Session Objectives

- Describe the disclosure requirements set forth by the Texas Medical Disclosure Panel.
- Evaluate the consent requirements established by other relevant entities including CMS and the subject accreditation organization.
- Analyze the documentation constraints and need to stay current with disclosure requirement updates.
- Design a system to ensure continuous compliance with the Texas Medical Disclosure Panel requirements.
- Synthesize a process, based on disclosure documentation, to reduce the risk of surgical errors.
Informed Consent and Disclosure

Shared Decision-Making: evaluation of all treatment options for a particular condition

Informed Consent: evaluation of a particular treatment or procedure including alternatives and prognosis if declined

Disclosure: evaluation of the risks and complications specific to the planned treatment or procedure
Disclosure Standards

- **Professional Standard**
  - Approximately 23 states
  - Require that patients be presented with the information that would be communicated by other physicians with similar background and experience and practicing within their community

- **Patient Standard**
  - Approximately 23 states
  - Requires that patients be presented with the information that a reasonable or prudent patient would want to know in order to make a decision about a treatment or procedure

Disclosure Standards for Informed Consent*


*Depicts laws in place through 2002.

*Colorado and Georgia are classified as "hybrid" because their laws blend aspects of the patient and professional standards, without expressing a clear preference for either.
Background – Compliance Relative to Informed Consent

Compliance
- Requirements
  - Medicare Conditions of Participation (CoPs)
  - State-specific requirements
  - Other standards
  - Case law
CMS CoPs – Interpretive Guidelines

- A properly executed informed consent form contains the following minimum elements:
  - Name of the hospital
  - Name of the specific procedure(s) or type of medical treatment
  - Name of the responsible practitioner who is performing the procedure or administering the medical treatment
  - Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative
  - Signature of the patient or the patient’s legal representative
  - Date and time the informed consent form is signed by the patient or the patient’s legal representative

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records

CMS CoPs – Interpretive Guidelines

- A well-designed informed consent form might also include:
  - Name of the practitioner who conducted the informed consent discussion
  - Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form
  - Indication or listing of the material risks of the procedure or treatment that were discussed
  - Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records
CMS CoPs – Interpretive Guidelines

- A well-designed informed consent form might also include:
  - Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records

State Law

- Medical Disclosure Panel
- Consent by a minor

Sec. 32.003. CONSENT TO TREATMENT BY CHILD.
(a) A child may consent to medical, dental, psychological, and surgical treatment for the child by a licensed physician or dentist if the child:
(1) is on active duty with the armed services of the United States of America;
(2) is:
(A) 16 years of age or older and resides separate and apart from the child’s parents, managing conservator, or guardian, with or without the consent of the parents, managing conservator, or guardian and regardless of the duration of the residence; and
(B) managing the child’s own financial affairs, regardless of the source of the income;
Case Law

• Patient suffered a stroke during a chiropractic manipulation
• Texas Supreme Court found that the Chiropractor is not a “physician” and thus cannot provide “medical care” and thus statute does not apply
• Court did find that Texas common law applied; including the duty to disclose the risk of possible stroke


Compliance

• Survey/Accreditation Organizations
  – State Survey Agencies
  – CMS Regional Office
  – The Joint Commission
  – DNV
  – HFAP
**DNV**

- Deeming authority in 2008
- Have accredited almost 500 hospitals
- Integrates ISO 9001 with the Medicare Conditions of Participation
  - Does require ISO 9001 certification
  - Quality focus with emphasis on organizational compliance with policy and procedures


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**CMS Survey**

- Review policies and procedures
  - Procedures that require informed consent
  - When procedures may be considered emergent (no consent required)
- Review a minimum of six non-emergent informed consent forms
  - Will ideally review the records of patients who are about to undergo surgery or who are located in a surgical recovery area
- Confirm presence in chart prior to surgery
- Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients’ representatives, to see how satisfied they are with the informed consent discussion prior to their surgery

Interpretive Guidelines §482.51(b)(2) – Surgical Services
Texas Medical Disclosure Panel

• Established by the Texas Legislature in 1977
• Comprised of 9 members
  – 3 attorneys
  – 6 physicians
• The panel determines:
  – Which procedures require disclosure
    o List A – Full Disclosure of specific risks and hazards
    o List B – No Disclosure of specific risks and hazards
  – The risks and hazards that physicians must disclose to their patients
  – General form to be employed

List A and List B

<table>
<thead>
<tr>
<th>Title 24</th>
<th>Texas Administrative Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part 2</td>
<td>HEALTH SERVICES TEXAS MEDICAL DISCLOSURE PANEL</td>
</tr>
<tr>
<td>Chapter 601</td>
<td>Procedures Requiring Full Disclosure of Specific Risks and Hazards</td>
</tr>
<tr>
<td>Rule 601.2</td>
<td>(a) Anesthesia. (b) Epidural.</td>
</tr>
<tr>
<td></td>
<td>(A) Nerve damage. (C) Headache.</td>
</tr>
<tr>
<td></td>
<td>(D) Blending/spinal lumbar block. (E) Infection.</td>
</tr>
<tr>
<td></td>
<td>(F) Medical necessity to convert to general anesthesia.</td>
</tr>
<tr>
<td></td>
<td>(G) Brain damage. (H) Chronic pain.</td>
</tr>
</tbody>
</table>

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<td>Chapter 601</td>
<td>Procedures Requiring No Disclosure of Specific Risks and Hazards</td>
</tr>
<tr>
<td>Rule 601.3</td>
<td>(a) Anesthesia. Local.</td>
</tr>
<tr>
<td></td>
<td>(b) Cardiovascular system.</td>
</tr>
<tr>
<td></td>
<td>(1) Excision and ligation of varicose veins of the leg.</td>
</tr>
<tr>
<td></td>
<td>(2) Arterial liga for monitoring purposes.</td>
</tr>
<tr>
<td></td>
<td>(c) Digestive system.</td>
</tr>
<tr>
<td></td>
<td>(1) Appendectomy.</td>
</tr>
<tr>
<td></td>
<td>(2) Hemorrhoidectomy with fistulotomy or fissurectomy.</td>
</tr>
<tr>
<td></td>
<td>(3) Hemorrhoidectomy.</td>
</tr>
<tr>
<td></td>
<td>(4) Incision or excision of parotid tissue.</td>
</tr>
<tr>
<td></td>
<td>(5) Local excision and destruction of lesion, anus and rectum.</td>
</tr>
</tbody>
</table>

Symptoms of Non-Compliance
Deficient Consent Forms

- 157-hospital study
- Only 26 percent of forms included all of the “basic elements”
  - Description of the procedure
  - Risks
  - Benefits
  - Alternatives


Poor Consent Form Execution

- Missing information
- Illegible writing
- Abbreviations
- Version control
- Provider-to-provider variation

### Date and Time

- Four specific consent forms are cited as lacking date and time or the time of signature.

**CMS. Statement of Deficiencies and Plan of Correction. Survey Completed 12/04/2012.**

### Errors and Omissions

- “During a recent CMS survey at XXXXXXXX, the surveyors found a couple deficiencies on 2 documentation items. The surgical consent is a paper form scanned into the record after all signatures are documented. This requires manual dating and timing with the signatures which was missed by the providers on a few cases.”

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**C. 300: ABN ABORTIONS PROTECTIONS OR RECORD MAINTENANCE**

- The chart demonstrated the number of patients who signed the consent form. The report included the number of patients who signed the consent form and the dates they signed.

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**MORNING CMO REPORT**

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient Name</th>
<th>Diagnosis</th>
<th>Treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>07.15.2015</td>
<td>John Doe</td>
<td>Diabetes</td>
<td>Insulin</td>
<td>Recovered</td>
</tr>
</tbody>
</table>

- Key points:
  - The report mentions a patient with diabetes requiring insulin treatment. The outcome described is recovery.
Identifying, Checking and Initialing the Correct Box(es)

- A typical Texas consent form
  - 14 total pages
  - 9 pages of List A procedures and disclosures

Lost or Misplaced Consents

- 66 percent of patients had the consent missing from their record at the time of surgery
- Delayed 10 percent of total cases


Recommendations

• At a minimum, automate your informed consent process to:
  – Maintain the List A library
    o Ensure that the planned procedure(s) are disclosed
  – Establish precise version control
  – Support digitized signature capture/e-signatures
    o Automatic date and time stamping
  – Ensure that the consent is electronically placed in the medical record
Options for Automating This Process

**DYI**
- EHR
- Fillable PDF, Excel, SQL

**Third-Party**
- eForms Solution
- Automated Informed Consent Tool

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**eConsent Toolkit. HealthIT.gov.**
https://www.healthit.gov/providers-professionals/econsent-toolkit
Recommendations

- Consider the patient in the design
  - Present only the relevant information
  - Employ easy-to-understand language and presentation techniques
  - Support multiple languages and learning mechanisms

Two Ideas – Patient Satisfaction

1. Electronic Informed Consent
   - 96 percent of patients preferred procedure-specific electronic consent to traditional fill-in-the-blank consent

2. Employ Teach-Back
   - 575-subject, 7-site randomized controlled trial
   - Improved comprehension and satisfaction
   - Required only 2.6 additional minutes

Recommendations

- Pay special attention to your policies along with disclosure and documentation of:
  - Overlapping procedures
  - Use of residents
  - Use of assistive personnel

Overlapping Surgery

- Boston Globe series spurs Senate review and inquiry
- Guidance available from the American College of Surgeons

*Boston Globe, April 13, 2016.*

*Pittsburgh Post-Gazette, March 28, 2016.*

Overlapping Surgery

- Concise review of best practices
- Example of how automating the consent process can ensure compliance with guidelines and policy


Recommendations

- Employ appropriate business rules to prevent errors and omissions
- Design the system to ensure automatic placement of the completed consent in the medical record (immediately after execution)
OR Start Time Delays

- Missing or problematic consents had a negative impact upon OR start times in 46 percent of cases
- Declined to less than 1 percent of cases with implementation of an electronic informed consent process


Recommendations

- Establish policies and procedures for obtaining informed consent outside the walls of your institution:
  - Ensure that your consent documentation process operates seamlessly in remote physician offices
Where to Obtain Consent

- In malpractices cases, alleging inadequate informed consent, consents obtained in the pre-operative holding area, compared to in the surgeon’s office, resulted in significantly higher legal expenses and indemnity payouts
  - $322,000 higher, on average, for the orthopedic procedures studied


Recommendations

- Ensure that all appropriate List A disclosures are populated for the planned procedure
- Handle all special scenarios:
  - List A disclosures for blood transfusion
  - List A disclosures for laparoscopic approach
  - List A disclosures when multiple procedures are contemplated
List A Risks

- Capture all relevant disclosures for the planned treatment(s) and procedures(s)

Recommendations

- Leverage your detailed, procedure-specific consents to serve as an additional layer of protection against errors
Avoiding Errors

- An instance of wrong-patient/wrong-procedure/wrong-site surgery reaches a patient, on average, once per year in a 300-bed hospital


Avoiding Errors

- The most effective mechanism for avoiding wrong-patient/wrong-procedure/wrong-site surgery is verification of the consent form.
  - 30-month study of all hospitals in Pennsylvania

Recommendations

- Develop procedures to stay current on all relevant updates:
  - State of Texas Chapter 601 updates
  - CMS updates and Black Box Warnings
Staying Current

- Updates are published periodically in the Texas Register
  - Subscribe to notifications with the Texas Department of State Health Services

Email notification received at 3:28pm EDT on 4/7/17.

This is to provide notice that proposed changes to Chapter 601, Texans' Unique Disclosure Requirements, were published in the Texas Register April 7, 2017, and will be open for public comment for 90 days. Comments on the proposal may be submitted to Pamela Adams, Program Specialist, Regulatory Liaison Unit, Division of Regulatory Services, Department of State Health Services, Mail Code 2131, P.O. Box 131867, Austin, Texas 78713-1867, (512) 454-6000, extension 2081, by fax to (512) 454-6153, or by email to providersanddata@texas.gov. Viewers across the state can search the Texas Register website at http://www.texasregister.gov/tr.aspx. Thank you.
Amendments Published April 7, 2017

- An additional risk:
  - Potential long-term negative effects on memory, behavior, and learning with prolonged (greater than 3 hours) or repeated exposure to anesthesia on the fetus of a woman in her 3rd trimester of pregnancy and on a child up to 3 years of age.

- Added to two procedures:
  - General Anesthesia
  - Monitored Anesthesia Care (MAC) (conscious sedation)

- Also, some minor form changes to the related forms (both English and Spanish versions).

Summary

- Texas is a uniquely progressive state
  - This adds a significant degree of complexity to the informed consent and disclosure process

- Automate your consent process if you do not do so already

- Pay attention to:
  - CMS and State requirements
  - Patient experience
  - Minimizing the potential for errors and omissions (leverage automation)

- Ensure that your system is:
  - Easy to update (or it updates automatically)
  - Electronically stores documents to the medical record
  - Supports safety initiatives (pre-procedure verification and/or time-out verification of patient, procedure and site)
Questions

Additional Information:

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Vice President of Sponsorships, Dallas/Fort Worth HIMSS Chapter  
Peter.Ravalico@taylorcommunications.com

**Slides:**  
www.iMedConsent.com