

**TEXAS MEDICAL
DISCLOSURE PANEL**

INFORMED CONSENT

CHAPTER 601

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INDEX

§601.1 General.....	Page 1
§601.2 Procedures Requiring Full Disclosure of Specific Risks and Hazards -- List A.....	Page 2
(a) Anesthesia.....	Page 2
(b) Cardiovascular system.....	Page 3
(c) Digestive system treatments and procedures.....	Page 11
(d) Ear treatments and procedures.....	Page 14
(e) Endocrine system treatments and procedures.....	Page 14
(f) Eye treatments and procedures.....	Page 15
(g) Female genital system treatments and procedures.....	Page 17
(h) Hematic and lymphatic system.....	Page 21
(i) Integumentary system treatments and procedures.....	Page 22
(j) Male genital system.....	Page 23
(k) Maternity and related cases.....	Page 23
(l) Musculoskeletal system treatments and procedures.....	Page 24
(m) Nervous system treatments and procedures.....	Page 27
(n) Radiology.....	Page 29
(o) Respiratory system treatments and procedures.....	Page 31
(p) Urinary system.....	Page 33
(q) Psychiatric procedures.....	Page 40
(r) Radiation therapy.....	Page 40
(s) Laparoscopic/Thoracoscopic surgery.....	Page 52
(t) Pain management procedures.....	Page 52
(u) Dental surgery procedures.....	Page 53
(v) Plastic surgery.....	Page 58
§601.3 Procedures Requiring No Disclosure of Specific Risks and Hazards -- List B.....	Page 62
(a) Anesthesia.....	Page 62
(b) Cardiovascular system.....	Page 62
(c) Digestive system.....	Page 62
(d) Ear.....	Page 62
(e) Endocrine system.....	Page 63
(f) Eye.....	Page 63
(g) Female genital system.....	Page 63
(h) Hematic and lymphatic system.....	Page 63
(i) Integumentary system.....	Page 63
(j) Male genital system.....	Page 64
(k) Maternity and related cases.....	Page 64
(l) Musculoskeletal system.....	Page 64
(m) Nervous system.....	Page 64
(n) Radiology.....	Page 65

(o) Respiratory system.....	Page 67
(p) Urinary system.....	Page 67
(q) Psychiatric procedures.....	Page 67
(r) Radiation therapy.....	Page 67
(s) Endoscopic surgery.....	Page 68
(t) Pain management procedures.....	Page 68
(u) Dental surgery procedures.....	Page 68
§601.4 Disclosure and Consent Form.....	Page 69
§601.5 Disclosure and Consent Form for Radiation Therapy.....	Page 74
§601.6 History.....	Page 79
§601.7 Informed Consent for Electroconvulsive Therapy.....	Page 82
§601.8 Disclosure and Consent Form for Hysterectomy.....	Page 83
§601.9 Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia).....	Page 90

§601.1 General

(a) The purpose of this chapter is to implement the requirements of Texas Civil Practice and Remedies Code, Chapter 74, Medical Liability, Subchapter C, §74.102 (relating to Texas Medical Disclosure Panel).

(b) The treatments and procedures requiring full disclosure by a physician or health care provider to a patient or person authorized to consent for the patient are found in §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A).

(c) The treatments and procedures requiring no disclosure by a physician or health care provider to a patient or person authorized to consent for the patient are found in §601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B).

§601.2 Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A.

(a) Anesthesia.

(1) Epidural.

- (A) Nerve damage.
- (B) Persistent back pain.
- (C) Headache.
- (D) Bleeding/epidural hematoma.
- (E) Infection.
- (F) Medical necessity to convert to general anesthesia.
- (G) Brain damage.
- (H) Chronic pain.

(2) General.

- (A) Permanent organ damage.
- (B) Memory dysfunction/memory loss.
- (C) Injury to vocal cords, teeth, lips, eyes.
- (D) Awareness during the procedure.
- (E) Brain damage.

(3) Spinal.

- (A) Nerve damage.
- (B) Persistent back pain.
- (C) Bleeding/epidural hematoma.
- (D) Infection.
- (E) Medical necessity to convert to general anesthesia.

(F) Brain damage.

(G) Headache.

(H) Chronic pain.

(4) Regional block.

(A) Nerve damage.

(B) Persistent pain.

(C) Bleeding/hematoma.

(D) Infection.

(E) Medical necessity to convert to general anesthesia.

(F) Brain damage.

(5) Monitored Anesthesia Care (MAC) (conscious sedation).

(A) Permanent organ damage.

(B) Memory dysfunction/memory loss.

(C) Medical necessity to convert to general anesthesia.

(D) Brain damage.

(b) Cardiovascular system.

(1) Cardiac.

(A) Surgical.

(i) Coronary artery bypass, valve replacement.

(I) Acute myocardial infarction.

(II) Hemorrhage.

(III) Kidney failure.

(IV) Stroke.

(V) Sudden death.

(VI) Infection of chest wall/chest cavity.

(VII) Valve related delayed onset infection.

(ii) Heart transplant.

(I) Infection.

(II) Rejection.

(III) Death.

(B) Non-Surgical--Coronary angioplasty, coronary stent insertion, pacemaker insertion, AICD insertion, and cardioversion.

(i) All associated risks as listed under paragraph (2)(B) of this subsection.

(ii) Acute myocardial infarction (heart attack).

(iii) Rupture of myocardium (hole in wall of heart).

(iv) Life threatening arrhythmias (irregular heart rhythm).

(v) Need for emergency open heart surgery.

(vi) Sudden death.

(vii) Device related delayed onset infection (infection related to the device that happens sometime after surgery).

(C) Diagnostic.

(i) Cardiac catheterization.

(I) All associated risks as listed under paragraph (2)(B) of this subsection.

(II) Acute myocardial infarction (heart attack).

(III) Contrast nephropathy (injury to kidney function due to use of contrast material during procedure).

life threatening. (IV) Heart arrhythmias (irregular heart rhythm), possibly

(V) Need for emergency open heart surgery.

(ii) Electrophysiologic studies.

(I) Cardiac perforation.

(II) Life threatening arrhythmias.

intervention. (III) Injury to vessels that may require immediate surgical

(iii) Stress testing--Acute myocardial infarction.

(iv) Transesophageal echocardiography--Esophageal perforation.

(2) Vascular.

(A) Open surgical repair of aortic, subclavian, and iliac, artery aneurysms or occlusions, and renal artery bypass.

(i) Hemorrhage.

(ii) Paraplegia.

(iii) Kidney damage.

(iv) Stroke.

(v) Acute myocardial infarction.

(vi) Infection of graft.

(B) Angiography (inclusive of aortography, arteriography, venography) - Injection of contrast material into blood vessels.

(i) Injury to or occlusion (blocking) of artery which may require immediate surgery or other intervention.

(ii) Hemorrhage (severe bleeding).

(iii) Damage to parts of the body supplied by the artery with resulting loss of use or amputation (removal of body part).

(iv) Worsening of the condition for which the procedure is being done.

(v) Stroke and/or seizure (for procedures involving blood vessels supplying the spine, arms, neck or head).

(vi) Contrast-related, temporary blindness or memory loss (for studies of the blood vessels of the brain).

(vii) Paralysis (inability to move) and inflammation of nerves (for procedures involving blood vessels supplying the spine).

(viii) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).

(ix) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

(C) Angioplasty (intravascular dilatation technique).

(i) All associated risks as listed under paragraph (2)(B) of this subsection.

(ii) Failure of procedure or injury to blood vessel requiring stent (small, permanent tube placed in blood vessel to keep it open) placement or open surgery.

(D) 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.

(i) All associated risks as listed under paragraph (2)(B) of this subsection.

(ii) Change in procedure to open surgical procedure.

(iii) Failure to place stent/endoluminal graft (stent with fabric covering it).

(iv) Stent migration (stent moves from location in which it was placed).

(v) Vessel occlusion (blocking).

(vi) Impotence (difficulty with or inability to obtain penile erection) (for abdominal aorta and iliac artery procedures).

(E) Vascular thrombolysis (removal or dissolving of blood clots) - percutaneous (mechanical or chemical).

(i) All associated risks as listed under paragraph (2)(B) of this subsection.

(ii) Increased risk of bleeding at or away from site of treatment (when using medications to dissolve clots).

(iii) For arterial procedures: distal embolus (fragments of blood clot may travel and block other blood vessels with possible injury to the supplied tissue).

(iv) For venous procedures: pulmonary embolus (fragments of blood clot may travel to the blood vessels in the lungs and cause breathing problems or if severe could be life threatening).

(v) Kidney injury or failure which may be temporary or permanent (for procedures using certain mechanical thrombectomy devices).

(vi) Need for emergency surgery.

(F) Angiography with occlusion techniques (including embolization and sclerosis) - therapeutic.

(i) For all embolizations.

(I) Angiography risks (inclusive of aortography, arteriography, venography) - injection of contrast material into blood vessels.

(-a-) Unintended injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.

(-b-) Hemorrhage (severe bleeding).

(-c-) Damage to parts of the body supplied by the artery with resulting loss of use or amputation (removal of body part).

(-d-) Worsening of the condition for which the procedure is being done.

(-e-) Contrast nephropathy (kidney damage due to the contrast agent used during procedure).

(-f-) Unintended thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

(II) Loss or injury to body parts with potential need for surgery, including death of overlying skin for sclerotherapy/treatment of superficial lesions/vessels and nerve injury with associated pain, numbness or tingling or paralysis (inability to move).

(III) Infection in the form of abscess (infected fluid collection) or septicemia (infection of blood stream).

(IV) Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues supplied by those vessels).

(ii) For procedures involving the thoracic aorta and/or vessels supplying the brain, spinal cord, head, neck or arms, these risks in addition to those under clause (i) of this subparagraph:

(I) Stroke.

(II) Seizure.

(III) Paralysis (inability to move).

(IV) Inflammation or other injury of nerves.

(V) For studies of the blood vessels of the brain: contrast-related, temporary blindness or memory loss.

(iii) For female pelvic arterial embolizations including uterine fibroid embolization, these risks in addition to those under clause (i) of this subparagraph.

(I) Premature menopause with resulting sterility.

(II) Injury to or infection involving the uterus which might necessitate hysterectomy (removal of the uterus) with resulting sterility.

(III) After fibroid embolization: prolonged vaginal discharge.

(IV) After fibroid embolization: expulsion/delayed expulsion of fibroid tissue possibly requiring a procedure to deliver/remove the tissue.

(iv) For male pelvic arterial embolizations, in addition to the risks under clause (i) of this subparagraph: impotence (difficulty with or inability to obtain penile erection).

(v) For embolizations of pulmonary arteriovenous fistulae/malformations, these risks in addition to those under clause (i) of this subparagraph.

(I) New or worsening pulmonary hypertension (high blood pressure in the lung blood vessels).

(II) Paradoxical embolization passage of air or an occluding device beyond the fistula/malformation and into the arterial circulation) causing blockage of blood flow to tissues supplied by the receiving artery and damage to tissues served (for example the blood vessels supplying the heart (which could cause chest pain and/or heart attack) or brain (which could cause stroke, paralysis (inability to move) or other neurological injury)).

(vi) For varicocele embolization, these risks in addition to those under clause (i) of this subparagraph.

(I) Phlebitis/inflammation of veins draining the testicles leading to decreased size and possibly decreased function of affected testis and sterility (if both sides performed).

(II) Nerve injury (thigh numbness or tingling).

(vii) For ovarian vein embolization/pelvic congestion syndrome embolization: general angiography and embolization risks as listed in clause (i) of this subparagraph.

(viii) For cases utilizing ethanol (alcohol) injection, in addition to the risks under clause (i) of this subparagraph: shock or severe lowering of blood pressure.

(ix) For varicose vein treatments (with angiography) see subparagraph (L) of this paragraph.

(G) Mesenteric angiography with infusional therapy (Vasopressin) for gastrointestinal bleeding.

(i) All associated risks as listed under paragraph (2)(B) of this subsection.

(ii) Ischemia/infarction of supplied or distant vascular beds (reduction in blood flow causing lack of oxygen with injury or death of tissues supplied by the treated vessel or tissues supplied by blood vessels away from the treated site including heart, brain, bowel, extremities).

(iii) Antidiuretic hormone side effects of vasopressin (reduced urine output with disturbance of fluid balance in the body, rarely leading to swelling of the brain).

(H) Inferior vena caval filter insertion and removal.

subsection. (i) All associated risks as listed under paragraph (2)(B) of this

(ii) Injury to the inferior vena cava (main vein in the abdomen).

(iii) Filter migration or fracture (filter could break and/or move from where it was placed).

(iv) Caval thrombosis (clotting of the main vein in the abdomen and episodes of swelling of legs).

(v) Risk of recurrent pulmonary embolus (continued risk of blood clots going to blood vessels in the lungs despite filter).

(vi) Inability to remove filter (for “optional”/retrievable filters).

(I) Pulmonary angiography.

subsection. (i) All associated risks as listed under paragraph (2)(B) of this

(heart stops beating). (ii) Cardiac arrhythmia (irregular heart rhythm) or cardiac arrest

(iii) Cardiac injury/perforation (heart injury).

(iv) Death.

(J) Percutaneous treatment of pseudoaneurysm (percutaneous thrombin injection versus compression).

territory. (i) Thrombosis (clotting) of supplying vessel or branches in its

(ii) Allergic reaction to thrombin (agent used for direct injection).

(K) Vascular access - nontunneled catheters, tunneled catheters, implanted access.

(i) Pneumothorax (collapsed lung).

(ii) Injury to blood vessel.

(iii) Hemothorax/hemomediastinum (bleeding into the chest around the lungs or around the heart).

(iv) Air embolism (passage of air into blood vessel and possibly to the heart and/or blood vessels entering the lungs).

(v) Vessel thrombosis (clotting of blood vessel).

(L) Varicose vein treatment (percutaneous via laser, RFA, chemical or other method) without angiography.

(i) Burns.

(ii) Deep vein thrombosis (blood clots in deep veins).

(iii) Hyperpigmentation (darkening of skin).

(iv) Skin wound (ulcer).

(v) Telangiectatic matting (appearance of tiny blood vessels in treated area).

(vi) Paresthesia and dysesthesia (numbness or tingling in the area or limb treated).

(vii) Injury to blood vessel requiring additional procedure to treat.

(c) Digestive system treatments and procedures.

(1) Cholecystectomy with or without common bile duct exploration.

(A) Pancreatitis.

(B) Injury to the tube between the liver and the bowel.

(C) Retained stones in the tube between the liver and the bowel.

(D) Narrowing or obstruction of the tube between the liver and the bowel.

(E) Injury to the bowel and/or intestinal obstruction.

(2) Bariatric surgery.

(A) Laparoscopic.

(i) Conversion to open procedure.

(ii) Injury to organs.

- (iii) Failure of device requiring additional surgical procedure.
- (iv) Obstructive symptoms requiring additional surgical procedure.
- (v) Development of gallstones (Roux-En-Y).
- (vi) Development of metabolic and vitamin disorders (Roux-En-Y).
- (vii) Suture line leak with abscess or fistula formation.

Y).

(B) Open.

- wound).
- (i) Failure of wound to heal or wound dehiscence (separation of wound).
 - (ii) Injury to organs.
 - (iii) Failure of device requiring additional surgical procedure.
 - (iv) Obstructive symptoms requiring additional surgical procedure.
 - (v) Development of gallstones (Roux-En-Y).
 - (vi) Development of metabolic and vitamin disorders (Roux-En-Y).

Y).

(3) Pancreatectomy (subtotal or total).

- (A) Pancreatitis (subtotal).
- (B) Diabetes (total).
- (C) Lifelong requirement of enzyme and digestive medication.
- (D) Anastamotic leaks.

(4) Total colectomy.

- (A) Permanent ileostomy.
- (B) Injury to organs.
- (C) Infection.

(5) Subtotal colectomy.

- (A) Anastomotic leaks.
- (B) Temporary colostomy.
- (C) Infection.
- (D) Second surgery.
- (E) Injury to organs.

(6) Hepatobiliary drainage/intervention including percutaneous transhepatic cholangiography, percutaneous biliary drainage, percutaneous cholecystostomy, biliary stent placement (temporary or permanent), biliary stone removal/therapy.

- (A) Leakage of bile at the skin site or into the abdomen with possible peritonitis (inflammation of the abdominal lining and pain or if severe can be life threatening).
- (B) Pancreatitis (inflammation of the pancreas).
- (C) Hemobilia (bleeding into the bile ducts).
- (D) Cholangitis, cholecystitis, sepsis (inflammation/infection of the bile ducts, gallbladder or blood).
- (E) Pneumothorax (collapsed lung) or other pleural complications (complication involving chest cavity).

(7) Gastrointestinal tract stenting.

- (A) Stent migration (stent moves from location in which it was placed).
- (B) Esophageal/bowel perforation (creation of a hole or tear in the tube from the throat to the stomach or in the intestines).
- (C) Tumor ingrowth or other obstruction of stent.
- (D) For stent placement in the esophagus (tube from the throat to the stomach).
 - (i) Tracheal compression (narrowing of windpipe) with resulting or worsening of shortness of breath.
 - (ii) Reflux (stomach contents passing up into esophagus or higher).

(iii) Aspiration pneumonia (pneumonia from fluid getting in lungs)
(if stent in lower part of the esophagus).

(iv) Foreign body sensation (feeling like there is something in
throat) (for stent placement in the upper esophagus).

(d) Ear treatments and procedures.

(1) Stapedectomy.

(A) Diminished or bad taste.

(B) Total or partial loss of hearing in the operated ear.

(C) Brief or long-standing dizziness.

(D) Eardrum hole requiring more surgery.

(E) Ringing in the ear.

(2) Reconstruction of auricle of ear for congenital deformity or trauma.

(A) Less satisfactory appearance compared to possible alternative artificial
ear.

(B) Exposure of implanted material.

(3) Tympanoplasty with mastoidectomy.

(A) Facial nerve paralysis.

(B) Altered or loss of taste.

(C) Recurrence of original disease process.

(D) Total loss of hearing in operated ear.

(E) Dizziness.

(F) Ringing in the ear.

(e) Endocrine system treatments and procedures.

(1) Thyroidectomy.

(A) Acute airway obstruction requiring temporary tracheostomy.

(B) Injury to nerves resulting in hoarseness or impairment of speech.

(C) Injury to parathyroid glands resulting in low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness and muscle irritability.

(D) Lifelong requirement of thyroid medication.

(2) Parathyroidectomy.

(A) Acute airway obstruction requiring temporary tracheostomy.

(B) Injury to nerves resulting in hoarseness or impairment of speech.

(C) Low blood calcium levels that require extensive medication to avoid serious degenerative conditions, such as cataracts, brittle bones, muscle weakness, and muscle irritability.

(3) Adrenalectomy.

(A) Loss of endocrine functions.

(B) Lifelong requirement for hormone replacement therapy and steroid medication.

(C) Damage to kidneys.

(4) Other procedures.

(5) See also Pancreatectomy under subsection (c)(3) of this section (relating to digestive system treatments and procedures).

(f) Eye treatments and procedures.

(1) Eye muscle surgery.

(A) Additional treatment and/or surgery.

(B) Double vision.

(C) Partial or total blindness.

- (2) Surgery for cataract with or without implantation of intraocular lens.
 - (A) Complications requiring additional treatment and/or surgery.
 - (B) Need for glasses or contact lenses.
 - (C) Complications requiring the removal of implanted lens.
 - (D) Partial or total blindness.
- (3) Retinal or vitreous surgery.
 - (A) Complications requiring additional treatment and/or surgery.
 - (B) Recurrence or spread of disease.
 - (C) Partial or total blindness.
- (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.
 - (A) Worsening or unsatisfactory appearance.
 - (B) Creation of additional problems.
 - (i) Poor healing or skin loss.
 - (ii) Nerve damage with loss of use and/or feeling.
 - (iii) Painful or unattractive scarring.
 - (iv) Impairment of regional organs (inability or decreased ability of regional organs to work), such as eye or lip function.
 - (C) Recurrence of the original condition.
- (5) Photocoagulation and/or cryotherapy.
 - (A) Complications requiring additional treatment and/or surgery.
 - (B) Pain.
 - (C) Partial or total blindness.
- (6) Corneal surgery, such as corneal transplant, refractive surgery and pterygium.

- (A) Complications requiring additional treatment and/or surgery.
 - (B) Pain.
 - (C) Need for glasses or contact lenses.
 - (D) Partial or total blindness.
- (7) Glaucoma surgery by any method.
- (A) Complications requiring additional treatment and/or surgery.
 - (B) Worsening of the glaucoma.
 - (C) Pain.
 - (D) Partial or total blindness.
- (8) Removal of the eye or its contents (enucleation or evisceration).
- (A) Complications requiring additional treatment and/or surgery.
 - (B) Worsening or unsatisfactory appearance.
 - (C) Recurrence or spread of disease.
- (9) Surgery for penetrating ocular injury, including intraocular foreign body.
- (A) Complications requiring additional treatment and/or surgery.
 - (B) Possible removal of eye.
 - (C) Pain.
 - (D) Partial or total blindness.

(g) Female genital system treatments and procedures.

- (1) Abdominal hysterectomy (total).
- (A) Uncontrollable leakage of urine.
 - (B) Injury to bladder.
 - (C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(F) Injury resulting from use of a power morcellator in laparoscopic surgery (see subsection (s)(2) of this section).

(2) Vaginal hysterectomy.

(A) Uncontrollable leakage of urine.

(B) Injury to bladder.

(C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(F) Completion of operation by abdominal incision.

(G) Injury resulting from use of a power morcellator in laparoscopic surgery (see subsection (s)(2) of this section).

(3) All fallopian tube and ovarian surgery with or without hysterectomy, including removal and lysis of adhesions.

(A) Injury to the bowel and/or bladder.

(B) Sterility.

(C) Failure to obtain fertility (if applicable).

(D) Failure to obtain sterility (if applicable).

(E) Loss of ovarian functions or hormone production from ovary(ies).

(4) Reserved.

(5) Removing fibroids (uterine myomectomy).

(A) Uncontrollable leakage of urine.

(B) Injury to bladder.

(C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(6) Uterine suspension.

(A) Uncontrollable leakage of urine.

(B) Injury to bladder.

(C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(7) Removal of the nerves to the uterus (presacral neurectomy).

(A) Uncontrollable leakage of urine.

(B) Injury to bladder.

(C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(F) Hemorrhage, complications of hemorrhage, with additional operation.

(8) Removal of the cervix.

(A) Uncontrollable leakage of urine.

(B) Injury to bladder.

(C) Sterility.

(D) Injury to the tube (ureter) between the kidney and the bladder.

(E) Injury to the bowel and/or intestinal obstruction.

(F) Completion of operation by abdominal incision.

(9) Repair of vaginal hernia (anterior and/or posterior colporrhaphy and/or enterocele repair).

- (A) Uncontrollable leakage of urine.
- (B) Injury to bladder.
- (C) Sterility.
- (D) Injury to the tube (ureter) between the kidney and the bladder.
- (E) Injury to the bowel and/or intestinal obstruction.

(10) Abdominal suspension of the bladder (retropubic urethropexy).

- (A) Uncontrollable leakage of urine.
- (B) Injury to bladder.
- (C) Injury to the tube (ureter) between the kidney and the bladder.
- (D) Injury to the bowel and/or intestinal obstruction.

(11) Conization of cervix.

- (A) Hemorrhage with possible hysterectomy to control.
- (B) Sterility.
- (C) Injury to bladder.
- (D) Injury to rectum.
- (E) Failure of procedure to remove all of cervical abnormality.

(12) Dilation and curettage of uterus (diagnostic/therapeutic).

- (A) Hemorrhage with possible hysterectomy.
- (B) Perforation of the uterus.
- (C) Sterility.
- (D) Injury to bowel and/or bladder.
- (E) Abdominal incision and operation to correct injury.

(13) Surgical abortion/dilation and curettage/dilation and evacuation.

- (A) Hemorrhage with possible hysterectomy to control.
- (B) Perforation of the uterus.
- (C) Sterility.
- (D) Injury to the bowel and/or bladder.
- (E) Abdominal incision and operation to correct injury.
- (F) Failure to remove all products of conception.

(14) Medical abortion/non-surgical.

- (A) Hemorrhage with possible need for surgical intervention.
- (B) Failure to remove all products of conception.
- (C) Sterility.

(15) Selective salpingography and Fallopian tube recanalization.

- (A) Perforation (hole) created in the uterus or Fallopian tube.
- (B) Ectopic pregnancy (pregnancy outside of the uterus).
- (C) Pelvic infection.

(16) Fallopian tube occlusion (for sterilization).

- (A) Risks listed in selective salpingography and Fallopian tube recanalization.
- (B) Failure to provide sterilization.
- (C) Coil expulsion (coil falls out of Fallopian tube).

(h) Hematic and lymphatic system.

- (1) Transfusion of blood and blood components.

(A) Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.

(B) Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system.

(C) Severe allergic reaction, potentially fatal.

(2) Splenectomy.

(A) Susceptibility to infections and increased severity of infections.

(B) Increased immunization requirements.

(i) Integumentary system treatments and procedures.

(1) Radical or modified radical mastectomy. (Simple mastectomy excluded).

(A) Limitation of movement of shoulder and arm.

(B) Swelling of the arm.

(C) Loss of the skin of the chest requiring skin graft.

(D) Recurrence of malignancy, if present.

(E) Decreased sensation or numbness of the inner aspect of the arm and chest wall.

(2) Reconstruction and/or plastic surgical operations of the face and neck.

(A) Worsening or unsatisfactory appearance.

(B) Creation of several additional problems.

(i) Poor healing or skin loss.

(ii) Nerve damage.

(iii) Painful or unattractive scarring.

(iv) Impairment of regional organs, such as eye or lip function.

(C) Recurrence of the original condition.

(j) Male genital system.

(1) Orchidopexy (reposition of testis(es)).

(A) Removal of testicle.

(B) Atrophy (shriveling) of the testicle with loss of function.

(2) Orchiectomy (removal of the testis(es)).

(A) Decreased sexual desire.

(B) Difficulties with penile erection.

(C) Permanent sterility (inability to father children) if both testes are removed.

(3) Vasectomy.

(A) Loss of testicle.

(B) Failure to produce permanent sterility (inability to father children).

(k) Maternity and related cases.

(1) Delivery (vaginal).

(A) Injury to bladder and/or rectum, including a fistula (hole) between bladder and vagina and/or rectum and vagina.

(B) Hemorrhage (severe bleeding) possibly requiring blood administration and/or hysterectomy (removal of uterus) and/or artery ligation (tying off) to control.

(C) Sterility (inability to get pregnant).

(D) Brain damage, injury or even death occurring to the fetus before or during labor and/or vaginal delivery whether or not the cause is known.

(2) Delivery (cesarean section).

(A) Injury to bowel and/or bladder.

(B) Sterility (inability to get pregnant).

(C) Injury to ureter (tube between kidney and bladder).

(D) Brain damage, injury or even death occurring to the fetus before or during labor and/or cesarean delivery whether or not the cause is known.

(E) Uterine disease or injury requiring hysterectomy (removal of uterus).

(3) Cerclage.

(A) Premature labor.

(B) Injury to bowel and/or bladder.

(I) Musculoskeletal system treatments and procedures.

(1) Arthroplasty of any joints with mechanical device.

(A) Impaired function such as shortening or deformity.

(B) Blood vessel or nerve injury.

(C) Pain or discomfort.

(D) Blood clot in blood vessels which can block flow of blood to lungs or limbs and/or cause swelling in limbs.

(E) Failure of bone to heal.

(F) Bone infection.

(G) Removal or replacement of any implanted device or material.

(H) Various functional or cosmetic growth deformities requiring additional surgery.

(I) If performed on a child age 12 or under, include the following additional risks: problems with appearance, use, or growth requiring additional surgery.

(2) Arthroscopy of any joint.

(A) Blood vessel or nerve injury.

(B) Continued pain.

(C) Stiffness of joint.

(D) Blood clot in blood vessels which can block flow of blood to lungs or limbs and/or cause swelling in limbs.

(E) Joint infection.

(F) Various functional or cosmetic growth deformities requiring additional surgery.

(G) If performed on a child age 12 or under, include the following additional risks: problems with appearance, use, or growth requiring additional surgery.

(3) Open reduction with internal fixation.

(A) Impaired function such as shortening or deformity.

(B) Blood vessel or nerve injury.

(C) Pain or discomfort.

(D) Blood clot in blood vessels which can block flow of blood to lungs or limbs and/or cause swelling in limbs.

(E) Failure of bone to heal.

(F) Bone infection.

(G) Removal or replacement of any implanted device or material.

(H) Problems with appearance, use, or growth requiring additional surgery.

(4) Osteotomy.

(A) Impaired function such as shortening or deformity.

(B) Blood vessel or nerve injury.

(C) Pain or discomfort.

(D) Blood clot in blood vessels which can block flow of blood to lungs or limbs and/or cause swelling in limbs.

(E) Failure of bone to heal.

(F) Bone infection.

(G) Removal or replacement of any implanted device or material.

(H) If performed on a child age 12 or under, include the following additional risks: problems with appearance, use, or growth requiring additional surgery.

(5) Ligamentous reconstruction of joints.

(A) Failure of reconstruction to work.

(B) Continued instability of the joint.

(C) Degenerative arthritis.

(D) Continued pain.

(E) Stiffness of joint.

(F) Blood vessel or nerve injury.

(G) Impaired function and/or scarring.

(H) Blood clot in blood vessels which can block flow of blood to lungs or limbs and/or cause swelling in limbs.

(I) If performed on a child age 12 or under, include the following additional risks: problems with appearance, use, or growth requiring additional surgery.

(6) Vertebroplasty/kyphoplasty.

(A) Nerve/spinal cord injury.

(B) Need for emergency surgery.

(C) Embolization of cement (cement used passes into blood vessels and possibly all the way to the blood vessels in the lungs).

(D) Fracture of adjacent vertebrae (bones in spine).

(E) Leak of cerebrospinal fluid (fluid around the brain and spinal cord).

(F) Pneumothorax (collapsed lung).

(G) Worsening of pain.

(H) Rib or vertebral (spine) fracture.

(7) If the following procedures are performed on a child age 12 or under, problems with appearance, use, or growth requiring additional surgery should be disclosed.

- (A) Arthrotomy, arthrocentesis, or joint injection.
- (B) Closed reduction without internal fixation.
- (C) Wound debridement.
- (D) Needle biopsy or aspiration, bone marrow.
- (E) Partial excision of bone.
- (F) Removal of external fixation device.
- (G) Traction or fixation without manipulation for reduction.

(m) Nervous system treatments and procedures.

(1) Craniotomy, craniectomy or cranioplasty.

- (A) Additional loss of brain function including memory.
- (B) Recurrence, continuation or worsening of the condition that required this operation.
- (C) Stroke.
- (D) Blindness, deafness, inability to smell, double vision, coordination loss, seizures, pain, numbness and paralysis.
- (E) Cerebral spinal fluid leak with potential for meningitis and severe headaches.
- (F) Meningitis.
- (G) Brain abscess.
- (H) Persistent vegetative state.
- (I) Heart attack.

(2) Cranial nerve operations.

(A) Numbness, impaired muscle function or paralysis.

(B) Recurrence, continuation or worsening of the condition that required this operation.

(C) Seizures.

(D) New or different pain.

(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).

(A) Pain, numbness or clumsiness.

(B) Impaired muscle function or paralysis.

(C) Incontinence, impotence or impaired bowel function.

(D) Unstable spine.

(E) Recurrence, continuation or worsening of the condition that required the operation.

(F) Injury to major blood vessels.

(G) Hemorrhage.

(4) Peripheral nerve operation; nerve grafts, decompression, transposition or tumor removal; neurorrhaphy, neurectomy or neurolysis.

(A) Numbness.

(B) Impaired muscle function.

(C) Recurrence, continuation or worsening of the condition that required the operation.

(D) Continued, increased or different pain.

(5) Transphenoidal hypophysectomy or other pituitary gland operation.

(A) Spinal fluid leak.

(B) Necessity for hormone replacement.

operation.

- (C) Recurrence or continuation of the condition that required this

- (D) Nasal septal deformity or perforation.

- (E) Facial numbness and disfigurement.

- (F) Blindness.

(6) Cerebral spinal fluid shunting procedure or revision.

- (A) Shunt obstruction, migration or infection.

- (B) Seizure disorder.

- (C) Recurrence or continuation of brain dysfunction.

- (D) Injury to internal organs.

- (E) Possible brain injury or hemorrhage.

(n) Radiology.

(1) Splenoportography (needle injection of contrast media into the spleen).

- (A) All associated risks as listed under subsection (b)(2)(B) of this section.

- (B) Injury to the spleen requiring blood transfusion and/or removal of the spleen.

(2) Chemoembolization.

- (A) All associated risks as listed under subsection (b)(2)(B) of this section.

- (B) Tumor lysis syndrome (rapid death of tumor cells, releasing their contents which can be harmful).

- (C) Injury to or failure of liver (or other organ in which tumor is located).

- (D) Risks of the chemotherapeutic agent(s) utilized.

- (E) Cholecystitis (inflammation of the gallbladder) (for liver or other upper GI embolizations).

(F) Abscess (infected fluid collection) in the liver or other embolized organ requiring further intervention.

(G) Biloma (collection of bile in or near the liver requiring drainage) (for liver embolizations).

(3) Radioembolization.

(A) All associated risks as listed under subsection (b)(2)(B) of this section.

(B) Tumor lysis syndrome (rapid death of tumor cells, releasing their contents which can be harmful).

(C) Injury to or failure of liver (or other organ in which tumor is located).

(D) Radiation complications: pneumonitis (inflammation of lung) which is potentially fatal; inflammation of stomach, intestines, gallbladder, pancreas; stomach or intestinal ulcer; scarring of liver.

(4) Thermal and other ablative techniques for treatment of tumors (for curative intent or palliation) including radiofrequency ablation, microwave ablation, cryoablation, and high intensity focused ultrasound (HIFU).

(A) Injury to tumor-containing organ or adjacent organs/structures.

(B) Injury to nearby nerves potentially resulting in temporary or chronic (continuing) pain and/or loss of use and/or feeling.

(C) Failure to completely treat tumor.

(5) TIPS (Transjugular Intrahepatic Portosystemic Shunt) and its variants such as DIPS (Direct Intrahepatic Portocaval Shunt).

(A) All associated risks as listed under subsection (b)(2)(B) - (D) of this section.

(B) Hepatic encephalopathy (confusion/decreased ability to think).

(C) Liver failure or injury.

(D) Gallbladder injury.

(E) Hemorrhage (severe bleeding).

(F) Recurrent ascites (fluid building up in abdomen) and/or bleeding.

(G) Kidney failure.

(H) Heart failure.

(I) Death.

(6) Myelography.

(A) Chronic (continuing) pain.

(B) Nerve injury with loss of use and/or feeling.

(C) Transient (temporary) headache, nausea, and/or vomiting.

(D) Numbness.

(E) Seizure.

(7) Percutaneous abscess/fluid collection drainage (percutaneous abscess/seroma/lymphocele drainage and/or sclerosis (inclusive of percutaneous, transgluteal, transrectal and transvaginal routes)).

(A) Sepsis (infection in the blood stream), possibly resulting in shock (severe decrease in blood pressure).

(B) Injury to nearby organs.

(C) Hemorrhage (severe bleeding).

(D) Infection of collection which was not previously infected, or additional infection of abscess.

(8) Procedures utilizing prolonged fluoroscopy.

(A) Skin injury (such as epilation (hair loss), burns, or ulcers).

(B) Cataracts (for procedures in the region of the head).

(o) Respiratory system treatments and procedures.

(1) Biopsy and/or excision of lesion of larynx, vocal cords, trachea.

(A) Loss or change of voice.

(B) Swallowing or breathing difficulties.

(C) Perforation (hole) or fistula (connection) in esophagus (tube from throat to stomach).

(2) Rhinoplasty or nasal reconstruction with or without septoplasty.

(A) Deformity of skin, bone or cartilage.

(B) Creation of new problems, such as perforation of the nasal septum (hole in wall between the right and left halves of the nose) or breathing difficulty.

(3) Submucous resection of nasal septum or nasal septoplasty.

(A) Persistence, recurrence or worsening of the obstruction.

(B) Perforation of nasal septum (hole in wall between the right and left halves of the nose) with dryness and crusting.

(C) External deformity of the nose.

(4) Lung biopsy.

(A) Pneumothorax (collapsed lung).

(B) Hemothorax (blood in the chest around the lung).

(5) Segmental resection of lung.

(A) Hemothorax (blood in the chest around the lung).

(B) Abscess (infected fluid collection) in chest.

(C) Insertion of tube into space between lung and chest wall or repeat surgery.

(D) Need for additional surgery.

(6) Thoracotomy.

(A) Hemothorax (blood in the chest around the lung).

(B) Abscess (infected fluid collection) in chest.

(C) Pneumothorax (collapsed lung).

(D) Need for additional surgery.

(7) Thoracotomy with drainage.

- (A) Hemothorax (blood in the chest around the lung).
- (B) Abscess (infected fluid collection) in chest.
- (C) Pneumothorax (collapsed lung).
- (D) Need for additional surgery.

(8) Open tracheostomy.

- (A) Loss of voice.
- (B) Breathing difficulties.
- (C) Pneumothorax (collapsed lung).
- (D) Hemothorax (blood in the chest around the lung).
- (E) Scarring in trachea (windpipe).
- (F) Fistula (connection) between trachea into esophagus (tube from throat to stomach) or great vessels.

(9) Respiratory tract/tracheobronchial balloon dilatation/stenting.

- (A) Stent migration (stent moves from position in which it was placed).
 - (B) Pneumomediastinum (air enters the space around the airways including the space around the heart).
 - (C) Mucosal injury (injury to lining of airways).
-

(p) Urinary system.

(1) Partial nephrectomy (removal of part of the kidney).

- (A) Incomplete removal of stone(s) or tumor, if present.
- (B) Blockage of urine.
- (C) Leakage of urine at surgical site.

- (D) Injury to or loss of the kidney.
 - (E) Damage to organs next to kidney.
- (2) Radical nephrectomy (removal of kidney and adrenal gland for cancer).
- (A) Loss of the adrenal gland (gland on top of kidney that makes certain hormones/chemicals the body needs).
 - (B) Incomplete removal of tumor.
 - (C) Damage to organs next to kidney.
- (3) Nephrectomy (removal of kidney).
- (A) Incomplete removal of tumor if present.
 - (B) Damage to organs next to kidney.
 - (C) Injury to or loss of the kidney.
- (4) Nephrolithotomy and pyelolithotomy (removal of kidney stone(s)).
- (A) Incomplete removal of stone(s).
 - (B) Blockage of urine.
 - (C) Leakage of urine at surgical site.
 - (D) Injury or loss of the kidney.
 - (E) Damage to organs next to kidney.
- (5) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system).
- (A) Blockage of urine.
 - (B) Leakage of urine at surgical site.
 - (C) Injury to or loss of the kidney.
 - (D) Damage to organs next to kidney.
- (6) Exploration of kidney or perinephric mass.

(A) Incomplete removal of stone(s) or tumor, if present.

(B) Leakage of urine at surgical site.

(C) Injury to or loss of the kidney.

(D) Damage to organs next to kidney.

(7) Ureteroplasty (reconstruction of ureter (tube between kidney and bladder)).

(A) Leakage of urine at surgical site.

(B) Incomplete removal of the stone or tumor (when applicable).

(C) Blockage of urine.

(D) Damage to organs next to ureter.

(E) Damage to or loss of the ureter.

(8) Ureterolithotomy (surgical removal of stone(s) from ureter (tube between kidney and bladder)).

(A) Leakage of urine at surgical site.

(B) Incomplete removal of stone.

(C) Blockage of urine.

(D) Damage to organs next to ureter.

(E) Damage to or loss of ureter.

(9) Ureterectomy (partial/complete removal of ureter (tube between kidney and bladder)).

(A) Leakage of urine at surgical site.

(B) Incomplete removal of tumor (when applicable).

(C) Blockage of urine.

(D) Damage to organs next to ureter.

(10) Ureterolysis (partial/complete removal of ureter (tube between kidney and bladder from adjacent tissue)).

- (A) Leakage of urine at surgical site.
- (B) Blockage of urine.
- (C) Damage to organs next to ureter.
- (D) Damage to or loss of ureter.

(11) Ureteral reimplantation (reinserting ureter (tube between kidney and bladder) into the bladder).

- (A) Leakage of urine at surgical site.
- (B) Blockage of urine.
- (C) Damage to or loss of ureter.
- (D) Backward flow of urine from bladder into ureter.
- (E) Damage to organs next to ureter.

(12) Prostatectomy (partial or total removal of prostate).

- (A) Leakage of urine at surgical site.
- (B) Blockage of urine.
- (C) Incontinence (difficulty with control of urine flow).
- (D) Semen passing backward into bladder.
- (E) Difficulty with penile erection (possible with partial and probable with total prostatectomy).

(13) Total cystectomy (removal of urinary bladder).

- (A) Probable loss of penile erection and ejaculation in the male.
- (B) Damage to organs next to bladder.
- (C) This procedure will require an alternate method of urinary drainage.

(14) Radical cystectomy.

- (A) Probable loss of penile erection and ejaculation in the male.

- (B) Damage to organs next to bladder.
- (C) This procedure will require an alternate method of urinary drainage.
- (D) Chronic (continuing) swelling of thighs, legs and feet.
- (E) Recurrence or spread of cancer if present.

(15) Partial cystectomy (partial removal of bladder).

- (A) Leakage of urine at surgical site.
- (B) Incontinence (difficulty with control of urine flow).
- (C) Backward flow of urine from bladder into ureter (tube between kidney and bladder).
- (D) Blockage of urine.
- (E) Damage to organs next to bladder.

(16) Urinary diversion (ileal conduit, colon conduit).

- (A) Blood chemistry abnormalities requiring medication.
- (B) Development of stones, strictures or infection in the kidneys, ureter or bowel (intestine).
- (C) Leakage of urine at surgical site.
- (D) This procedure will require an alternate method of urinary drainage.

(17) Ureterosigmoidostomy (placement of kidney drainage tubes into the large bowel (intestine)).

- (A) Blood chemistry abnormalities requiring medication.
- (B) Development of stones, strictures or infection in the kidneys, ureter or bowel (intestine).
- (C) Leakage of urine at surgical site.
- (D) Difficulty in holding urine in the rectum.

(18) Urethroplasty (construction/reconstruction of drainage tube from bladder).

- (A) Leakage of urine at surgical site.
- (B) Stricture formation (narrowing of urethra (tube from bladder to outside)).
- (C) Need for additional surgery.

(19) Percutaneous nephrostomy/stenting/stone removal.

- (A) Pneumothorax or other pleural complications (collapsed lung or filling of the chest cavity on the same side with fluid).
- (B) Septic shock/bacteremia (infection of the blood stream with possible shock/severe lowering of blood pressure) when pyonephrosis (infected urine in the kidney) present.
- (C) Bowel (intestinal) injury.
- (D) Blood vessel injury with or without significant bleeding.

(20) Dialysis (technique to replace functions of kidney and clean blood of toxins).

- (A) Hemodialysis.
 - (i) Hypotension (low blood pressure).
 - (ii) Hypertension (high blood pressure).
 - (iii) Air embolism (air bubble in blood vessel) resulting in possible death or paralysis.
 - (iv) Cardiac arrhythmias (irregular heart rhythms).
 - (v) Infections of blood stream, access site, or blood borne (for example: Hepatitis B, C, or HIV).
 - (vi) Hemorrhage (severe bleeding as a result of clotting problems or due to disconnection of the bloodline).
 - (vii) Nausea, vomiting, cramps, headaches, and mild confusion during and/or temporarily after dialysis.
 - (viii) Allergic reactions.

change in blood minerals).
(ix) Chemical imbalances and metabolic disorders (unintended

(x) Pyrogenic reactions (fever).

(xi) Hemolysis (rupture of red blood cells).

(xii) Graft/fistula damage including bleeding, aneurysm, formation (ballooning of vessel), clotting (closure) of graft/fistula.

(B) Peritoneal dialysis.

(i) Infections, including peritonitis (inflammation or irritation of the tissue lining the inside wall of abdomen and covering organs), catheter infection and catheter exit site infection.

(ii) Development of hernias of umbilicus (weakening of abdominal wall or muscle).

(iii) Hypertension (high blood pressure).

(iv) Hypotension (low blood pressure).

(v) Hydrothorax (fluid in chest cavity).

(vi) Arrhythmia (irregular heart rhythm).

(vii) Perforation of the bowel.

(viii) Sclerosis or scarring of the peritoneum.

(ix) Weight gain leading to obesity.

(x) Abdominal discomfort/distension.

(xi) Heartburn or reflux.

(xii) Increase in need for anti-diabetic medication.

(xiii) Muscle weakness.

(xiv) Dehydration (extreme loss of body fluid).

(xv) Chemical imbalances and metabolic disorders (unintended change in blood minerals).

(xvi) Allergic reactions.

(xvii) Nausea, vomiting, cramps, headaches, and mild confusion during and/or temporarily after dialysis.

(q) Psychiatric procedures.

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

(A) Memory changes of events prior to, during, and immediately following the treatment.

(B) Fractures or dislocations of bones.

(C) Significant temporary confusion requiring special care.

(2) Other Procedures. No other procedures are assigned at this time.

(r) Radiation therapy. A child is defined for the purpose of this subsection as an individual who is not physiologically mature as determined by the physician using the appropriate medical parameters.

(1) Head and neck.

(A) Early reactions.

(i) Reduced and sticky saliva, loss of taste and appetite, altered sense of smell, nausea.

(ii) Sore throat, difficulty swallowing, weight loss, fatigue.

(iii) Skin changes: redness, irritation, scaliness, blistering or ulceration, color change, thickening, hair loss.

(iv) Hoarseness, cough, loss of voice, and swelling of airway.

(v) Blockage and crusting of nasal passages.

(vi) Inflammation of ear canal, feeling of "stopped up" ear, hearing loss, dizziness.

(vii) Dry and irritable eye(s).

(viii) In children, these reactions are likely to be intensified by chemotherapy before, during or after radiation therapy.

(ix) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

(i) Dry mouth and altered sense, or loss, of taste.

(ii) Tooth decay and gum changes.

(iii) Bone damage, especially in jaws.

(iv) Stiffness and limitation of jaw movement.

(v) Changes in skin texture and/or coloration, permanent hair loss, and scarring of skin.

(vi) Swelling of tissues, particularly under the chin.

(vii) Throat damage causing hoarseness, pain or difficulty breathing or swallowing.

(viii) Eye damage causing dry eye(s), cataract, loss of vision, or loss of eye(s).

(ix) Ear damage causing dryness of ear canal, fluid collection in middle ear, hearing loss.

(x) Brain, spinal cord or nerve damage causing alteration of thinking ability or memory, and/or loss of strength, feeling or coordination in any part of the body.

(xi) Pituitary or thyroid gland damage requiring long-term hormone replacement therapy.

(xii) In children, there may be additional late reactions.

(I) Disturbance of bone and tissue growth.

(II) Bone damage to face causing abnormal development.

(III) Brain damage causing a loss of intellectual ability, learning capacity, and reduced intelligence quotient (IQ).

(IV) Second cancers developing in the irradiated area.

(2) Central nervous system.

(A) Early reactions.

(i) Skin and scalp reaction with redness, irritation, scaliness, blistering, ulceration, change in color, thickening, hair loss.

(ii) Nausea, vomiting, headaches.

(iii) Fatigue, drowsiness.

(iv) Altered sense of taste or smell.

(v) Inflammation of ear canal, feeling of "stopped-up" ear, hearing loss, dizziness.

(vi) Depression of blood count leading to increased risk of infection and/or bleeding.

(vii) In children, these reactions are likely to be intensified by chemotherapy before, during or after radiation therapy.

(viii) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

(i) Permanent hair loss of variable degrees, altered regrowth, texture and color of hair.

(ii) Persistent drowsiness and tiredness.

(iii) Brain damage causing a loss of some degree of thinking ability or memory, or personality changes.

(iv) Scarring of skin.

(v) Spinal cord or nerve damage causing loss of strength, feeling or coordination in any part of the body.

(vi) Damage to eye(s), or optic nerve(s) causing loss of vision.

(vii) Ear damage causing dryness of ear canal, fluid collection in middle ear, hearing loss.

(viii) Pituitary gland damage requiring long-term hormone replacement therapy.

(ix) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to spine, causing stunting of growth, curvature and/or reduction in height.

(III) Bone damage to face, or pelvis causing stunting of bone growth and/or abnormal development.

(IV) Brain damage causing a loss of intellectual ability, learning capacity, and reduced intelligence quotient (IQ).

(V) Second cancers developing in the irradiated area.

(3) Thorax.

(A) Early reactions.

(i) Skin changes: redness, irritation, scaliness, ulceration, change in color, thickening, hair loss.

(ii) Inflammation of esophagus causing pain on swallowing, heartburn, or sense of obstruction.

(iii) Loss of appetite, nausea, vomiting.

(iv) Weight loss, weakness, vomiting.

(v) Inflammation of the lung with pain, fever and cough.

(vi) Inflammation of the heart sac with chest pain and palpitations.

(vii) Bleeding or creation of a fistula resulting from tumor destruction.

(viii) Depression of blood count leading to increased risk of infection and/or bleeding.

(ix) Intermittent electric shock-like feelings in the lower spine or legs on bending the neck.

(x) In children, these reactions are likely to be intensified by chemotherapy before, during or after radiation therapy.

(xi) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

(i) Changes in skin texture and/or coloration, permanent hair loss and scarring of skin.

(ii) Lung scarring or shrinkage causing shortness of breath.

(iii) Narrowing of esophagus causing swallowing problems.

(iv) Constriction of heart sac which may require surgical correction.

(v) Damage to heart muscle or arteries leading to heart failure.

(vi) Fracture of ribs.

(vii) Nerve damage causing pain, loss of strength or feeling in arms.

(viii) Spinal cord damage causing loss of strength or feeling in arms and legs, and/or loss of control of bladder and rectum.

(ix) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to spine, causing stunting of growth, curvature and/or reduction in height.

(III) Underdevelopment or absence of development of female breast.

(IV) Second cancers developing in the irradiated area.

(4) Breast.

(A) Early reactions.

(i) Skin changes: redness, irritation, scaliness, blistering, ulceration, coloration, thickening, and hair loss.

(ii) Breast changes including swelling, tightness, or tenderness.

(iii) Inflammation of the esophagus causing pain or swallowing, heartburn, or sense of obstruction.

(iv) Lung inflammation with cough.

(v) Inflammation of heart sac with chest pain and palpitations.

(B) Late reactions.

(i) Changes in skin texture and/or coloration, permanent hair loss, scarring of skin.

(ii) Breast changes including thickening, firmness, tenderness, shrinkage.

(iii) Swelling of arm.

(iv) Stiffness and discomfort in shoulder joint.

(v) Rib or lung damage causing pain, fracture, cough, shortness of breath.

(vi) Nerve damage causing pain, loss of strength or feeling in arm.

(vii) Damage to heart muscle or arteries or heart sac leading to heart failure.

(5) Abdomen.

(A) Early reactions.

(i) Skin changes: redness, irritation, scaliness, ulceration, coloration, thickening, hair loss.

(ii) Loss of appetite, nausea, vomiting.

(iii) Weight loss, weakness, fatigue.

(iv) Inflammation of stomach causing indigestion, heartburn, and ulcers.

(v) Inflammation of bowel causing cramping and diarrhea.

(vi) Depression of blood count leading to increased risk of infections and/or bleeding.

(vii) In children, these reactions are likely to be intensified by chemotherapy before, during and after radiation therapy.

(viii) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

(i) Changes in skin texture and/or coloration, permanent hair loss, scarring of skin.

(ii) Stomach damage causing persistent indigestion, pain, and bleeding.

(iii) Bowel damage causing narrowing or adhesions of bowel with obstruction, ulceration, or bleeding which may require surgical correction, chronic diarrhea, or poor absorption of food elements.

(iv) Kidney damage leading to kidney failure and/or high blood pressure.

(v) Liver damage leading to liver failure.

(vi) Spinal cord or nerve damage causing loss of strength or feeling in legs and/or loss of control of bladder and/or rectum.

(vii) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to spine causing stunting of growth, curvature and/or reduction in height.

(III) Bone damage to pelvis causing stunting of bone growth and/or abnormal development.

(IV) Second cancers developing in the irradiated area.

(6) Female pelvis.

(A) Early reactions.

(i) Inflammation of bowel causing cramping and diarrhea.

- discharge, bleeding.
- (ii) Inflammation of rectum and anus causing pain, spasm,
- pain, bleeding.
- (iii) Bladder inflammation causing burning, frequency, spasm,
- (iv) Skin changes: redness, irritation, scaliness, blistering or ulceration, coloration, thickening, hair loss.
- (v) Disturbance of menstrual cycle.
- (vi) Vaginal discharge, pain, irritation, bleeding.
- (vii) Depression of blood count leading to increased risk of infection and/or bleeding.
- (viii) In children, these reactions are likely to be intensified by chemotherapy before, during, or after radiation therapy.
- (ix) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

- (i) Bowel damage causing narrowing or adhesions of the bowel with obstruction, ulceration, bleeding, chronic diarrhea, or poor absorption of food elements and may require surgical correction or colostomy.
- (ii) Bladder damage with loss of capacity, frequency of urination, blood in urine, recurrent urinary infections, pain, or spasm which may require urinary diversion and/or removal of bladder.
- scarring of skin.
- (iii) Changes in skin texture and/or coloration, permanent hair loss,
- (iv) Bone damage leading to fractures.
- menopause.
- (v) Ovarian damage causing infertility, sterility, or premature
- or sexual dysfunction.
- (vi) Vaginal damage leading to dryness, shrinkage, pain, bleeding,
- (vii) Swelling of the genitalia or legs.

(viii) Nerve damage causing pain, loss of strength or feeling in legs, and/or loss of control of bladder or rectum.

(ix) Fistula between the bladder and/or bowel and/or vagina.

(x) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to pelvis and hips causing stunting of bone growth and/or abnormal development.

(III) Second cancers developing in the irradiated area.

(7) Male pelvis.

(A) Early reactions.

(i) Inflammation of bowel causing cramping and diarrhea.

(ii) Inflammation of rectum and anus causing pain, spasm, discharge, bleeding.

(iii) Bladder inflammation causing burning, frequency, spasm, pain, and/or bleeding.

(iv) Skin changes: redness, irritation, scaliness, blistering or ulceration, coloration, thickening, hair loss.

(v) Depression of blood count leading to increased risk of infection and/or bleeding.

(vi) In children, these reactions are likely to be intensified by chemotherapy before, during or after radiation therapy.

(vii) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

(i) Bowel damage causing narrowing or adhesions of the bowel with obstruction, ulceration, bleeding, chronic diarrhea, or poor absorption of food elements and may require surgical correction or colostomy.

(ii) Bladder damage with loss of capacity, frequency of urination, blood in urine, recurrent urinary infections, pain, or spasm which may require urinary diversion and/or removal of bladder.

(iii) Changes in skin texture and/or coloration, permanent hair loss, scarring of skin.

(iv) Bone damage leading to fractures.

(v) Testicular damage causing reduced sperm counts, infertility, sterility, or risk of birth defects.

(vi) Impotence (loss of erection) or sexual dysfunction.

(vii) Swelling of the genitalia or legs.

(viii) Nerve damage causing pain, loss of strength or feeling in legs, and/or loss of control of bladder or rectum.

(ix) Fistula between the bowel and other organs.

(x) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to pelvis and hips causing stunting of bone growth and/or abnormal development.

(III) Second cancers developing in the irradiated area.

(8) Skin.

(A) Early reactions.

(i) Redness, irritation, or soreness.

(ii) Scaliness, ulceration, crusting, oozing, discharge.

(iii) Hair loss.

(iv) These reactions are likely to be intensified by chemotherapy.

(B) Late reactions.

(i) Changes in skin texture causing scaly or shiny smooth skin, thickening with contracture, puckering, scarring of skin.

- (ii) Changes in skin color.
- (iii) Prominent dilated small blood vessels.
- (iv) Permanent hair loss.
- (v) Chronic or recurrent ulcerations.
- (vi) Damage to adjacent tissues including underlying bone or cartilage.
- (vii) In children, second cancers may develop in the irradiated area.

(9) Extremities.

(A) Early reactions.

- (i) Skin changes: redness, irritation, scaliness, ulceration, coloration, thickening, hair loss.
- (ii) Inflammation of soft tissues causing tenderness, swelling, and interference with movement.
- (iii) Inflammation of joints causing pain, swelling and limitation of joint motion.
- (iv) In children, these reactions are likely to be intensified by chemotherapy before, during or after radiation therapy.
- (v) In children, depression of blood count leading to increased risk of infection and/or bleeding is more common.

(B) Late reactions.

- (i) Changes in skin reaction and/or coloration, permanent hair loss and scarring of the skin.
- (ii) Scarring or shrinkage of soft tissues and muscle causing loss of flexibility and movement, swelling of the limb.
- (iii) Nerve damage causing loss of strength, feeling or coordination.
- (iv) Bone damage causing fracture.

(v) Joint damage causing permanent stiffness, pains and arthritis.

(vi) Swelling of limb below the area treated.

(vii) In children, there may be additional late reactions.

(I) Disturbances of bone and tissue growth.

(II) Bone damage to limbs causing stunting of bone growth and/or abnormal development.

(III) Second cancers developing in the irradiated area.

(10) Total body irradiation.

(A) Early reactions.

(i) Loss of appetite, nausea, vomiting.

(ii) Diarrhea.

(iii) Reduced and sticky saliva, swelling of the salivary gland(s),
loss of taste.

(iv) Hair loss.

(v) Sore mouth and throat, difficulty swallowing.

(vi) Permanent destruction of bone marrow leading to infection,
bleeding, and possible death.

(vii) Inflammation of the lung with fever, dry cough and difficulty
breathing with possible fatal lung failure.

(viii) Damage to liver with possible fatal liver failure.

(ix) In children, these reactions are likely to be intensified by
chemotherapy before, during or after radiation therapy.

(x) In children, depression of blood count leading to increased risk
of infection and/or bleeding is more common.

(B) Late reactions.

(i) Lung scarring causing shortness of breath, infection, and fatal
lung failure.

- (ii) Cataract formation in the eyes, possible loss of vision.
 - (iii) Testicular damage in males causing sterility.
 - (iv) Ovarian damage in females causing premature menopause and sterility.
 - (v) Increased risk of second cancer.
-

(s) Laparoscopic/Thoracoscopic surgery.

(1) Laparoscopic/Thoracoscopic risks. The following shall be in addition to risks and hazards of the same surgery when done as an open procedure.

- (A) Damage to adjacent structures.
 - (B) Abscess and infectious complications.
 - (C) Trocar site complications (e.g., hematoma/bleeding, leakage of fluid, or hernia formation).
 - (D) Cardiac dysfunction.
 - (E) Postoperative pneumothorax.
 - (F) Subcutaneous emphysema.
 - (G) Conversion of the procedure to an open procedure.
- (2) Use of a power morcellator in laparoscopic surgery.
- (A) If cancer is present, may increase the risk of the spread of cancer.
 - (B) Increased risk of damage to adjacent structures.
-

(t) Pain management procedures.

- (1) Neuroaxial procedures (injections into or around spine).
- (A) Failure to reduce pain or worsening of pain.
 - (B) Nerve damage including paralysis (inability to move).

(C) Epidural hematoma (bleeding in or around spinal canal).
(D) Infection.
(E) Seizure.
(F) Persistent leak of spinal fluid which may require surgery.
(G) Breathing and/or heart problems including cardiac arrest (heart stops beating).

(2) Peripheral and visceral nerve blocks and/or ablations.

- (A) Failure to reduce pain or worsening of pain.
- (B) Bleeding.
- (C) Nerve damage including paralysis (inability to move).
- (D) Infection.
- (E) Damage to nearby organ or structure.
- (F) Seizure.

(3) Implantation of pain control devices.

- (A) Failure to reduce pain or worsening of pain.
- (B) Nerve damage including paralysis (inability to move).
- (C) Epidural hematoma (bleeding in or around spinal canal).
- (D) Infection.
- (E) Persistent leak of spinal fluid which may require surgery.

(u) Dental surgery procedures.

(1) Oral surgery.

- (A) Extraction (removing teeth).
 - (i) Dry socket (inflammation in the socket of a tooth).

- (ii) Permanent or temporary numbness or altered sensation.
- (iii) Sinus communication (opening from tooth socket into the sinus cavity).
- (iv) Fracture of alveolus and/or mandible (upper and/or lower jaw).
- (B) Surgical exposure of tooth in order to facilitate orthodontics.
 - (i) Injury to tooth or to adjacent teeth and structures.
 - (ii) Failure to get proper attachment to tooth requiring additional procedure.
- (2) Endodontics (deals with diseases of the dental pulp).
 - (A) Apicoectomy (surgical removal of root tip or end of the tooth, with or without sealing it).
 - (i) Shrinkage of the gums and crown margin exposure.
 - (ii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iii) Displacement of teeth or foreign bodies into nearby tissues, spaces, and cavities.
 - (B) Root amputation (surgical removal of portion of one root of a multi-rooted tooth).
 - (i) Shrinkage of the gums and crown margin exposure.
 - (ii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iii) Displacement of teeth or foreign bodies into nearby tissues, spaces, and cavities.
 - (C) Root canal therapy (from an occlusal access in order to clean and fill the canal system).
 - (i) Instrument separation (tiny files which break within the tooth canal system).
 - (ii) Fenestration (penetration of walls of tooth into adjacent tissue).

(iii) Failure to find and/or adequately fill all canals.

(iv) Expression of irrigants or filling material past the apex of the tooth (chemicals used to clean or materials used to fill a root may go out the end of the root and cause pain or swelling).

(v) Damage to adjacent tissues from irrigants or clamps.

(vi) Fracture or loss of tooth.

(3) Periodontal surgery (surgery of the gums).

(A) Gingivectomy and gingivoplasty (involves the removal of soft tissue).

(i) Tooth sensitivity to hot, cold, sweet, or acid foods.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(B) Anatomical crown exposure (removal of enlarged gingival tissue and supporting bone to provide an anatomically correct gingival relationship).

(i) Tooth sensitivity to hot, cold, sweet, or acid foods.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(C) Gingival flap procedure, including root planing (soft tissue flap is laid back or removed to allow debridement (cleaning) of the root surface and the removal of granulation tissue (unhealthy soft tissue)).

(i) Permanent or temporary numbness or altered sensation.

(ii) Tooth sensitivity to hot, cold, sweet, or acid foods.

(iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(D) Apically positioned flap (used to preserve keratinized gingival (attached gum tissue) in conjunction with osseous resection (removal) and second stage implant procedure).

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(E) Clinical crown lengthening (removal of gum tissue and/or bone from around tooth).

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(F) Osseous surgery-including flap entry and closure (modification of the bony support of the teeth).

(i) Permanent or temporary numbness or altered sensation.

(ii) Tooth sensitivity to hot, cold, sweet, or acid foods.

(iii) Loss of tooth.

(iv) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(G) Guided tissue regeneration-resorbable barrier.

(i) Permanent or temporary numbness or altered sensation.

(ii) Accidental aspiration (into the lungs) of foreign matter.

(iii) Rejection of donor materials.

(H) Guided tissue regeneration-nonresorbable barrier (includes membrane removal).

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(iii) Accidental aspiration (into the lungs) of foreign matter.

(iv) Rejection of donor materials.

(I) Pedicle soft tissue graft procedure.

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(iii) Rejection of donor materials.

(J) Free soft tissue graft protection-including donor site surgery.

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(iii) Rejection of graft.

(K) Sub epithelial connective tissue graft procedures.

(i) Permanent or temporary numbness or altered sensation.

(ii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(iii) Rejection of graft.

(L) Distal or proximal wedge procedure (taking off gum tissue from the very back of the last tooth or between teeth). Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(M) Soft tissue allograft and connective tissue double pedicle graft from below (creates or augments gum tissue).

(i) Permanent or temporary numbness or altered sensation.

(ii) Tooth sensitivity to hot, cold, sweet, or acid foods.

(iii) Shrinkage of the gums upon healing resulting in teeth appearing longer and greater spaces between some teeth.

(4) Implant procedures.

(A) Bone grafting (replacing missing bone).

(i) Permanent or temporary numbness or altered sensation.

(ii) Rejection of bone particles or graft from donor or recipient sites.

- (iii) Damage to adjacent teeth or bone.
 - (B) Surgical placement of implant body.
 - (i) Blood vessel or nerve injury.
 - (ii) Damage to adjacent teeth or bone fracture.
 - (iii) Sinus communication (opening from tooth socket into the sinus cavity).
 - (iv) Failure of implant requiring corrective surgery.
 - (v) Cyst formation, bone loss, or gum disease around the implant.
-

(v) Plastic surgery.

- (1) Augmentation mammoplasty (breast enlargement with implant).
 - (A) Bleeding around implant.
 - (B) Sensory changes or loss of nipple sensitivity.
 - (C) Failure, deflation, or leaking of implant requiring replacement.
 - (D) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).
 - (E) Problems with or the inability to breastfeed.
 - (F) Capsular contracture (hardening of breast).
- (2) Bilateral breast reduction.
 - (A) Skin flap or fat necrosis (injury or death of skin and fat).
 - (B) Loss of nipple or areola.
 - (C) Sensory changes or loss of nipple sensitivity.
 - (D) Problems with or the inability to breastfeed.
 - (E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape or not desired size).

(3) Rhinoplasty or nasal reconstruction with or without septoplasty (repairing the middle wall of the nose).

(A) Development of new problems, such as perforation of the nasal septum (hole in wall between the right and left halves of the nose) or breathing difficulty.

(B) Spinal fluid leak.

(C) Worsening or unsatisfactory appearance.

(4) Reconstruction and/or plastic surgery operations of the face and neck.

(A) Impairment of regional organs, such as eye or lip function.

(B) Recurrence of the original condition.

(C) Worsening or unsatisfactory appearance.

(5) Liposuction (removal of fat by suction).

(A) Shock.

(B) Pulmonary fat embolism (fat escaping with possible damage to vital organs).

(C) Damage to skin with possible skin loss.

(D) Loose skin.

(E) Worsening or unsatisfactory appearance.

(6) Breast reconstruction with other flaps and/or implants.

(A) Bleeding around implant.

(B) Sensory changes or loss of nipple sensitivity.

(C) Failure, deflation, or leaking of implant requiring replacement.

(D) Damage to internal organs.

(E) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).

(7) Nipple Areolar Reconstruction.

- (A) Loss of graft.
 - (B) Unsatisfactory appearance.
- (8) Panniculectomy (removal of skin and fat).
- (A) Persistent swelling in the legs.
 - (B) Nerve damage.
 - (C) Worsening or unsatisfactory appearance.
- (9) Tendonitis, tendon release, and trigger releases.
- (A) Recurrence of symptoms.
 - (B) Damage to blood vessels, nerves, tendons, or muscles.
 - (C) Worsening function.
- (10) Breast reconstruction with flaps.
- (A) Damage to blood vessels, nerves, or muscles.
 - (B) Loss of flap possibly requiring additional surgery.
 - (C) Damage to internal organs.
 - (D) Increased risk of abdominal wall complications with pregnancy.
 - (E) Abdominal hernias with abdominal flaps.
 - (F) Chronic abdominal pain with abdominal flaps.
 - (G) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).
- (11) Flap or graft surgery.
- (A) Damage to blood vessels, nerves, or muscles.
 - (B) Deep vein thrombosis (blood clot in legs or arms).
 - (C) Loss of flap possibly requiring additional surgery.
 - (D) Worsening or unsatisfactory appearance.

(12) Tendons, nerves, or blood vessel repair.

(A) Damage to nerves.

(B) Deep vein thrombosis (blood clot in legs or arms).

(C) Rupture of repair.

(D) Worsening of function.

(13) Reconstruction and/or plastic surgical procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma.

(A) Blindness.

(B) Nerve damage with loss of use and/or feeling.

(C) Painful or unattractive scarring.

(D) Worsening or unsatisfactory appearance.

(E) Dry eye.

§601.3 Procedures Requiring No Disclosure of Specific Risks and Hazards--List B.

(a) Anesthesia.

- (1) Local.
-

(b) Cardiovascular system.

- (1) Excision and ligation of varicose veins of the leg.
 - (2) Arterial line for monitoring purposes.
-

(c) Digestive system.

- (1) Appendectomy.
 - (2) Hemorrhoidectomy with fistulectomy or fissurectomy.
 - (3) Hemorrhoidectomy.
 - (4) Incision or excision of perirectal tissue.
 - (5) Local excision and destruction of lesion, anus and rectum.
 - (6) Operations for correction of cleft palate.
 - (7) Repair of inguinal or ventral hernia.
 - (8) Repair and plastic operations on anus and rectum.
 - (9) Colonoscopy.
 - (10) Tonsillectomy with adenoidectomy.
 - (11) Tonsillectomy without adenoidectomy.
-

(d) Ear.

- (1) Myringotomy.
- (2) Reconstruction of auricle of ear for skin cancer.
- (3) Tympanoplasty without mastoidectomy.

(e) Endocrine system. No procedures assigned at this time.

(f) Eye.

(1) Administration of topical, parenteral (such as IV), or oral drugs or pharmaceuticals, including, but not limited to, fluorescein angiography, orbital injection or periocular injections.

(2) Removal of extraocular foreign bodies.

(3) Chalazion excision.

(g) Female genital system. No procedures assigned at this time.

(h) Hematic and lymphatic system.

(1) Biopsy of lymph nodes.

(2) Other procedures. No other procedures are assigned at this time.

(i) Integumentary system.

(1) Biopsy of breast.

(2) Cutting and preparation of skin grafts or pedicle flaps.

(3) Removal or treatment of local skin or subcutaneous lesion.

(4) Excision of pilonidal sinus or cyst.

(5) Suture of skin.

(6) Wide or radical excision of skin lesion with or without graft.

(7) Z plasty without excision.

(8) Biopsy of skin or mucus membrane.

(9) Incision and drainage of skin or mucus membrane lesion.

(10) Debridement of ulceration of the skin.

(j) Male genital system.

- (1) Biopsy of testicle.
 - (2) Placement of testicular prosthesis.
 - (3) Hydrocelectomy (removal/drainage of cyst in scrotum).
 - (4) Circumcision.
 - (5) Cystoscopy.
-

(k) Maternity and related cases. Intrauterine Devices (IUD).

(l) Musculoskeletal system.

- (1) Arthrotomy, arthrocentesis, or joint injection (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A)).
 - (2) Closed reduction without internal fixation (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
 - (3) Wound debridement (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
 - (4) Needle biopsy or aspiration, bone marrow (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
 - (5) Partial excision of bone (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
 - (6) Removal of external fixation device (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
 - (7) Traction or fixation without manipulation for reduction (unless performed on a child age 12 or under, see List A in §601.2(l)(7) of this title).
-

(m) Nervous system.

- (1) Lumbar puncture.
 - (2) Closure of meningomyelocele.
 - (3) Ventriculostomy with or without air ventriculogram.
 - (4) Cisternal puncture (diagnostic).
 - (5) Stereotactic surgery for dystonia.
 - (6) Insertion of skeletal tongs.
 - (7) Intravenous cut-down.
 - (8) Elevation of depressed skull fracture.
 - (9) Cervical 1-2 puncture (diagnostic).
-

(n) Radiology.

- (1) Lymphangiography.
- (2) Discography.
- (3) Lumbar puncture with/without injection of medication.
- (4) Nerve root injection, epidural injection, nerve blocks, and radiofrequency treatments for pain control.
- (5) Venography (Venogram) with contrast media by peripheral IV.
- (6) Cholangiography with contrast media through existing drain; T-tube cholangiography.
- (7) Urography (IVP) with contrast media.
- (8) Radionuclide scans and/or blood flow studies.
- (9) Gastrointestinal (GI) tract radiography and fluoroscopy.
- (10) Nasogastric/nasojejunal tube placement with fluoroscopy.
- (11) Percutaneous gastrostomy/gastrojejunostomy.
- (12) Fistula or sinus tract injection.

- (13) Sialography.
- (14) Dacryocystography, stenting.
- (15) Cystography, cystourethrography.
- (16) Retrograde and antegrade urography.
- (17) Larynogography, bronchography.
- (18) Hysterosalpingography.
- (19) ERCP (Endoscopic retrograde cholangio pancreatography).
- (20) Galactography.
- (21) Skeletal radiography and/or fluoroscopy (skull, mastoids, sinuses and facial bones; spine, ribs, pelvis; extremities).
- (22) Foreign body radiography and/or fluoroscopy and foreign body retrieval.
- (23) Chest and abdomen radiography and fluoroscopy.
- (24) Portable radiography/fluoroscopy.
- (25) Pelvimetry, fetogram.
- (26) Magnetic Resonance Imaging/Magnetic Resonance Angiography without and with contrast.
- (27) Computed tomography scan/computed tomography angiogram without and with contrast media.
- (28) Ultrasound and Doppler studies.
- (29) Laminography, polytomography.
- (30) Soft-tissue radiography including xeroradiography and xeromammography.
- (31) Arthrography, arthrocentesis, tenography.
- (32) Ureteral or urethral balloon dilatation/stent.
- (33) Percutaneous suprapubic cystostomy.

(34) Cyst aspiration/drainage/sclerosis.

(35) Percutaneous or transvascular biopsy.

(36) Paracentesis.

(37) Thoracentesis.

(o) Respiratory system.

(1) Aspiration of bronchus.

(2) Reduction of nasal fracture.

(3) Percutaneous tracheostomy.

(p) Urinary system.

(1) Nephrotomy (placement of drainage tubes).

(2) Biopsy of prostate, bladder or urethra.

(3) Cystolithotomy (surgical removal of stone(s) from the bladder).

(4) Cystolitholapaxy (cystoscopic crushing and removal of bladder stone(s)).

(5) Cystostomy (placement of tube into the bladder).

(6) Urethrotomy (incision of the urethra).

(7) Diverticulectomy of the bladder (removal of outpouching of the bladder).

(8) Diverticulectomy or diverticulotomy of the urethra (repair or drainage of outpouching of the urethra).

(9) Lithotripsy (sound wave removal of stones from kidney and ureter).

(q) Psychiatric procedures. No procedures assigned at this time.

(r) Radiation therapy. No procedures assigned at this time.

(s) Endoscopic surgery. No procedures assigned at this time.

(t) Pain management procedures.

(1) Trigger point injection (injection into tendon or muscle).

(2) Scar injection.

(u) Dental surgery procedures. No procedures assigned at this time.

§601.4 Disclosure and Consent Form

(a) The Texas Medical Disclosure Panel adopts the following form which shall be used by a physician or health care provider to inform a patient or person authorized to consent for the patient of the possible risks and hazards involved in the medical treatments and surgical procedures named in the form. Except for the procedures shown in subsection (b) of this section, the following form shall be used for the medical treatments and surgical procedures described in §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A). Providers shall have the form available in both English and Spanish language versions. Both versions are available from the Department of State Health Services.

(b) Informed consent for:

(1) radiation therapy shall be provided in accordance with §601.5 of this title (relating to Disclosure and Consent Form for Radiation Therapy);

(2) electroconvulsive therapy shall be provided in accordance with §601.7 of this title (relating to Informed Consent for Electroconvulsive Therapy);

(3) hysterectomy procedures shall be provided in accordance with §601.8 of this title (relating to Disclosure and Consent Form for Hysterectomy); and

(4) anesthesia and/or perioperative pain management (analgesia) procedures shall be in accordance with §601.9 of this title (relating to Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia)).

DISCLOSURE AND CONSENT

Medical and Surgical Procedures

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I (we) voluntarily request _____,
name, credential (e.g. MD/DO, NP, DDS, etc.)
as my physician or health care provider, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as: _____

_____.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures _____

_____.

I (we) understand that my physician may discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician or health care provider, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

I (we) (do) (do not) consent to the use of blood and blood products as deemed necessary. I (we) understand that the following risks and hazards may occur in connection with the use of blood and blood products:

1. Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.
2. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system.
3. Severe allergic reaction, potentially fatal.

I (we) understand that no warranty or guarantee has been made to me as to result or cure.

Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical, and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I (we) also realize that the following risks and hazards may occur in connection with this particular procedure: _____

_____.

I (we) have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of nontreatment, the procedures to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me (us) , that I (we) have read it or have had it read to me (us), that the blank spaces have been filled in, and that I (we) understand its contents.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON (signature required):

DATE: _____ TIME: _____ A.M./P.M.

WITNESS:

Signature

Name (Print)

Address (Street or P.O. Box)

City, State, Zip Code

DIVULGACIÓN DE INFORMACIÓN Y CONSENTIMIENTO

Procedimientos médicos y quirúrgicos

AL PACIENTE: Usted tiene el derecho como paciente a que se le informe sobre su condición y a que se le recomiende el procedimiento quirúrgico, médico o diagnóstico que se utilizará para que, después de conocer los riesgos y peligros involucrados, usted pueda tomar la decisión de seguir con el procedimiento o no. Esta divulgación de información no tiene como propósito el asustarle ni alarmarle; es sencillamente una medida para mejor informarle para que así usted pueda dar o negar su consentimiento al procedimiento.

Yo solicito (nosotros solicitamos) voluntariamente al (a la) _____ como mi médico o proveedor de cuidados
nombre, credenciales (por ejemplo MD/DO, NP, DDS, etc.)
de la salud, y tales socios, ayudantes técnicos, y otros proveedores de atención de salud como ellos
estimen necesario, que traten mi condición, la cual se me (se nos) ha explicado
como: _____

_____.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que los siguientes
procedimientos quirúrgicos, médicos y / o diagnósticos son planificados para mí, y doy (damos) el
consentimiento voluntariamente para estos procedimientos y autorizo (autorizamos) estos
procedimientos: _____

_____.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que quizá mi médico descubra
otras o diferentes condiciones que requerirán procedimientos adicionales o distintos a los ya
planificados. Yo autorizo (nosotros autorizamos) que mi médico o proveedor de cuidados de la
salud, y tales socios, ayudantes técnicos y otros proveedores de atención de salud realicen tales
procedimientos adicionales que son prudentes en su opinión profesional.

Yo doy (nosotros damos) / Yo no doy (nosotros no damos) consentimiento para el uso de
sangre y productos de sangre, como se estime necesario. Yo (nosotros) entiendo que se pueden
presentar los siguientes riesgos y peligros en relación con el uso de sangre y productos
sanguíneos:

1. La infección grave, incluyendo pero no limitado a la hepatitis y el VIH que puede conducir a daños en los órganos y el deterioro permanente.
2. Lesión relacionada con la transfusión dando lugar a alteraciones de los pulmones, el corazón, el hígado, los riñones y el sistema inmunológico.
3. Reacción alérgica grave, potencialmente mortal.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que ninguna seguridad ni
garantía se me (se nos) ha dado con relación al resultado o a la cura.

Asimismo que podrían haber riesgos y peligros al seguir en mi condición actual sin tratamiento, también hay riesgos y peligros relacionados a la realización de los procedimientos quirúrgicos, médicos y / o diagnósticos planificados para mí. Yo comprendo (nosotros comprendemos) que el potencial para infección, coágulos de sangre en las venas y los pulmones, hemorragia, reacciones alérgicas, y aún muerte, son comunes en los procedimientos quirúrgicos, médicos y / o diagnósticos. Asimismo, yo comprendo (nosotros comprendemos) que podrían ocurrir los siguientes riesgos y peligros con respecto a este procedimiento en particular:_____

Se me (se nos) ha dado una oportunidad de hacer preguntas sobre mi condición, formas alternativas de tratamiento, los riesgos si no se recibe tratamiento, los procedimientos que se utilizarán y los riesgos y peligros involucrados en ellos, y que según mi (nuestro) leal saber y entender yo tengo (nosotros tenemos) la información suficiente para dar este consentimiento consciente.

Yo afirmo (nosotros afirmamos) que se me (se nos) explicó este formulario en su totalidad y que lo he (hemos) leído o que se me (se nos) ha leído, que se han llenado los espacios en blanco, y que entiendo y acepto (entendemos y aceptamos) su contenido.

FIRMA DEL PACIENTE / OTRA PERSONA LEGALMENTE RESPONSABLE (firma requerida)

FECHA:_____HORA:_____A.M./P.M

TESTIGO:

Firma

Nombre (letra de molde)

Dirección (Calle o Apartado Postal)

Ciudad, Estado, Código Postal

§601.5 Disclosure and Consent Form for Radiation Therapy.

The Texas Medical Disclosure Panel adopts the following form to be used by a physician or health care provider to inform a patient or person authorized to consent for a patient of the possible risks and hazards involved in the radiation therapy named in the form. This form is to be used in lieu of the general disclosure and consent form adopted in §601.4(a) of this title (relating to Disclosure and Consent Form) for disclosure and consent relating to only radiation therapy procedures. If a surgical or anesthetic procedure is required in combination with a radiation therapy procedure, the general disclosure and consent form as adopted in §601.4(a) of this title and the form adopted in this section shall be used. The general disclosure and consent form shall be used for the surgical or anesthetic procedure and the radiation therapy disclosure and consent form shall be used for the radiation therapy procedure. Providers shall have the form available in both English and Spanish language versions. Both versions are available from the Department of State Health Services.

DISCLOSURE AND CONSENT FOR RADIATION THERAPY

As a patient, you have the right to be informed about your condition and the recommended radiation therapy procedure to be used to treat your condition. This disclosure is not meant to alarm you; however, there are certain risks which are associated with radiation therapy. This explanation is intended to inform you of those risks so that you may give or withhold your consent to the recommended procedure on an informed basis. Please carefully review the following and if you choose to proceed with this treatment, sign this consent in the space below:

I (we) hereby voluntarily request and authorize Dr. _____ as my physician, and such associates, technicians and the health care providers as they may deem necessary to treat my condition which has been explained to me (us) as: _____

I (we) understand that my condition may be treated with external beam radiation therapy alone, with internal radiation implant alone or with both or in planned combination with surgery and/or chemotherapy.

I (we) understand that the following radiation therapy procedure(s) are planned for me and I (we) consent to and authorize these procedure(s) (specify technique and site):

I (we) further authorize the taking of photographs or placing of tattoo or skin marks necessary for treatment.

ALL FEMALES MUST COMPLETE: I (we) understand that radiation can be harmful to the unborn child.

I am, I could be, I am not pregnant.

I (we) understand that there may be side-effects or complications from radiation therapy, either during or shortly after the course of treatment ("early reactions"), or some time later ("late reactions"). Any of the side-effects or complications may be temporary or permanent.

These reactions may be worsened by chemotherapy or surgery before, during or after radiation therapy or by previous radiation therapy to the same area. Early and late reactions which could occur as a result of the procedure(s) are listed below. With few exceptions, these reactions affect only the areas actually receiving radiation therapy.

(Place list(s) for specific region or regions of the body receiving radiation therapy here. A single form may be used for multiple regions or a separate form may be used for each separate region.)

The nature and purpose of the proposed procedure, the alternative methods of treatment, and the risks and hazards if treatment is withheld have been explained to me (us) by my physician. I (we) have had an opportunity to discuss these matters with my physician and to ask questions about my condition, alternative methods of treatment and the proposed procedure(s). I (we) understand that no warranty or guarantee has been made to me (us) as to result or cure.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON (signature required)

DATE: _____ **TIME:** _____ **A.M./P.M.**

WITNESS:

Signature

Name (Print)

Address (Street or P. O. Box)

City, State, Zip Code

DIVULGACIÓN DE INFORMACIÓN Y CONSENTIMIENTO PARA RADIOTERAPIA

Effective 03/04/07 – Page 76

Como paciente, usted tiene el derecho a que se le informe sobre su condición y el procedimiento de radioterapia que se recomienda utilizar para tratar su condición. Esta divulgación de información no tiene como propósito el alarmarle; sin embargo, hay ciertos riesgos que son asociados con la radioterapia. Esta explicación tiene el propósito de informarle sobre esos riesgos para que usted pueda dar o denegar su consentimiento al procedimiento recomendado de una base informada. Favor de revisar cuidadosamente lo siguiente, y si usted elige seguir con este tratamiento, firme este consentimiento en el espacio de abajo:

Yo (nosotros), por este medio, voluntariamente solicito (solicitamos) y autorizo (autorizamos) al (a la) Dr(a). _____ como mi médico, y tales socios, técnicos, y los proveedores de atención de salud como ellos estimen necesario, que traten mi condición, la cual se me (se nos) ha explicado como: _____

Yo entiendo y acepto (nosotros entendemos y aceptamos) que mi condición podría ser tratada con la radioterapia externa solamente, con la braquiterapia (radiación interna) solamente o con las dos, o en una combinación planificada con cirugía y / o quimioterapia.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que el (los) siguiente(s) procedimiento(s) radiológico(s) son planificados para mí, y doy (damos) el consentimiento para y autorizo (autorizamos) este (estos) procedimiento(s) (especifique la técnica y el sitio): _____

Adicionalmente, yo autorizo (nosotros autorizamos) el tomar de fotografías o el poner tatuajes o marcas en la piel que sea necesario para tratamiento.

TODAS LAS HEMBRAS TIENEN QUE COMPLETAR: Yo entiendo y acepto (nosotros entendemos y aceptamos) que la radiación puede ser dañina al bebé aún no nacido.

Yo estoy Es posible que yo esté Yo no estoy embarazada.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que podría haber efectos secundarios o complicaciones de la radioterapia durante o poco después del curso de tratamiento (“reacciones precoces”), o a cierto tiempo después (“reacciones tardías”). Cualquiera de los efectos secundarios o las complicaciones podrían ser transitorios o permanentes.

Estas reacciones podrían empeorarse por quimioterapia o cirugía antes, durante, o después de la radioterapia, o por radioterapia previa en la misma área. Las reacciones precoces y tardías que podrían ocurrir como resultado del (de los) procedimiento(s) están listadas más abajo. Con pocas excepciones, estas reacciones afectan solamente las áreas realmente sometidas a la radioterapia.

(Ponga aquí lista(s) de la(s) region(es) específica(s) que será(n) sometida(s) a la radioterapia. Se puede utilizar un solo formulario para regiones múltiples, o se puede usar un formulario separado para cada región diferente.)

La naturaleza y el objetivo del procedimiento propuesto, los métodos alternativos de tratamiento, y los riesgos y peligros si el tratamiento es retenido me (nos) han sido explicados por mi médico. Yo he (nosotros hemos) tenido la oportunidad de discutir estos asuntos con mi médico y de hacer preguntas sobre mi condición, los métodos alternativos de tratamiento, y el (los) procedimiento(s) propuesto(s). Yo entiendo y acepto (nosotros entendemos y aceptamos) que ninguna seguridad ni garantía se me (se nos) ha dado con relación al resultado o a la cura.

FIRMA DEL PACIENTE / OTRA PERSONA LEGALMENTE RESPONSABLE (firma requerida)

FECHA: _____ **HORA:** _____ **A.M./P.M**

TESTIGO:

Firma

Nombre (letra de molde)

Dirección (Calle o Apartado Postal)

Ciudad, Estado, Código Postal

§601.6 History

(a) The procedures requiring full disclosure-List A, the procedures requiring no disclosure-List B and the disclosure and consent form were first published in the December 15, 1981, issue of the *Texas Register* as §601.1 of this title (relating to Procedures Requiring Full Disclosure (List A)), §601.2 of this title (relating to Procedures Requiring No Disclosure (List B)), and §601.3 of this title (relating to Disclosure and Consent Form) and initially became effective on June 1, 1982.

(b) The first amendments to §601.1 of this title and §601.2 of this title were published in the December 3, 1982, issue of the *Texas Register* and became effective on January 1, 1983.

(c) The second amendments to §601.1 of this title and §601.2 of this title were published in the November 23, 1984, issue of the *Texas Register* and became effective on January 1, 1985.

(d) The third amendments to §601.1 of this title and §601.2 of this title were published in the April 19, 1988, issue of the *Texas Register* and became effective on May 2, 1988.

(e) The fourth amendment to §601.1 of this title was published in the July 21, 1989, issue of the *Texas Register* and became effective on August 3, 1989.

(f) Further amendments to §601.1 of this title and §602.2 of this title and new §601.4 of this title (relating to Radiation Therapy Disclosure and Consent Form) were published in the February 2, 1990, issue of the *Texas Register* and became effective on May 3, 1990.

(g) Effective October 3, 1995, §§601.1- 601.4 of this title were repealed and replaced with new §601.1 of this title (relating to General), §601.2 of this title (relating to Procedures Requiring Full Disclosure (List A)), §601.3 of this title (relating to Procedures Requiring No Disclosure (List B)), and §601.4 of this title (relating to Disclosure and Consent Form), §601.5 of this title (relating to Radiation Therapy Disclosure and Consent Form), this section, and §601.7 of this title (relating to Informed Consent for Electroconvulsive Therapy). The sections were repealed to incorporate List A and List B into *Texas Register* format. In addition, sections were added to include general provisions; to provide a history of the rules of the panel; and to adopt a section which addresses informed consent for electroconvulsive therapy.

(h) Effective October 23, 1997, §601.2 of this title was amended to update risks and hazards requiring full disclosure prior to performing abdominal endoscopic/laparoscopy procedures and endoscopic surgery of the thorax.

(i) Effective February 18, 1998, §601.4 of this title and this section were amended and new §601.8 of this title (relating to Hysterectomy Disclosure and Consent Form) were added to address legislative requirements relating to informed consent for hysterectomies. Section 601.8 of this title adopts a form to be used in providing informed consent prior to performing a hysterectomy and applies to hysterectomies performed at least 90 days after the date of publication of adopted §601.8 of this title in the *Texas Register*.

(j) Effective September 1, 2003, by Acts 2003, 78th Texas Legislature, Regular Session, Chapter 204, §10.01, Texas Civil Statutes, Article 4590i, Subchapter F, relating to informed consent was recodified to the Texas Civil Practice and Remedies Code, Chapter 74, Medical Liability, Subchapter C, §74.102 (relating to Texas Medical Disclosure Panel).

(k) Effective March 18, 2004, §601.2 of this title (relating to Procedures Requiring Full Disclosure--List A) was amended to include the addition of clarifying and new language to subsection (g) concerning female genital system treatments and procedures. Risks were identified for dilation and curettage of uterus (diagnostic/therapeutic); surgical abortion/dilation and curettage/dilation and curettage/dilation and evacuation; and medical abortion/non-surgical procedures.

(l) Effective October 16, 2005, §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A) was amended to include the addition of clarifying and new language concerning the cardiovascular system and nervous system treatments and procedures. Section 601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B) was amended to remove procedures relating to the nervous system and radiology. Sections 601.4 and 601.5 were amended to include a Spanish language version of the disclosure and consent form for medical and surgical procedures, and the disclosure and consent form for radiation therapy. Section 601.8 was amended to make editorial corrections to the disclosure and consent for hysterectomy form and correct a difference between the English and Spanish language versions of the form.

(m) Effective March 4, 2007, §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A) was amended to include procedures and risks and hazards for anesthesia, the digestive system treatments and procedures, the endocrine system treatments and procedures, and the hematic and lymphatic system. Section 601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B) was amended to add and rename procedures relating to the digestive system.

(n) Effective January 16, 2012, §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A) was amended to revise and include procedures and risks and hazards for the cardiovascular system, digestive system treatments and procedures, eye treatments and procedures, female genital system treatments and procedures, male genital system, maternity and related cases, musculoskeletal system treatments and procedures, radiology, respiratory system treatments and procedures, urinary system and pain management procedures. Section 601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B) was amended to revise and include procedures relating to maternity and related cases, musculoskeletal system, respiratory system, urinary system, and pain management procedures. Section 601.9 of this title (relating to Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia)) was added to include a disclosure and consent form for anesthesia and/or perioperative pain management (analgesia).

(o) Effective December 5, 2012, §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A) was amended to revise and include procedures and risks and hazards for the following systems: anesthesia, cardiovascular, musculoskeletal, and radiology. Section 601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B) was amended to revise and include procedures for the following systems:

cardiovascular, musculoskeletal, and radiology. A Spanish language version of the Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia) was added to §601.9 of this title (relating to Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia)).

(p) Effective January 15, 2015, §601.2 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A) was amended to revise procedures and risks and hazards for the Hematic and Lymphatic System. Additionally, a new subsection (u) was added for Dental Surgery Procedures. Section 601.3 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B) was amended to revise procedures for anesthesia. Section 601.9 of this title (relating to Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia) was amended to add Deep Sedation and Moderate Sedation to the anesthesia consent form. Both the English and Spanish language versions of the forms were amended.

§601.7 Informed Consent for Electroconvulsive Therapy

(a) The Health and Safety Code (HSC), §578.003, requires the Texas Department of State Health Services (DSHS) to adopt a standard written consent form to be used when electroconvulsive therapy is considered. HSC §578.003 requires that the form include the minimum information which is also required by the Texas Medical Disclosure Panel (panel) for electroconvulsive therapy. HSC §578.003 states that use of the consent form prescribed by (DSHS) in the manner described by HSC §578.003 creates a rebuttable presumption that the disclosure requirements of Texas Civil Practice and Remedies Code, §74.102 have been met.

(b) The panel recognizes that DSHS has adopted a written consent form for electroconvulsive therapy in §405.108 of this title (relating to Informed Consent to ECT).

(c) If the DSHS consent form is in compliance with the HSC §578.003, and contains the minimum information required by the panel, a physician or health care provider using the DSHS consent form for electroconvulsive therapy is not required to use both the DSHS form and the panel's disclosure and consent form. This section does not constitute approval of DSHS's current consent form or of DSHS's assessment of the risks and hazards associated with electroconvulsive therapy.

§601.8 Disclosure and Consent Form for Hysterectomy.

The Texas Medical Disclosure Panel adopts the following form which shall be used to provide informed consent to a patient or person authorized to consent for the patient of the possible risks and hazards involved in the hysterectomy surgical procedure named in the form. This form is to be used in lieu of the general disclosure and consent form adopted in §601.4(a) of this title (relating to Disclosure and Consent Form) for disclosure and consent relating to only hysterectomy procedures. Providers shall have the form available in both English and Spanish language versions. Both versions are available from the Department of State Health Services.

DISCLOSURE AND CONSENT FOR HYSTERECTOMY

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

NOTICE: Refusal to consent to a hysterectomy will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving federal funds or otherwise affect your right to future care or treatment.

I (we) voluntarily request Dr. _____, as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as: _____

_____.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures: _____

_____.

I (we) understand that a hysterectomy is a removal of the uterus through an incision in the lower abdomen or vagina. I (we) also understand that additional surgery may be necessary to remove or repair other organs, including an ovary, tube, appendix, bladder, rectum, or vagina.

I (we) understand that the hysterectomy is permanent and not reversible. I (we) understand that I will not be able to become pregnant or bear children. I (we) understand that I have the right to seek consultation from a second physician.

I (we) understand that my physician may discover other or different conditions which require additional different procedures than those planned. I (we) authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures, which are advisable in their professional judgment.

I (we) (do) (do not) consent to the use of blood and blood products as deemed necessary. I (we) understand that the following risks and hazards may occur in connection with the use of blood and blood products:

1. Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.
2. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys, and immune system.
3. Severe allergic reaction, potentially fatal.

I (we) understand that no warranty or guarantee has been made to me as to result or cure.

Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical, and/or diagnostic procedures are the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I (we) also realize that the following risks and hazards may occur in connection with this particular procedure (check applicable procedure):

<p>ABDOMINAL HYSTERECTOMY</p> <ol style="list-style-type: none"> 1. Uncontrollable leakage of urine. 2. Injury to the bladder. 3. Sterility. 4. Injury to the tube (ureter) between the kidney and the bladder. 5. Injury to the bowel and/or intestinal obstruction. 	<p>VAGINAL HYSTERECTOMY</p> <ol style="list-style-type: none"> 1. Uncontrollable leakage of urine. 2. Injury to the bladder. 3. Sterility. 4. Injury to the tube (ureter) between the kidney and the bladder. 5. Injury to the bowel and/or intestinal obstruction. 6. Completion of operation by abdominal incision.
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† For laparoscopically assisted hysterectomy, the additional risks include: damage to intra-abdominal structures (e.g. bowel, bladder, blood vessels, or nerves); intra-abdominal abscess and infectious complications; trocar site complications (e.g., hematoma/bleeding, leakage of fluid, or hernia formation); conversion of the procedure to an open procedure; cardiac dysfunction.

† If a power morcellator is used, the additional risks include: if cancer is present, increased risk the cancer may spread; increased risk of damage to adjacent structures.

ADDITIONAL COMMENTS: _____

I (we) have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of no treatment, the procedures to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me (us), that I (we) have read it or have had it read to me (us) , that the blank spaces have been filled in, and that I (we) understand its contents.

NAME OF PHYSICIAN EXPLAINING PROCEDURE:

NAME OF PERSON PROVIDING MATERIALS:

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON (signature required):

DATE: _____ TIME: _____ A.M./P.M.

WITNESS:

Signature

Name (Print)

Address (Street or P.O. Box)

City, State, Zip Code

DIVULGACIÓN DE INFORMACIÓN Y CONSENTIMIENTO PARA HISTERECTOMÍA

AL PACIENTE: Como paciente, usted tiene el derecho a que se le informe sobre su condición y a que se le recomiende el procedimiento quirúrgico, médico o diagnóstico que se utilizará para que, después de conocer los riesgos o peligros involucrados, usted pueda tomar la decisión de seguir con el procedimiento o no. Esta divulgación de información no tiene como propósito el asustarle ni alarmarle; es sencillamente una medida para mejor informarle y así usted pueda dar o negar su consentimiento al procedimiento.

AVISO: El negar dar consentimiento a la histerectomía no resultará en el retirar ni en la retención de ningunos de los beneficios proporcionados por programas o proyectos que reciben fondos federales, ni tampoco le afectará de ninguna manera su derecho a la atención o al tratamiento en el futuro.

Yo solicito (nosotros solicitamos) voluntariamente que el (la) Dr(a). _____ como mi médico, y tales socios, ayudantes técnicos, y otros proveedores de atención de salud como ellos estimen necesario, traten mi condición, la cual se me (se nos) ha explicado como: _____

Yo entiendo y acepto (nosotros entendemos y aceptamos) que los siguientes procedimientos quirúrgicos, médicos y / o diagnósticos son planificados para mí, y doy (damos) el consentimiento voluntariamente para estos procedimientos y autorizo (autorizamos) estos procedimientos: _____

Yo entiendo y acepto (nosotros entendemos y aceptamos) que una histerectomía es la extirpación del útero a través de una incisión en el abdomen inferior o a través de la vagina. Además entiendo y acepto (entendemos y aceptamos) que podría ser necesaria una cirugía adicional para extirpar o componer otros órganos, inclusive un ovario, una trompa de Falopio, el apéndice, la vejiga, el recto, o la vagina.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que la histerectomía es permanente e irreversible. Entiendo y acepto (entendemos y aceptamos) que no podré embarazarme ni dar a luz. Entiendo y acepto (entendemos y aceptamos) que tengo el derecho a procurar una consulta de un segundo médico.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que quizá mi médico descubra otras o diferentes condiciones que requerirán procedimientos adicionales distintos a los ya planificados. Yo autorizo (nosotros autorizamos) que mi médico, y tales socios, ayudantes técnicos y otros proveedores de atención de salud realicen tales procedimientos adicionales que son prudentes en su opinión profesional.

Yo doy (nosotros damos) / Yo no doy (nosotros no damos) consentimiento para el uso de sangre y productos de sangre, como se estime necesario. Entiendo y acepto (entendemos y aceptamos) que los siguientes riesgos y peligros podrían ocurrir con relación a la utilización de sangre y productos de sangre:

1. La infección grave, incluyendo pero no limitado a la hepatitis y el VIH que puede conducir a daños en los órganos y el deterioro permanente.
2. Lesión relacionada con la transfusión dando lugar a alteraciones de los pulmones, el corazón, el hígado, los riñones y el sistema inmunológico.
3. Reacción alérgica grave, potencialmente mortal.

Yo entiendo y acepto (nosotros entendemos y aceptamos) que ninguna seguridad ni garantía se me ha dado con relación al resultado o a la cura.

Asimismo que podrían haber riesgos y peligros al seguir en mi condición actual sin tratamiento, también hay riesgos y peligros relacionados a la realización de los procedimientos quirúrgicos, médicos y / o diagnósticos planificados para mí. Yo comprendo (nosotros comprendemos) que el potencial para infección, coágulos de sangre en las venas y los pulmones, hemorragia, reacciones alérgicas, y aún muerte, son comunes en los procedimientos quirúrgicos, médicos y / o diagnósticos. Asimismo, Yo comprendo (nosotros comprendemos) que podrían ocurrir los siguientes riesgos y peligros con respecto a este procedimiento en particular (marque el procedimiento aplicable):

<p>HISTERECTOMÍA ABDOMINAL</p> <ol style="list-style-type: none"> 1. Goteo no controlable de orina. 2. Daño a la vejiga. 3. Esterilidad. 4. Daño al tubo (uréter) entre el riñón y la vejiga. 5. Daño al intestino y / u obstrucción intestinal. 	<p>HISTERECTOMÍA VAGINAL</p> <ol style="list-style-type: none"> 1. Goteo no controlable de orina. 2. Daño a la vejiga. 3. Esterilidad. 4. Daño al tubo (uréter) entre el riñón y la vejiga. 5. Daño al intestino y / u obstrucción intestinal. 6. Conclusión de la operación a través de una incisión abdominal.
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† Para histerectomía asistida por laparoscopia, los riesgos adicionales incluyen: daño a las estructuras intra abdominales (por ejemplo: el intestino, la vejiga, los vasos sanguíneos o los nervios); absceso intra abdominal y complicaciones infecciosas; complicaciones en el sitio del trocar (por ejemplo: hematoma/sangrado, escape de líquido, o formación de una hernia); conversión del procedimiento a un procedimiento abierto; disfunción cardíaca.)

† Si se utiliza un fragmentador de energía, los riesgos adicionales incluyen: si el cáncer está presente, el aumento del riesgo de cáncer puede extenderse; aumento del riesgo de daños a las estructuras adyacentes.

COMENTARIOS ADICIONALES: _____

Se me (se nos) ha dado una oportunidad de hacer preguntas sobre mi condición, formas alternativas de tratamiento, los riesgos si no se recibe tratamiento, los procedimientos que se utilizarán y los riesgos y peligros involucrados en ellos, y que según mi leal saber y entender tengo (tenemos) la información suficiente para dar este consentimiento consciente.

Yo afirmo (nosotros afirmamos) que se me (se nos) explicó este formulario en su totalidad y que lo he (hemos) leído o que se me (se nos) ha leído, que se han llenado los espacios en blanco, y que entiendo y acepto (entendemos y aceptamos) su contenido.

NOMBRE DEL MÉDICO QUE EXPLICÓ EL PROCEDIMIENTO:

NOMBRE DE LA PERSONA QUE PROPORCIONÓ LOS MATERIALES:

FIRMA DEL PACIENTE / OTRA PERSONA LEGALMENTE RESPONSABLE (firma requerida)

FECHA: _____ HORA: _____ A.M./P.M

TESTIGO:

Firma

Nombre (letra de molde)

Dirección (Calle o Apartado Postal)

Ciudad, Estado, Código Postal

§601.9. Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia).

The Texas Medical Disclosure Panel adopts the following form which shall be used to provide informed consent to a patient or person authorized to consent for the patient of the possible risks and hazards involved in anesthesia and/or perioperative pain management (analgesia).

DISCLOSURE AND CONSENT - ANESTHESIA and/or PERIOPERATIVE PAIN MANAGEMENT (ANALGESIA)

TO THE PATIENT: *You have the right, as a patient, to be informed about your condition and the recommended anesthesia/analgesia to be used so that you may make the decision whether or not to receive the anesthesia/analgesia after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the anesthesia/analgesia.*

I voluntarily request that anesthesia and/or perioperative pain management care (analgesia) as indicated below be administered to me (the patient). I understand it will be administered by an anesthesia provider and/or the operating practitioner, and such other health care providers as necessary. Perioperative means the period shortly before, during and shortly after the procedure.

I understand that anesthesia/analgesia involves additional risks and hazards but I request the use of anesthetics/analgesia for the relief and protection from pain during the planned and additional procedures. I realize the type of anesthesia/analgesia may have to be changed possibly without explanation to me.

I understand that serious, but rare, complications can occur with all anesthetic/analgesic methods. Some of these risks are breathing and heart problems, drug reactions, nerve damage, cardiac arrest, brain damage, paralysis, or death.

I also understand that other complications may occur. Those complications include but are not limited to:

Check planned anesthesia/analgesia method(s) and have the patient/other legally responsible person initial.

_____GENERAL ANESTHESIA – injury to vocal cords, teeth, lips, eyes; awareness during the procedure; memory dysfunction/memory loss; permanent organ damage; brain damage.

_____REGIONAL BLOCK ANESTHESIA/ANALGESIA - nerve damage; persistent pain; bleeding/hematoma; infection; medical necessity to convert to general anesthesia; brain damage.

_____SPINAL ANESTHESIA/ANALGESIA - nerve damage; persistent back pain; headache; infection; bleeding/epidural hematoma; chronic pain; medical necessity to convert to general anesthesia; brain damage.

_____EPIDURAL ANESTHESIA/ANALGESIA - nerve damage; persistent back pain; headache; infection; bleeding/epidural hematoma; chronic pain; medical necessity to convert to general anesthesia; brain damage.

_____MONITORED ANESTHESIA CARE (MAC) - memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.

_____DEEP SEDATION – memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.

_____MODERATE SEDATION – memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage.

Additional comments/risks:

I understand that no promises have been made to me as to the result of anesthesia/analgesia methods.

I have been given an opportunity to ask questions about my anesthesia/analgesia methods, the procedures to be used, the risks and hazards involved, and alternative forms of anesthesia/analgesia. I believe that I have sufficient information to give this informed consent.

This form has been fully explained to me, I have read it or have had it read to me, the blank spaces have been filled in, and I understand its contents.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON (signature required)

DATE: _____ **TIME:** _____ **A.M. /P.M.**

WITNESS:

Signature

Name (Print)

Address (Street or P.O. Box)

City, State, Zip

REVELACIÓN Y CONSENTIMIENTO -ANESTESIA y CONTROL DE DOLOR (ANALGESIA) PERIOPERATORIO

AL PACIENTE: *tiene derecho, como paciente, a ser informado sobre su enfermedad y la anestesia/analgesia recomendada que se usará, de modo que usted pueda tomar la decisión de si recibir la anestesia/analgesia o no después de conocer los riesgos y los peligros relacionados. Esta revelación no tiene como fin asustarlo o alarmarlo; es simplemente un esfuerzo por tenerlo mejor informado para que usted pueda dar o negar su consentimiento para la anestesia/analgesia.*

Solicito voluntariamente que me administren a mí (el paciente) la anestesia y la atención de control de dolor (analgesia) perioperatoria, según lo indicado a continuación. Entiendo que será administrada por un proveedor de anestesia, el profesional que realice la operación o algún otro proveedor de salud de ese tipo, de ser necesario. Perioperatorio significa el periodo poco antes de, durante y poco después del procedimiento.

Aunque entiendo que la anestesia/analgesia implica riesgos y peligros adicionales, solicito que usen anestésicos/analgesia para el alivio de y la protección contra el dolor durante los procedimientos planeados y adicionales. Comprendo que el tipo de anestesia/analgesia podría tener que cambiarse, posiblemente sin darme una explicación.

Entiendo que pueden ocurrir complicaciones graves, pero raras, con todos los métodos anestésicos/analgésicos. Algunos de estos riesgos son problemas de respiración y del corazón, reacciones a la medicina, daño nervioso, paro cardíaco, daño cerebral, parálisis o la muerte.

También entiendo que podrían ocurrir otras complicaciones. Entre esas complicaciones se incluyen:

Marque los métodos de anestesia/analgesia planeados y haga que el paciente/otra persona legalmente responsable ponga sus iniciales.

____ ANESTESIA GENERAL –lesión a las cuerdas vocales, los dientes, los labios, los ojos; estar consciente durante el procedimiento; disfunción de la memoria/pérdida de la memoria; daño a órganos permanente; daño cerebral.

____ ANESTESIA/ANALGESIA DE BLOQUEO REGIONAL -daño nervioso; dolor persistente; sangrado/hematoma; infección; necesidad médica de usar anestesia general en vez; daño cerebral.

____ ANESTESIA/ANALGESIA ESPINAL -daño nervioso; dolor de espalda persistente; dolor de cabeza; infección; sangrado/hematoma epidural; dolor crónico; necesidad médica de usar anestesia general en vez; daño cerebral.

____ ANESTESIA/ANALGESIA EPIDURAL -daño nervioso; dolor de espalda persistente; dolor de cabeza; infección; sangrado/hematoma epidural; dolor crónico; necesidad médica de usar anestesia general en vez; daño cerebral.

____ ATENCIÓN DE ANESTESIA VIGILADA (MAC) - disfunción de la memoria/pérdida de la memoria; necesidad médica de usar anestesia general en vez; daño a órganos permanente; daño cerebral.

____ SEDACIÓN PROFUNDA - disfunción de la memoria/pérdida de la memoria; necesidad médica de usar anestesia general en vez; daño a órganos permanente; daño cerebral.

____ MODERADA SEDACIÓN - disfunción de la memoria/pérdida de la memoria; necesidad médica de usar anestesia general en vez; daño a órganos permanente; daño cerebral.

Comentarios/riesgos adicionales:

Entiendo que no me han prometido nada con respecto al resultado de los métodos de anestesia/analgesia.

Me han dado la oportunidad de hacer preguntas sobre los métodos de anestesia/analgesia, los procedimientos que se usarán, los riesgos y los peligros relacionados, y las formas de anestesia/analgesia alternativas. Creo tener suficiente información para dar este consentimiento informado.

Me han explicado completamente este formulario, lo he leído o me lo han leído, se han rellenado los espacios en blanco, y entiendo el contenido de éste.

PACIENTE/OTRA PERSONA LEGALMENTE RESPONSABLE (se requiere una firma)

FECHA: _____ **HORA:** _____ **a.m. /p.m.**

TESTIGO:

Firma

Nombre (en letra de molde)

Domicilio (calle y número o apartado postal)

Ciudad, estado y código postal