Texas Administrative Code

TITLE 25 HEALTH SERVICES
PART 7 TEXAS MEDICAL DISCLOSURE PANEL
CHAPTER 601 INFORMED CONSENT
25 TAC §601.2 (2002)

§601.2 Procedures Requiring Full Disclosure (List A).

(a) ANESTHESIA.
   (1) Epidural.
      (A) Persistent Back Pain.
      (B) Bleeding/epidural hematoma.
      (C) Infection.
      (D) Potential to convert to a general anesthetic if the block fails or the procedure outlasts the block.
      (E) Brain damage.
   (2) General.
      (A) Permanent organ damage.
      (B) Memory dysfunction/memory loss.
   (3) Spinal.
      (A) Nerve Damage.
      (B) Persistent back pain.
      (C) Bleeding/epidural hematoma.
      (D) Infection.
      (E) Potential to convert to a general anesthetic if the block fails or the procedure outlasts the block.
      (F) Brain damage.
   (4) Monitored anesthesia care (MAC) (conscious sedation).
      (A) Permanent organ damage.
      (B) Memory dysfunction/memory loss.
      (C) Potential to convert to a general anesthetic if the sedation is not adequate.

(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.
      (B) Non-Surgical – Coronary angioplasty, coronary stent insertion, pacemaker insertion, AICD insertion, and cardioversion.
         (i) Acute myocardial infarction.
         (ii) Rupture of myocardium.
         (iii) Life threatening arrhythmias.
         (iv) Necessity for emergency open heart surgery.
         (v) Hemorrhage.
         (vi) Stroke.
         (vii) Sudden death.
         (viii) Device related delayed onset infection.
   (C) Diagnostic.
      (i) Cardiac catheterization.
         (I) Allergic sensitivity reaction to injected contrast media.
         (II) Acute myocardial infarction.
         (III) Kidney damage from IV contrast medium.
         (IV) Arrhythmias.
         (V) Stroke.
         (VI) Injury to vessels that may require immediate surgical intervention.
      (ii) Electrophysiologic studies.
         (I) Cardiac perforation.
         (II) Life threatening arrhythmias.
         (III) Injury to vessels that may require immediate surgical intervention.
         (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) Endovascular stenting of any portion of any portion of the aorta, iliac or carotid artery.
   (i) Hemorrhage.
   (ii) Injury to vessels that may require immediate surgical intervention.
   (iii) Conversion of procedure to open procedure.
   (iv) Failure to deliver stent/endoluminal graft.
   (v) Stent migration.
   (vi) Paraplegia (for thoracic aorta procedures only).
   (vii) Vessel occlusion.
   (viii) Pseudo aneurysm.
   (ix) Irreversible kidney damage.
   (x) Impotence (for abdominal aorta and iliac artery procedures only).
   (xi) Stroke (for carotid artery procedures only).
   (xii) Seizure (for carotid artery procedures only).

(C) Vascular thrombolysis.
   (i) Hemorrhage.
   (ii) Embolus.
   (iii) Pulmonary complications.
   (iv) Shock.

(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.

   (B) Open.
      (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).

(3) Pancreatectomy (subtotal or total).
   (A) Pancreatitis (subtotal).
   (B) Diabetes (total).
   (C) Lifelong requirement of enzyme and digestive medication.
   (D) Anastomotic 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.

(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 loss of vision.

(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 loss of vision.

(3) Retinal or vitreous surgery.
   (A) Complications requiring additional treatment and/or surgery.
   (B) Recurrence or spread of disease.
   (C) Partial or total loss of vision.

(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.
      (iii) Painful or unattractive scarring.
      (iv) Impairment of regional organs, 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 loss of vision.

(6) Corneal surgery, such as corneal transplant, refractive surgery and pterygium.
   (A) Complications requiring additional treatment and/or surgery.
   (B) Possible pain.
   (C) Need for glasses or contact lenses.
   (D) Partial or total loss of vision.

(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 loss of vision.

(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, including removal of the eye.
   (B) Chronic pain.
   (C) Partial or total loss of vision.

(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.

(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.

(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.

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

(9) Repair of vaginal hernia (anterior and/or posterior colporrhaphy and/or enterocoele 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).
    (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) Dilation and curettage of uterus (obstetrical).
    (A) Hemorrhage with possible hysterectomy to control.
    (B) Perforation of the uterus.
    (C) Sterility.
    (D) Injury to bowel and/or bladder.
    (E) Abdominal incision and operation to correct injury.
    (F) Failure to remove all products of conception.

(h) HEMATIC AND LYMPHATIC SYSTEM.

(1) Transfusion of blood and blood components.
   (A) Fever.
   (B) Transfusion reaction which may include kidney failure or anemia.
   (C) Heart failure.
   (D) Hepatitis.
   (E) AIDS (acquired immune deficiency syndrome).
   (F) Other infections.

(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.
   (3) Vasectomy.
      (A) Loss of testicle.
      (B) Failure to produce permanent sterility.

(k) MATERNITY AND RELATED CASES.
   (1) Delivery (vaginal).
      (A) Injury to bladder and/or rectum, including a hole (fistula) between bladder and vagina and/or rectum and vagina.
      (B) Hemorrhage possibly requiring blood administration and/or hysterectomy and/or artery ligation to control.
      (C) Sterility.
      (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.
      (C) Injury to tube (ureter) 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.
   (l) MUSCULOSKELETAL SYSTEM TREATMENTS AND PROCEDURES.
   (1) Arthroplasty of all joints with mechanical device.
      (A) Impaired function such as shortening or deformity of an arm or leg, limp or foot drop.
      (B) Blood vessel or nerve injury.
      (C) Pain or discomfort.
      (D) Fat escaping from bone with possible damage to a vital organ.
      (E) Failure of bone to heal.
      (F) Bone infection.
      (G) Removal or replacement of any implanted device or material.
   (2) Mechanical internal prosthetic device.
      (A) Impaired function such as shortening or deformity of an arm or leg, limp or foot drop.
      (B) Blood vessel or nerve injury.
      (C) Pain or discomfort.
      (D) Fat escaping from bone with possible damage to a vital organ.
      (E) Failure of bone to heal.
      (F) Bone infection.
      (G) Removal or replacement of any implanted device or material.
   (3) Open reduction with internal fixation.
      (A) Impaired function such as shortening or deformity of an arm or leg, limp or foot drop.
      (B) Blood vessel or nerve injury.
      (C) Pain or discomfort.
      (D) Fat escaping from bone with possible damage to a vital organ.
      (E) Failure of bone to heal.
      (F) Bone infection.
      (G) Removal or replacement of any implanted device or material.
   (4) Osteotomy.
      (A) Impaired function such as shortening or deformity of an arm or leg, limp or foot drop.
      (B) Blood vessel or nerve injury.
      (C) Pain or discomfort.
      (D) Fat escaping from bone with possible damage to a vital organ.
      (E) Failure of bone to heal.
      (F) Bone infection.
      (G) Removal or replacement of any implanted device or material.
   (5) Ligamentous reconstruction of joints.
      (A) Failure of reconstruction to work.
      (B) Continued loosening of the joint.
      (C) Degenerative arthritis.
      (D) Continued pain.
      (E) Increased stiffening.
      (F) Blood vessel or nerve injury.
      (G) Cosmetic and/or functional deformity.
   (6) Children's orthopedics (bone, joint, ligament or muscle).
      (A) Growth deformity.
      (B) Additional surgery.
   (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.
(C) Recurrence or continuation of the condition that required this operation.
(D) Nasal septal deformity or perforation.

(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) Angiography, aortography, arteriography (arterial injection of contrast media-diagnostic).
(A) Injury to artery.
(B) Damage to parts of the body supplied by the artery with resulting loss of function or amputation.
(C) Swelling, pain, tenderness or bleeding at the site of the blood vessel perforation.
(D) Aggravation of the condition that necessitated the procedure.
(E) Allergic sensitivity reaction to injected contrast media.
(2) Myelography.
(A) Chronic pain.
(B) Transient headache, nausea, vomiting.
(C) Numbness.
(D) Impaired muscle function.
(3) Angiography with occlusion techniques-therapeutic.
(A) Injury to artery.
(B) Loss or injury to body parts.
(C) Swelling, pain, tenderness or bleeding at the site of the blood vessel perforation.
(D) Aggravation of the condition that necessitated the procedure.
(E) Allergic sensitivity reaction to injected contrast media.
(4) Angioplasty (intravascular dilatation technique).
(A) Swelling, pain, tenderness, or bleeding at the site of vessel puncture.
(B) Damage to parts of the body supplied by the artery with resulting loss of function or amputation.
(C) Injury to the vessel that may require immediate surgical intervention.
(D) Recurrence or continuation of the original condition.
(E) Allergic sensitivity reaction to injected contrast media.
(5) Splenoportography (needle injection of contrast media into the spleen).
(A) Injury to the spleen requiring blood transfusion and/or removal of the spleen.
(B) No other risks are assigned at this time.

(o) RESPIRATORY SYSTEM TREATMENTS AND PROCEDURES
(1) Excision of lesion of larynx, vocal cords, trachea. No risks or hazards assigned at this time.
(2) Rhinoplasty or nasal reconstruction with or without septoplasty.
   (A) Deformity of skin, bone or cartilage.
   (B) Creation of new problems, such as septal perforation 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 with dryness and crusting.
   (C) External deformity of the nose.

(p) URINARY SYSTEM
(1) Partial nephrectomy (removal of part of the kidney).
   (A) Incomplete removal of stone(s) or tumor, if present.
   (B) Obstruction of urinary flow.
   (C) Leakage of urine at surgical site.
   (D) Injury to or loss of the kidney.
   (E) Damage to adjacent organs.
(2) Radical nephrectomy (removal of kidney and adrenal gland for cancer).
   (A) Loss of the adrenal gland.
   (B) Incomplete removal of tumor.
   (C) Damage to adjacent organs.
(3) Nephrectomy (removal of kidney).
   (A) Incomplete removal of tumor if present.
   (B) Damage to adjacent organs.
   (C) Injury to or loss of the kidney.
(4) Nephrolithotomy and pyelolithotomy (removal of kidney stone(s)).
   (A) Incomplete removal of stone(s).
   (B) Obstruction of urinary flow.
   (C) Leakage of urine at surgical site.
   (D) Injury or loss of the kidney.
   (E) Damage to adjacent organs.
(5) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system).
   (A) Obstruction of urinary flow.
   (B) Leakage of urine at surgical site.
   (C) Injury to or loss of the kidney.
   (D) Damage to adjacent organs.
(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 adjacent organs.
(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) Obstruction of urine flow.
   (D) Damage to other adjacent organs.
   (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) Obstruction of urine flow.
   (D) Damage to other adjacent organs.
   (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) Obstruction of urine flow.
   (D) Damage to other adjacent organs.
(10) Ureterolysis (partial/complete removal of ureter (tube between kidney and bladder from adjacent tissue)).
    (A) Leakage of urine at surgical site.
    (B) Obstruction to urine flow.
    (C) Damage to other adjacent organs.
    (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) Obstruction to urine flow.
    (C) Damage to or loss of ureter.
    (D) Backward flow of urine from bladder into ureter.
    (E) Damage to other adjacent organs.
(12) Prostatectomy (partial or total removal of prostate).
    (A) Leakage of urine at surgical site.
    (B) Obstruction to urine flow.
    (C) Incontinence (difficulty with urinary control).
    (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 other adjacent organs.
(C) This procedure will require an alternate method of urinary drainage.

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

(15) Urinary diversion (ileal conduit, colon conduit).
   (A) Blood chemistry abnormalities requiring medication.
   (B) Development of stones, strictures or infection.
   (C) Routine lifelong medical evaluation.
   (D) Leakage of urine at surgical site.
   (E) Requires wearing a bag for urine collection.

(16) Ureterosigmoidostomy (placement of kidney drainage tubes into the large bowel).
   (A) Blood chemistry abnormalities requiring medication.
   (B) Development of stones, strictures or infection.
   (C) Routine lifelong medical evaluation.
   (D) Leakage of urine at surgical site.
   (E) Difficulty in holding urine in the rectum.

(17) Urethroplasty (construction/reconstruction of drainage tube from bladder).
   (A) Leakage of urine at surgical site.
   (B) Stricture formation.
   (C) Additional operation(s).

(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 with pain, fever 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) 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, 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, 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.

(5) Abdomen.
(A) Early reactions.
(i) Skin changes: redness, irritation, scaliness, blistering, ulceration, coloration, thickening, and hair loss.
(ii) Loss of appetite, nausea, vomiting.
(iii) Weight loss, weakness, fatigue.
(iv) Inflammation of stomach causing indigestion, heartburn, and ulcers.

(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.
(ii) Inflammation of rectum and anus causing pain, spasm, discharge, bleeding.
(iii) Bladder inflammation causing burning, frequency, spasm, pain, bleeding.
(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.

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

(iv) Bone damage leading to fractures.

(v) Ovarian damage causing infertility, sterility, or premature menopause.

(vi) Vaginal damage leading to dryness, shrinkage, pain, bleeding, 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 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 bladder 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.

ENDOSCOPIC SURGERY.
(1) Abdominal endoscopy/laparoscopy procedures. The following shall be in addition to risks and hazards of the same surgery when done as an open procedure.
(A) Damage to intra-abdominal structures (e.g., bowel, bladder, blood vessels, or nerves).
(B) Intra-abdominal abscess and infectious complications.
(C) Trocar site complications (e.g., hematoma/bleeding, leakage of fluid, or hernia formation).
(D) Conversion of the procedure to an open procedure.
(E) Cardiac dysfunction.

(2) Endoscopic surgery of the thorax. The following shall be in addition to risks and hazards of the same surgery when done as an open procedure.
(A) Postoperative pneumothorax.
(B) Subcutaneous emphysema.
(C) Conversion of the procedure to an open procedure.

SOURCE: The provisions of this §601.2 adopted to be effective October 3, 1995, 20 TexReg 7486; amended to be effective October 23, 1997, 22 TexReg 10318; amended to be effective March 18, 2004, 29 TexReg 2646; amended to be effective November 28, 2004, 29 TexReg 10780; amended to be effective October 16, 2005, 30 TexReg 6435; Amended to be effective March 4, 2007, 31 TexReg 8826.