Strategies for Automating Texas’ Unique Disclosure Requirements

HIMSS Houston Chapter – Lunch & Learn
June 23, 2017, Mays Clinic, Room ACB1.12345
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Session Outline
• Define disclosure
• Examine the compliance factors for informed consent
• Review potential compliance issues
• Analyze Texas requirements
• Recommendations
• Looking ahead – consent requirements on the horizon
• Take-away’s
Informed Consent and Disclosure

Shared Decision-Making:
evaluation of all treatment options for a particular condition considering patient goals and objectives

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

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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 That Shape Informed Consent
  – 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

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### 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
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;

Texas Administrative Code. Title 2, Subtitle A, Chapter 32, Subchapter A, Section 32.003
Case Law

- Patient suffered a stroke during a chiropractic manipulation.
- Texas Supreme Court found that a 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 (Baylor, CHI St. Luke’s, Harris Health, Houston Methodist)
- Integrates ISO 9001 with the Medicare Conditions of Participation
  - Does require ISO 9001 certification
  - Quality focus with emphasis on compliance with policy and procedures


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
    - List A – Full Disclosure of specific risks and hazards
    - 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

List A:

List B:

Symptoms of Non-Compliance
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

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.”

Identifying, Checking and Initialing the Correct Box(es)

• A typical Texas consent form
  – 14 total pages
  – 9 pages of List A procedures and disclosures
Recommendations

- At a minimum, automate your informed consent process to:
  - Maintain the List A library
    - Ensure that the planned procedure(s) are disclosed
  - Establish precise version control
  - Support digitized signature capture/e-signatures
    - 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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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

• 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 procedure(s)
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.
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).
Offering a Well-Designed and Frequently Updated List of Disclosures…

Manageable?

Hospital IQR Program – Proposed “Quality of Informed Consent Documents Measure”
Hospital IQR Program

- Incentivizes hospitals to report designated quality measures (ability to recoup a 2 percent Medicare holdback)
- Makes the information available to consumers through the Hospital Compare website

On April 28, CMS announced that it is inviting public comment on seven new measures to be included in the Hospital IQR Program

- One of the seven new measures is the “Quality of Informed Consent Documents Measure”

Federal Register / Vol. 82, No. 81 / Friday, April 28, 2017 / Proposed Rules.
Quality of Informed Consent Documents Proposed Measure

• CMS notes that comprehensive informed consent documents can:
  – Improve patient comprehension and satisfaction
  – Support patients in making decisions that are aligned with their expectations, preferences, and goals

Quality of Informed Consent Documents Proposed Measure

• CMS further observed that in spite of their importance, informed consent documents are frequently:
  – Generic
  – Lack information relevant to the procedure
  – Include illegible, hand-written information
  – Presented to patients for signature minutes before the start of a procedure when they are most vulnerable and least likely to ask questions
Quality of Informed Consent Documents Proposed Measure

- **Measure Development**
  - Developed in 8 hospitals
  - Validated in an additional 25 hospitals

- The participating hospitals reported that the information generated by the measure was useful to the hospitals’ efforts to improve their informed consent documents and processes by identifying important gaps in their existing documentation.

Quality of Informed Consent Documents Proposed Measure

- **Abstraction Tool**
  - 8 items will be rated
  - Maximum score of 20
  - Likely no more than 100 documents to be sampled
  - Abstractors can rate between 15 and 20 documents in an hour
  - Frequency of the data submission process has not been determined (it may be annually, every 6 months or quarterly)
Consent Form Scoring

Description of the Procedure

• Is language describing what the procedure is (beyond the medical name) provided for the patient?
  – 2 points

• If provided, is the information typed?
  – 1 point
Description of the Procedure

• Is a description of how the procedure will be performed provided for the patient?
  – 2 points
• If provided, is the information typed?
  – 1 point

Rationale for the Procedure

• Is the clinical rationale (condition-specific justification) for why the procedure will be performed provided?
  – 2 points - Fully meet criteria
  – 1 point - Context and condition given, but do not fully meet criteria
Rationale for the Procedure

• Is any patient-oriented benefit provided (intended impact on patient’s health, longevity, and/or quality of life)?
  – 2 points

Probability of Procedure-Specific Risks

• Is a quantitative probability provided for any procedure-specific risk?
  – 2 points
• Is a qualitative probability provided for any procedure-specific risk?
  – 1 point
Probability of Procedure-Specific Risks

- American College of Surgeons ACS NSQIP Surgical Risk Calculator
  - Detailed, quantitative surgical risks based on patient age, history and co-morbidities

ACS NSQIP Surgical Risk Calculator.
http://riskcalculator.facs.org/RiskCalculator/

Alternative(s) to the Procedures

- Is any alternative provided for the patient?
  - 2 points
Timing

• Date of patient's/proxy's signature – **at least one day before procedure** or patient opted out of viewing the informed consent document at least 1 day prior  
  – 5 points

Consent Form Timing
Medical Liability Risk

- In MedMal cases, alleging inadequate informed consent, consents obtained in the preoperative holding area, compared to in the surgeon’s office, resulted in significantly higher legal expenses and indemnity payouts
  - $322,000 higher, on average


OR Start Time Delays

- 66 percent of patients had the consent missing from their record at the time of surgery
- Delayed 14 percent of cases


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.


Will the Proposed Measure Stick?
Reading the Tea Leaves

- Well-researched
  - 33 hospitals
  - $91.7M project
- Aligns with the recommendations for a “well-designed” form and process
- Aligns with shared decision-making initiatives


Reading the Tea Leaves

- ACS was mostly on board when the measure was first floated in 2016
  - The College promoted the ACS NSQIP Surgical Risk Calculator
- Published public comments from the purchasers (patients) sector are positive

We strongly support the addition of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure and applaud CMS’ move to elevate the critical issue of patient consent in the IQR Program and support the recommendation to deploy the Quality of Informed Consent Documents measure immediately.

3. Measure at the Level of the Surgeon, Not the Hospital

Informed consent is a critical aspect of a surgeon’s relationship with the patient and the surgeon is responsible for obtaining informed consent. Yet, the proposed methodology measures informed consent at level of the hospital. ACS believes that this is a missed opportunity to enhance the surgeon/patient relationship and promote patient-centered decision-making. The responsibility for informed consent should be measured by the party whom is responsible for working with the patient to ensure comprehensive informed consent.
3 Take-Away Action Items

1. Score Your Forms

- Test your forms against the proposed quality measure
- Consider the patient- and procedure-specific risk elements in light of the Texas disclosure requirements

<table>
<thead>
<tr>
<th>Description of Procedure</th>
<th>Response</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Is language describing what the procedure is to be done the medical record provided for the patient?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td>2) If provided, is it typed?</td>
<td>&quot;Yes&quot;</td>
<td>1</td>
</tr>
<tr>
<td>3) Is a description of how the procedure will be performed provided for the patient?</td>
<td>&quot;Yes&quot;</td>
<td>1</td>
</tr>
<tr>
<td>4) If provided, is it typed?</td>
<td>&quot;Yes&quot;</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 1.3: Scoring Tool (Uncertainty/Non-specific Weighting)

- Patients' Clinical Severity:
  - "Yes": 2
  - "No" or "not applicable": 0

- Probability of Procedure-Specific Risk:
  - "Yes": 2
  - "No" or "not applicable": 0

- Is a qualitative probability provided for any procedure-specific risk?:
  - "Yes": 2
  - "No" or "not applicable": 0

- If a patient opted out of receiving the consent document:
  - "Yes": 2
  - "No" or "not applicable": 0

- Timing:
  - 31 day before (i.e. at least 1 day before the procedure):
    - "Yes": 3
  - 1 day before (i.e. not at least 1 day before the procedure):
    - "Yes": 0

- Minimum Quality Score: 20
## 2. Evaluate Your Consent Process

- Are lost/misplaced consents, or consent issues, delaying the start of cases?
- Evaluate the timing of your consent process against the proposed quality measure
  - Obtain consents for elective procedures at least one day prior to the date of the scheduled procedure

## 3. Consider 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

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Slides:
www.iMedConsent.com

Webinar on the Proposed Informed Consent Measure:
(I/C underscore Measure)