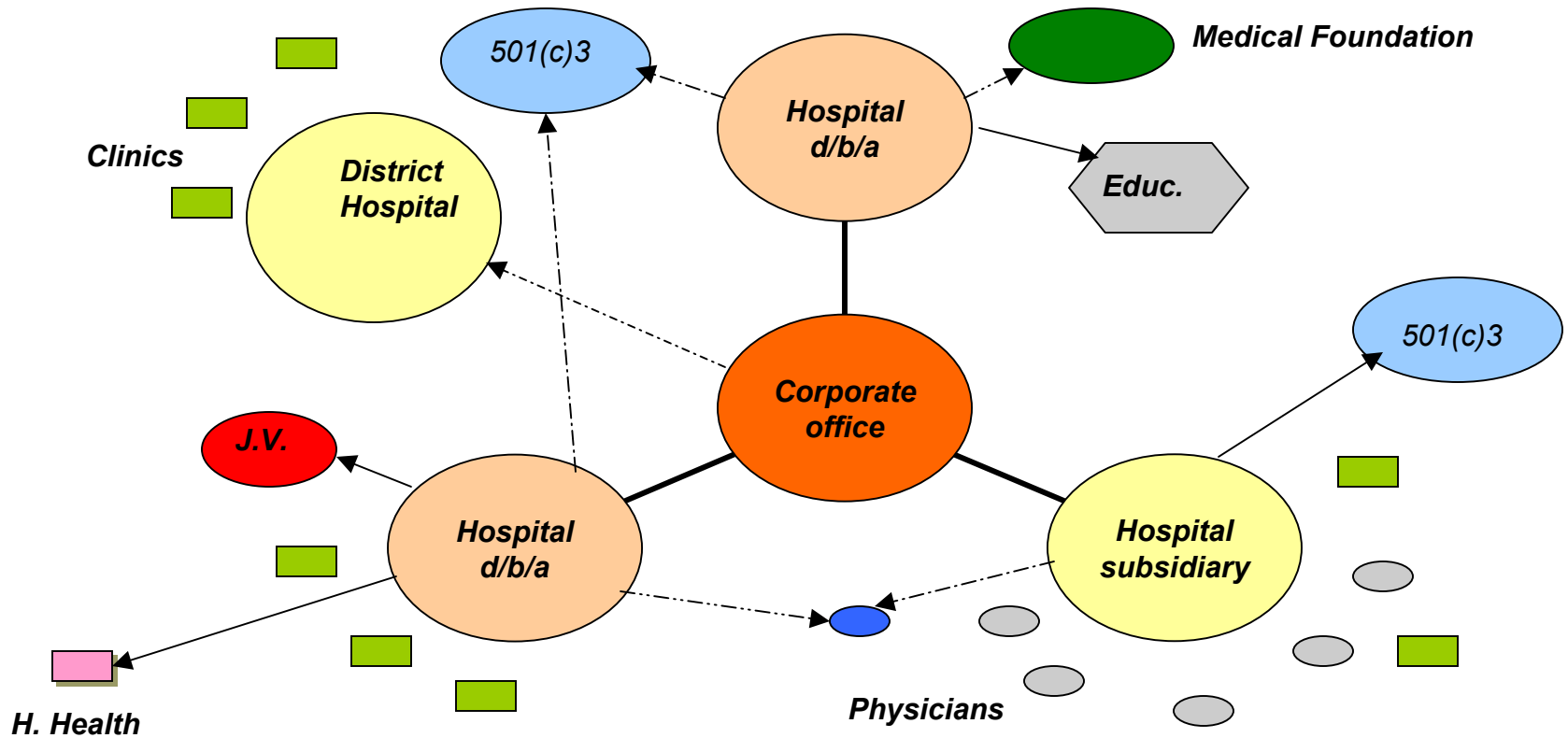
Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Capturing the Right HIPAA Org Structure



Catholic Healthcare West



Davis
Wright
Tremaine



LLP

Basic organizational structures and strategies

- ACE – horizontal integration
- Organized Health Care Arrangements (OHCAs) – vertical integration
- Hybrids – internal segregation
- Authorizations to permit disclosures between separate entities – external segregation



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Legal Relationships v. Operational Relationships

Legal

- Wholly owned subsidiary of parent
- Separate entities with a common parent
- Supporting organization (e.g. foundation)
- Joint venture

Operational

- Health system of multiple hospitals
- Hospital and freestanding clinic
- Hospital and research facilities
- Health clinic and social services



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Hybrids

- **Single legal entity**
- **Covered entity**
- **Business functions include both covered and non-covered functions**
- **Designates health care components that includes any component that would be a covered entity if a separate legal entity**



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Covered Entity (CE)

- **Identification necessary for patient enforcement**
 - **Responsible for PHI**
 - **Exercise of patient rights**
 - **Notice of Privacy Practices (NPPs)**
- **Separate covered entities**
 - **Share PHI for treatment and payment**
 - **Limited sharing for operations**



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Affiliated Covered Entity (ACE)

- CEs that are under common ownership or control may designate themselves as a single ACE.
 - “Common ownership is defined as an ownership or equity interest of five percent or more.”
 - Common control exists if an entity has the power - directly or indirectly - to significantly influence or direct the actions or policies of another entity. If the affiliated entity contains health care components, it must implement safeguards to prevent the larger entity from using protected health information maintained by the component entity. Privacy Rule, *December 2000 Preamble*



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Organized Health Care Arrangement (OHCA)

- 1. A clinically integrated care setting in which individuals typically receive health care from more than one healthcare provider (legally separate); or
- 2. An organized system of health care in which more than one CE participates, and they:
 - (i) hold themselves out to the public in a joint arrangement, and
 - (ii) participate in one or more of the following joint activities -- Utilization review, Quality Assessment and Improvement activities, Shared Risk Pool Program
- Note: an Acknowledgment obtained by one CE means the other CEs do not need to also seek one.



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Basic organizational structures and strategies - ACE

- An ACE may use a single NPP as if it were a single CE
- The CEs that together make up the ACE are jointly and severally liable for any civil monetary penalty under HIPAA
- An Authorization (beyond TPO) is sufficient for all CEs – not so for an OHCA
- California --Title 22 limitation on ACE structure
- Minimum necessary still applies



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Basic organizational structures and strategies - OHCA

- An OHCA may use a single NPP, just like a covered entity for all its activities.
- The CEs that together make up the OHCA are NOT jointly and severally liable for any civil monetary penalty under HIPAA.
- An Authorization (beyond TPO) is NOT sufficient for all CEs
- May need more BAA's in place
- Minimum necessary still applies



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Basic organizational structures and strategies - Hybrid

- Applies to multi-purpose organizations
- Limits exchange of PHI between health care components and non-health care components
- Rules on permitted uses and minimum necessary may otherwise limit such exchanges
- Minimizes regulatory burden on non-health care components



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Basic organizational structures and strategies - Authorizations

- **Trumps HIPAA's limitations on use and disclosure of PHI between**
 - Components of a single CE
 - Two CEs
 - A CE and a non-CE
- **Allows for use on health information for other purposes (e.g. education, social services, surveillance, research)**



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Customizing Authorizations

- To provide additional requirements required under State law
- To provide for use and disclosure of non-health related information subject to regulations
 - Financial information
 - Educational records
 - Employment information
- Limitation on compound authorizations



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Different Structures → Different Patient's Rights

- **Title 22 Limitations -- California**
- **Managing Patient Rights**
 - **Alternative Communication**
 - **Accounting for Disclosures**
 - Is disclosure on behalf of CE or ACE?
 - Approval of Restrictions and communication to all HIPAA entity members
 - Who receives Complaints and maintains required documentation on behalf of hospital, CE and ACE?
 - Who within ACE manages NPP Acknowledgements for hospital, CE, and ACE?



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Enforcement Issues

- Patient's rights against CE
- OCR rights actionable against ACE/OHCA/CE
 - A broader organization → expectation
 - Size of Organization → Resources → Ability of Organization
 - ACE may be viewed as larger than an OHCA which may be viewed as larger than a CE



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

HIPAA Enforcement Table

Rights of	CE	BA	OHCA	ACE*	Hybrid
Patients	Yes	No	No	No	Yes
OCR	Yes	No**	No	Yes	Yes

**Good uniform controls?*

**Consider Number of OCR “dings” and penalty caps*

***Yes if BA is already a CE*

Catholic Healthcare West



Davis
Wright
Tremaine



LLP

Examples of Collaboration Types where PHI may be exchanged

- **Joint Ventures**
- **Management Agreement (e.g. District Hospitals)**
- **Medical Foundations**
- **Multi-purpose agencies – Social Service Groups**
- **Research**



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

Examples of Collaboration Types where PHI may be exchanged

- **Education/Schools**
- **Public health**
- **Surveillance**
- **Electronic Community Health Records**



Catholic Healthcare West

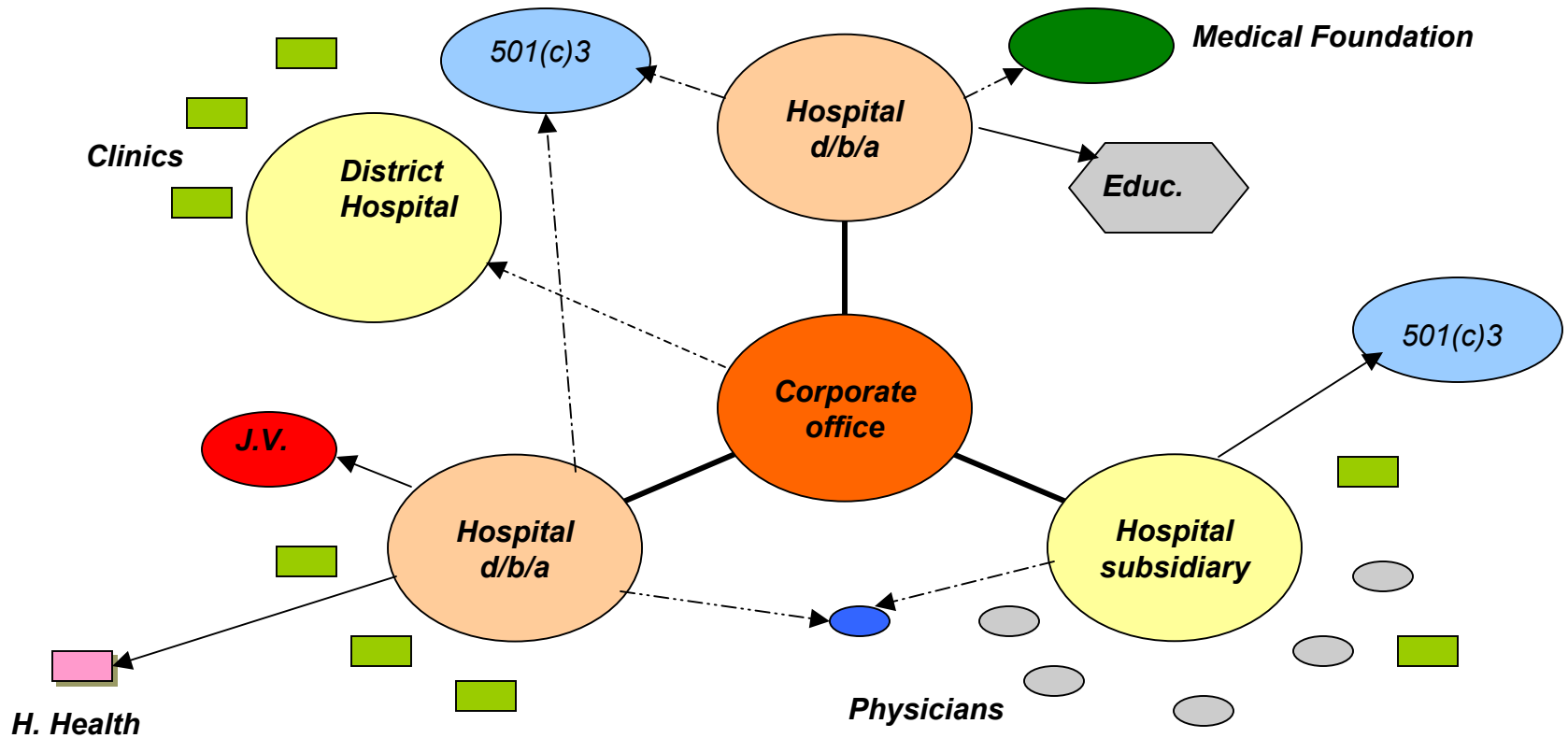
CHW

Davis
Wright
Tremaine



LLP

Capturing the Right HIPAA Org Structure



Catholic Healthcare West



Davis
Wright
Tremaine



LLP

HIPAA Org Documentation

The designation of an affiliated covered entity must be documented and the documentation maintained as required by § 164.530(j).



Catholic Healthcare West

CHW

Davis
Wright
Tremaine



LLP

CHW HIPAA Organization Chart

- **Part A** - List of hospitals and clinics and other entities and business units who may or may not be covered entities and their HIPAA status within CHW.
- **Part B** - List of 501(c)(3) fundraising foundations and their relationships to covered entities within the CHW ACE.
- **Part C** - List of plans, both insured and self-insured, and plan administrators.
- **Part D** - List of entities in which CHW or its affiliate may have an ownership interest but does not have management responsibility nor operating responsibility.



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

CHW HIPAA Org Chart – Part A

17 Columns – remaining 9 columns cont'd on next slide →

1. Level 1 Legal Entity																				
2. Level 2 Legal Entity or d/b/a																				
3. Level 3 Legal Entity or d/b/a																				
4. Level 4 Legal Entity or d/b/a																				
5. If Joint Venture, Managed or Operated by CHW Facility?																				
6. Using PHI?																				
7. Name of Hybrid (if applicable)																				
8. Name of Non-Covered Component																				



Catholic Healthcare West

Davis
Wright.
Tremaine



LLP

CHW HIPAA Org Chart – Part A

9. Name of CE
10. Name of ACE
11. Primary OHCA
12. Other OHCA
13. BA
14. Name of NPP
15. Hospital President
16. Hospital/ Facility FPO
17. Comments



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Who Documents HIPAA Org?

■ Recommendations

- Single Custodian
- Documentation needs to reflect both your legal and operational reporting structure
- Readily accessible internally
- Internalize HIPAA Org analysis into legal check off process for creating or changing status of JV's, partnerships, new corporations, 501(c)'s and other entities
- Annually review and update



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

HIPAA Org Annual Review

- **Who should be involved?**
 - **Custodian of HIPAA Org Document**
 - **Hospital/Facility Administrator**
 - **Legal Counsel**
 - **Privacy Official**
 - **Marketing and Communication Dept**
 - **501(c) President**
 - **Benefits Director**



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Notice of Privacy Practices (NPP)

- **Different for each CE**
 - **Must be consistent → Org Chart**
 - **clinics**
 - **hospital**
- **Non-HIPAA provisions related to other requirements (e.g. education, financial)**
- **If website supports multiple CEs**
 - **No ACE NPP → post all NPPs**
 - **ACE NPP → only One NPP**



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Closing Thoughts

- **Identify and distinguish legal and operational relationships**
- **Document your organization structure**
- **Make sure CE or health care component of hybrid maintains control and custody of medical records**
- **Authorizations may be the easier solution, business associate agreements are not when providing integrated services**



Catholic Healthcare West

Davis
Wright
Tremaine



LLP

Contact information

Thomas E. Jeffry, Jr.
Davis Wright Tremaine
(213) 633-6800
tomjeffry@dwt.com

Austin M. O'Flynn, Esq.
Catholic Healthcare West
(415) 438-5559
AOFlynn@chw.edu



Catholic Healthcare West

Davis
Wright
Tremaine



LLP