Informed Consent – 2012 New Law Update

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“. . . every human being of adult years and sound mind has a right to determine what should be done with his own body.”

Schloendorff v. Society of New York Hospital, 11 N.Y. 125, 105 N.E. 92 (1914).

I. Introduction: Principles

➢ Each patient has the legal and ethical right to direct what happens to his / her body and to be involved in decisions affecting his / her health care.
➢ A patient must have enough information about risks of procedure that could influence a reasonable person in deciding whether or not to consent.

II. Elements of Proper Informed Consent:

A. Condition for which procedure or treatment is necessary.
B. Procedure or treatment to be done.
C. Possibility of additional or different procedure(s) or treatment(s).
D. No warranty or guarantee as to result or cure can be given.
E. Significant risks and hazards associated with procedure or treatment.
F. Alternatives, if any, to procedure or treatment.
G. Risks of having no procedure or treatment at all.
H. Risks of anesthesia and alternative forms of anesthesia.
I. Person(s) expected to perform procedure or treatment.

III. “The Lists” from the Texas Medical Disclosure Panel (“Panel”)

A. List A: Treatments and procedures Panel has determined require disclosure of specific risks and hazards (25 Tex. Admin. Code § 601.2)

1. List A Categories (see attached)

➢ Anesthesia
➢ Cardiovascular system
➢ Digestive system treatments and procedures
➢ Ear treatments and procedures
➢ Endocrine system treatments and procedures
➢ Endoscopic surgery
➢ Eye treatments and procedures
➢ Female genital system treatments and procedures
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- Hematologic and lymphatic system
- Integumentary system treatments and procedures
- Male genital system
- Maternity and related cases
- Musculoskeletal system treatments and procedures
- Nervous system treatments and procedures
- Pain management procedures
- Psychiatric procedures
- Radiology
- Radiation therapy
- Respiratory system treatments and procedures
- Urinary system

2. Examples of List A

- Transfusion of blood and blood components
- Anesthesia and/or perioperative pain management
- Stress testing
- Angiography; angioplasty; stenting; vascular thrombolysis
- Abdominal endoscopy/laparoscopy procedures
- Vascular access - nontunneled catheters, tunneled catheters, implanted access
- Utilization of prolonged fluoroscopy
- All fallopian tube and ovarian surgery with or without hysterectomy, including removal and lysis of adhesions versus Fallopian tube occlusion (for sterilization)
- Certain orthopedic procedures on children age 12 or under

3. Special List A Consent Forms

- Hysterectomy (English and Spanish version)
- Radiation therapy (English and Spanish version)
- Anesthesia and/or perioperative pain management (General; Epidural; Spinal; MAC (conscious sedation); Regional block anesthesia / analgesia) (English and Spanish version – Summer 2012)

B. List B: Treatments and procedures Panel has determined do not require disclosure of specific risks and hazards (25 Tex. Admin. Code § 601.3)

C. Non-List A and Non-List B Procedures: Panel has not made a determination as to scope of physician’s duty to obtain informed consent.

- Thus, risks / hazards should be those which could influence a reasonable person in making decision to consent to treatment / procedure.

IV. The Law on Obtaining Informed Consent

A. Duty to obtain informed consent: Nondelegable duty imposed solely on the operating physician to obtain informed consent.
B. Manner of obtaining informed consent:

1. Be in writing; should use Panel’s consent form
2. Disclose all risks / hazards required by Panel for List A procedures
3. Signed, dated, timed by a competent patient (or person legally authorized to consent for patient)
4. Signed by competent witness [Physician?] 

C. Possible Legal Theories Related to Consents

1. Total (unexcused) lack of consent ➔ Battery (intentional tort; offensive touching)
2. Lack of proper informed consent ➔ Negligence (accident or mistake)
   a. If List A procedure, Panel’s form and risks / hazards is used ➔ Presumption physician not negligent.
   b. If List A procedure, Panel’s form and risks / hazards not used ➔ Presumption physician is negligent.
LIST A: TEXAS WRITTEN INFORMED CONSENTS
Procedures Requiring Disclosure of Specific Risks and Hazards
Effective January 16, 2012

ANESTHESIA
New Anesthesia consent form: Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia)
(1) Epidural
(2) General
(3) Spinal
(4) Monitored Anesthesia Care (MAC) (conscious sedation)

PAIN MANAGEMENT PROCEDURES
(1) Neuroaxial procedures (injections into or around spine)
(2) Peripheral and visceral nerve blocks and/or ablations
(3) Implantation of pain control devices

CARDIOVASCULAR SYSTEM
• CARDIAC: SURGICAL
  (1) Coronary artery bypass, valve replacement
  (2) Heart transplant

• CARDIAC: NON-SURGICAL
  (1) Coronary angioplasty, coronary stent insertion, pacemaker insertion, AICD insertion, and cardioversion

• CARDIAC: DIAGNOSTIC
  (1) Cardiac catheterization
  (2) Electrophysiologic studies
  (3) Stress testing--Acute myocardial infarction
  (4) Transesophageal echocardiography--Esophageal perforation

• VASCULAR
  (1) Open surgical repair of aortic, subclavian, and iliac, artery aneurysms or occlusions, and renal artery bypass
  (2) Angiography (inclusive of aortography, arteriography, venography) - Injection of contrast material into blood vessels
  (3) Angioplasty (intravascular dilatation technique)
CARDIOVASCULAR SYSTEM (cont)

- **Vascular**
  4. Endovascular stenting (placement of permanent tube into blood vessel to open it) of any portion of the aorta, iliac or carotid artery or other (peripheral) arteries or veins
  5. Vascular thrombolysis (removal or dissolving of blood clots) - percutaneous (mechanical or chemical)
  6. Angiography with occlusion techniques (including embolization and sclerosis) - therapeutic
  7. Mesenteric angiography with infusional therapy (Vasopressin) for gastrointestinal bleeding
  8. Inferior vena caval filter insertion and removal
  9. Pulmonary angiography
  10. Percutaneous treatment of pseudoaneurysm (percutaneous thrombin injection versus compression)
  11. Vascular access - nontunneled catheters, tunneled catheters, implanted access
  12. Varicose vein treatment (percutaneous via laser, RFA, chemical or other method) without angiography

DIGESTIVE SYSTEM TREATMENTS AND PROCEDURES

1. Cholecystectomy with or without common bile duct exploration
2. Bariatric surgery – Laparoscopic
3. Bariatric surgery - Open
4. Pancreatectomy (subtotal or total)
5. Total colectomy
6. Subtotal colectomy
7. Hepatobiliary drainage/intervention including percutaneous transhepatic cholangiography, percutaneous biliary drainage, percutaneous cholecystostomy, biliary stent placement (temporary or permanent), biliary stone removal/therapy
8. Gastrointestinal tract stenting

EAR TREATMENTS AND PROCEDURES

1. Stapedectomy
2. Reconstruction of auricle of ear for congenital deformity or trauma
3. Tympanoplasty with mastoidectomy

ENDOCRINE SYSTEM TREATMENTS AND PROCEDURES

1. Thyroidectomy
2. Parathyroidectomy
3. Adrenalectomy
4. Pancreatectomy (subtotal or total)
**EYE TREATMENTS AND PROCEDURES**
(1) Eye muscle surgery
(2) Surgery for cataract with or without implantation of intraocular lens
(3) Retinal or vitreous surgery
(4) Reconstructive and/or plastic surgical procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma
(5) Photocoagulation and/or cryotherapy
(6) Corneal surgery, such as corneal transplant, refractive surgery and pterygium
(7) Glaucoma surgery by any method
(8) Removal of the eye or its contents (enucleation or evisceration)
(9) Surgery for penetrating ocular injury, including intraocular foreign body

**FEMALE GENITAL SYSTEM TREATMENTS AND PROCEDURES**
(1) Abdominal hysterectomy (total)
(2) Vaginal hysterectomy
(3) All fallopian tube and ovarian surgery with or without hysterectomy, including removal and lysis of adhesions
(4) Removing fibroids (uterine myomectomy)
(5) Uterine suspension
(6) Removal of the nerves to the uterus (presacral neurectomy)
(7) Removal of the cervix
(8) Repair of vaginal hernia (anterior and/or posterior colporrhaphy and/or enterocele repair)
(9) Abdominal suspension of the bladder (retropubic urethropexy)
(10) Conization of cervix
(11) Dilation and curettage of uterus (diagnostic/therapeutic)
(12) Surgical abortion/dilation and curettage/dilation and evacuation
(13) Medical abortion/non-surgical
(14) Selective salpingography and Fallopian tube recanalization
(15) Fallopian tube occlusion (for sterilization)

**HEMATIC AND LYMPHATIC SYSTEM**
(1) Transfusion of blood and blood components
(2) Splenectomy

**INTEGUMENTARY SYSTEM TREATMENTS AND PROCEDURES**
(1) Radical or modified radical mastectomy (simple mastectomy excluded)
(2) Reconstruction and/or plastic surgical operations of the face and neck
MALE GENITAL SYSTEM
(1) Orchidopexy (reposition of testis(es))
(2) Orchiectomy (removal of the testis(es))
(3) Vasectomy

MATERNITY AND RELATED CASES
(1) Delivery (vaginal)
(2) Delivery (cesarean section)
(3) Cerclage

MUSCULOSKELETAL SYSTEM TREATMENTS AND PROCEDURES
(1) Arthroplasty of any joints with mechanical device
(2) Arthroscopy of any joint
(3) Open reduction with internal fixation
(4) Osteotomy
(5) Ligamentous reconstruction of joints
(6) All other orthopedic procedures on children age 12 or under. Problems with appearance, use, or growth requiring additional surgery
(7) Vertebroplasty/kyphoplasty

NERVOUS SYSTEM TREATMENTS AND PROCEDURES
(1) Craniotomy, craniectomy or cranioplasty
(2) Cranial nerve operations
(3) Spine operation, including laminectomy, decompression, fusion, internal fixation or procedures for nerve root or spinal cord compression; diagnosis; pain; deformity; mechanical instability; injury; removal of tumor, abscess or hematoma (excluding coccygeal operations)
(4) Peripheral nerve operation; nerve grafts, decompression, transposition or tumor removal; neurorrhaphy, neurectomy or neurolysis
(5) Transphenoidal hypophysectomy or other pituitary gland operation
(6) Cerebral spinal fluid shunting procedure or revision

RADIOLOGY
(1) Splenoportography (needle injection of contrast media into the spleen)
(2) Chemoembolization
(3) Radioembolization
(4) Thermal and other ablative techniques for treatment of tumors (for curative intent or palliation) including radiofrequency ablation, cryoablation, and high intensity focused ultrasound (HIFU), irreversible electroporation
RADIOLOGY (cont)
(5) TIPS (Transjugular Intrahepatic Portosystemic Shunt) and its variants such as DIPS (Direct Intrahepatic Portocaval Shunt)
(6) Myelography
(7) Percutaneous abscess/fluid collection drainage (percutaneous abscess/seroma/lymphocele drainage and/or sclerosis (inclusive of percutaneous, transgluteal, transrectal and transvaginal routes))
(8) Procedures utilizing prolonged fluoroscopy

RESPIRATORY SYSTEM TREATMENTS AND PROCEDURES
(1) Biopsy and/or excision of lesion of larynx, vocal cords, trachea
(2) Rhinoplasty or nasal reconstruction with or without septroplasty
(3) Submucous resection of nasal septum or nasal septroplasty
(4) Lung biopsy
(5) Segmental resection of lung
(6) Thoracotomy
(7) Thoracotomy with drainage
(8) Open tracheostomy
(9) Respiratory tract/tracheobronchial balloon dilatation/stenting

URINARY SYSTEM
(1) Partial nephrectomy (removal of part of the kidney)
(2) Radical nephrectomy (removal of kidney and adrenal gland for cancer)
(3) Nephrectomy (removal of kidney)
(4) Nephrolithotomy and pyelolithotomy (removal of kidney stone(s))
(5) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system)
(6) Exploration of kidney or perinephric mass
(7) Ureteroplasty (reconstruction of ureter (tube between kidney and bladder))
(8) Ureterolithotomy (surgical removal of stone(s) from ureter (tube between kidney and bladder))
(9) Ureterectomy (partial/complete removal of ureter (tube between kidney and bladder))
(10) Ureterolysis (partial/complete removal of ureter (tube between kidney and bladder from adjacent tissue))
(11) Ureteral reimplantation (reinserting ureter (tube between kidney and bladder) into the bladder)
(12) Prostatectomy (partial or total removal of prostate)
(13) Total cystectomy (removal of bladder)
(14) Radical cystectomy
(15) Partial cystectomy (partial removal of bladder)
URINARY SYSTEM (cont)
(16) Urinary diversion (ileal conduit, colon conduit)
(17) Ureterosigmoidostomy (placement of kidney drainage tubes into the large bowel (intestine))
(18) Urethroplasty (construction/reconstruction of drainage tube from bladder)
(19) Percutaneous nephrostomy/stenting/stone removal
(20) Hemodialysis (technique to replace functions of kidney and clean blood of toxins)
(21) Peritoneal dialysis (technique to replace functions of kidney and clean blood of toxins)

PSYCHIATRIC PROCEDURES
(1) Electroconvulsive therapy with modification by intravenous muscle relaxants and sedatives

RADIATION THERAPY
(1) Head and neck
(2) Central nervous system
(3) Thorax
(4) Breast
(5) Abdomen
(6) Female pelvis
(7) Male pelvis
(8) Skin
(9) Extremities
(10) Total body irradiation

ENDOSCOPIC SURGERY
(1) Abdominal endoscopy/laparoscopy procedures. (These risks shall be in addition to risks and hazards of the same surgery when done as an open procedure.)
(2) Endoscopic surgery of the thorax. (These risks shall be in addition to risks and hazards of the same surgery when done as an open procedure.)

References:
36 Tex. Reg. 8557
2011 WL 6262925 (Tex.Reg.)
25 TAC §§ 601.2 - 601.4; 601.6; 601.9