<u>25 TAC § 601.1</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 601. GENERAL

§ 601.1. Purpose

(a) The purpose of Chapters 601 - 604 of this title is to implement the duties of the Texas Medical Disclosure Panel under Texas Civil Practice and Remedies Code, Chapter 74 (relating to Medical Liability), Subchapter C (relating to Informed Consent), §§ 74.101-74.107.

(b) The treatments and procedures requiring full disclosure of related risks and hazards by a physician or health care provider to a patient or person authorized to consent for the patient are found in Chapter 602 of this title (relating to Procedures Requiring Full Disclosure of Specific Risks and Hazards--List A).

(c) The treatments and procedures requiring no disclosure of related risks and hazards by a physician or health care provider to a patient or person authorized to consent for the patient are found in Chapter 603 of this title (relating to Procedures Requiring No Disclosure of Specific Risks and Hazards--List B).

(d) The disclosure and consent forms adopted by the Panel are found in Chapter 604 of this title (relating to Disclosure Forms).

History

SOURCE:

The provisions of this § 601.1 adopted to be effective December 26, 2023, 48 TexReg 7984

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

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<u>25 TAC § 601.2</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 601. GENERAL

§ 601.2. 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.

(1) 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 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).

(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.

(q) Effective January 7, 2016, § 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 female genital system treatments and procedures and laparoscopic/thoracoscopic surgery, and adds a new subsection (v) plastic surgery. Section 601.4 of this title (relating to Disclosure and Consent Form) for medical and surgical procedures, and § 601.8 of this title (relating to Disclosure and Consent Form for Hysterectomy) were amended to add risks and hazards related to the use of blood and blood products, risks and hazards related to the use of a power morcellator in laparoscopic surgery, and deletion of references to anesthesia.

(r) Effective December 24, 2017, § 601.2 of this title was amended to revise procedures and risks and hazards 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 remove "Monitored Anesthesia Care" and to add risks and hazards related to potential long-term negative effects with the use of prolonged (greater than 3 hours) or repeated exposure to anesthesia on the fetus of a woman in her 3rd trimester of pregnancy and on a child up to 3 years of age.

History

SOURCE:

The provisions of this § 601.2 adopted to be effective December 26, 2023, 48 TexReg 7984

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.1</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.1. Anesthesia Treatments and Procedures

- (a) Epidural.
 - (1) Nerve damage.
 - (2) Persistent back pain.
 - (3) Headache.
 - (4) Bleeding/epidural hematoma.
 - (5) Infection.
 - (6) Medical necessity to convert to general anesthesia.
 - (7) Brain damage.
 - (8) Chronic pain.
- (b) General.
 - (1) Permanent organ damage.
 - (2) Memory dysfunction/memory loss.
 - (3) Injury to vocal cords, teeth, lips, eyes.
 - (4) Awareness during the procedure.
 - (5) Brain damage.

(c) Spinal.

- (1) Nerve damage.
- (2) Persistent back pain.
- (3) Bleeding/epidural hematoma.
- (4) Infection.
- (5) Medical necessity to convert to general anesthesia.
- (6) Brain damage.
- (7) Headache.

- (8) Chronic pain.
- (d) Regional block.
 - (1) Nerve damage.
 - (2) Persistent pain.
 - (3) Bleeding/hematoma.
 - (4) Infection.
 - (5) Medical necessity to convert to general anesthesia.
 - (6) Brain damage.
- (e) Deep sedation.
 - (1) Memory dysfunction/memory loss.
 - (2) Medical necessity to convert to general anesthesia.
 - (3) Permanent organ damage.
 - (4) Brain damage.
- (f) Moderate sedation.
 - (1) Memory dysfunction/memory loss.
 - (2) Medical necessity to convert to general anesthesia.
 - (3) Permanent organ damage.
 - (4) Brain damage.

(g) Prenatal/Early Childhood Anesthesia. Potential long-term negative effects on memory, behavior, and learning with prolonged or repeated exposure to general anesthesia/moderate sedation/deep sedation during pregnancy and in early childhood.

History

SOURCE:

The provisions of this § 602.1 adopted to be effective December 26, 2023, 48 TexReg 7985

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§ 602.2. Cardiovascular System Treatments and Procedures

- (a) Cardiac.
 - (1) Coronary artery bypass.
 - (A) Acute myocardial infarction (heart attack).
 - **(B)** Hemorrhage (severe bleeding).
 - (C) Kidney failure.
 - (D) Stroke.
 - (E) Sudden death.
 - (F) Infection of chest wall/chest cavity.
 - (2) Heart valve replacement by open surgery, structural heart surgery.
 - (A) Acute myocardial infarction (heart attack).
 - **(B)** Hemorrhage (severe bleeding).
 - (C) Kidney failure.
 - **(D)** Stroke.
 - (E) Sudden death.
 - (F) Infection of chest wall/chest cavity.
 - (G) Valve related delayed onset infection.
 - (H) Malfunction of new valve.

(I) Persistence of problem for which surgery was performed, including need for repeat surgery.

- (3) Heart transplant.
 - (A) Infection.
 - **(B)** Rejection.
 - **(C)** Death.

(4) Coronary angiography (Injection of contrast material into arteries of the heart), coronary angioplasty (opening narrowing in heart vessel), and coronary stent insertion (placement of permanent tube into heart blood vessel to open it).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(5) Percutaneous (through the skin) or minimally invasive heart valve insertion/replacement.

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(J) Malfunction of new valve.

(K) Need for permanent pacemaker implantation.

(6) Left atrial appendage closure (closing of small pouch on left side of heart) - percutaneous (through the skin) or minimally invasive.

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(J) Device embolization (device moves from intended location).

(K) Pericardial effusion (development of fluid in the sack around the heart) and cardiac tamponade (fluid around heart causing too much pressure for heart to pump properly).

(7) Patent foramen ovale/atrial septal defect/ventricular septal defect closure by percutaneous (through the skin) or minimally invasive procedure (closing of abnormal hole between the chambers of the heart).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(J) Atrial fibrillation (irregular heart rhythm).

(K) Pulmonary embolus (development of blood clot that travels to blood vessels in lungs).

(L) Device embolization (device moves from where it is placed).

(M) Cardiac perforation (creation of hole in wall of heart).

(8) Electrophysiology studies (exams of heart rhythm), arrhythmia ablation (procedure to control or stop abnormal heart rhythms).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(J) Rupture of myocardium/cardiac perforation (hole in wall of heart).

(K) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening.

(L) Pulmonary vein stenosis (narrowing of blood vessel going from lung to heart.

(9) Pacemaker insertion, AICD insertion (implanted device to shock the heart out of an abnormal rhythm).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

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

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

(J) Rupture of myocardium/cardiac perforation (hole in wall of heart).

(K) Cause or worsening of arrhythmia (damage to heart electrical system causing abnormal heart rhythm), possibly requiring permanent pacemaker implantation, possibly life threatening.

(L) Device related delayed onset infection (infection related to the device that happens at some time after surgery).

(10) Electrical cardioversion (shocking the heart out of an abnormal rhythm).

- (A) Heart arrhythmias (abnormal heart rhythm), possibly life threatening.
- (B) Skin burns on chest.

(11) Stress testing.

(A) Acute myocardial infarction (heart attack).

(B) Heart arrhythmias (abnormal heart rhythm), possibly life threatening.

(12) Transesophageal echocardiography (ultrasound exam of the heart from inside the throat).

- (A) Sore throat.
- (B) Vocal cord damage.
- (C) Esophageal perforation (hole or tear in tube from mouth to stomach).

(13) Circulatory assist devices (devices to help heart pump blood).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

(H) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself).

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

(J) Hemorrhage (severe bleeding) possibly leading to sudden death.

(K) Hemolysis (blood cells get broken apart).

- (L) Right heart failure (poor functioning of the side of heart not assisted by device).
- (M) Acquired von Willebrand syndrome (platelets do not work).
- **(N)** Arrhythmia (irregular or abnormal heart rhythm).
- (O) Cardiac or vascular injury or perforation (hole in heart or blood vessel).
- (P) Limb ischemia (lack of blood flow or oxygen to limb that device placed through).
- (Q) Device migration or malfunction.
- (R) Exposure of device/wound break down with need for surgery to cover/reimplant.

(14) Extracorporeal Membrane Oxygenation (ECMO).

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention including emergency open heart surgery.

(B) Arrhythmia (abnormal heart rhythm), possibly life threatening.

(C) Hemorrhage (severe bleeding).

(D) Myocardial infarction (heart attack).

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

(F) Sudden death.

(G) Stroke.

(H) Contrast nephropathy or other kidney injury (kidney damage due to the contrast agent used during the procedure or procedure itself).

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

(**J**) Thrombocytopenia (low platelets) or other coagulopathy (blood thinning).

(K) Vascular or cardiac perforation (hole in blood vessel or heart).

(L) Seizure.

(M) Device migration or malfunction.

(N) Ischemia to limb (lack of blood flow or oxygen to limb that device placed through).

(O) Thromboembolism (blood clots in blood vessels or heart and possibly traveling to blood vessels in lungs).

(b) Vascular.

(1) Open surgical repair of aortic, subclavian, iliac, or other artery aneurysms or occlusions, arterial or venous bypass or other vascular surgery.

(A) Hemorrhage (severe bleeding).

(B) Paraplegia (unable to move limbs) (for surgery involving the aorta or other blood vessels to the spine).

(C) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of body part).

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

(E) Stroke (for surgery involving blood vessels supplying the neck or head).

(F) Kidney damage.

(G) Myocardial infarction (heart attack).

(H) Infection of graft (material used to repair blood vessel).

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

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

(B) Hemorrhage (severe bleeding).

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

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

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

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

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

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

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

(3) Angioplasty (intravascular dilatation technique).

(A) 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 or drained by the vessel with resulting loss of use or amputation (removal of body part).

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

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

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

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

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

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

(J) 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.

(4) Endovascular stenting (placement of permanent tube into blood vessel to open it) of any portion of the aorta, iliac or carotid artery or other (peripheral) arteries or veins.

(A) 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 or drained by the vessel with resulting loss of use or amputation (removal of body part).

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

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

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

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

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

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

(J) 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.

(K) Change in procedure to open surgical procedure.

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

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

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

(5) Vascular thrombolysis (removal or dissolving of blood clots) - percutaneous (through the skin) (mechanical or chemical).

(A) 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 or drained by the vessel with resulting loss of use or amputation (removal of body part).

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

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

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

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

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

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

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

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

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

(M) 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).

(N) Need for emergency surgery.

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

(A) For all embolizations/sclerosis: (i) Injury to or occlusion (blocking) of blood vessel other than the one intended which may require immediate surgery or other intervention. (ii) Hemorrhage (severe bleeding). (iii) Damage to parts of the body supplied or drained by the vessel with resulting loss of use or amputation (removal of

body part). (iv) Worsening of the condition for which the procedure is being done. (v) Contrast nephropathy (kidney damage due to the contrast agent used during procedure). (vi) Unintended thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere. (vii) 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). (viii) Infection in the form of abscess (infected fluid collection) or septicemia (infection of blood stream). (ix) Nontarget embolization (blocking of blood vessels other than those intended) which can result in injury to tissues supplied by those vessels.

(B) 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 subparagraph (A) of this paragraph: (i) Stroke. (ii) Seizure. (iii) Paralysis (inability to move). (iv) Inflammation or other injury of nerves (for procedures involving blood vessels supplying the spine). (v) For studies of the blood vessels of the brain: contrast-related, temporary blindness or memory loss.

(C) For female pelvic arterial embolizations including uterine fibroid embolization, these risks in addition to those under subparagraph(A) of this paragraph: (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.

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

(E) For embolizations of pulmonary arteriovenous fistulae/malformations, these risks in addition to those under subparagraph (A) of this paragraph: (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)).

(F) For varicocele embolization, these risks in addition to those under subparagraph (A) of this paragraph: (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 numbress or tingling).

(G) For ovarian vein embolization/pelvic congestion syndrome embolization: general angiography and embolization risks as listed in subparagraph (A) of this paragraph.

(H) For cases utilizing ethanol (alcohol) injection, in addition to the risks under subparagraph (A) of this paragraph: shock or severe lowering of blood pressure (when more than small volumes are utilized).

(I) For varicose vein treatments (with angiography) see paragraph (12) of this subsection.

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

(A) 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 or drained by the vessel 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) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

(G) 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).

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

(8) Inferior vena caval filter insertion and removal.

(A) Injury to or occlusion (blocking) of blood vessel which may require immediate surgery or other intervention.

(B) Hemorrhage (severe bleeding).

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

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

(E) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere including caval thrombosis (clotting of main vein in abdomen and episodes of swelling of legs).

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

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

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

(I) Inability to remove filter (for "optional"/retrievable filters).

(9) Pulmonary angiography.

(A) 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 or drained by the vessel 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) Thrombosis (blood clot forming at or blocking the blood vessel) at access site or elsewhere.

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

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

(I) Death.

(10) Percutaneous treatment of pseudoaneurysm (percutaneous thrombin injection through the skin versus compression).

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

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

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

(A) Pneumothorax (collapsed lung).

(B) Injury to blood vessel.

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

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

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

(12) Varicose vein treatment (percutaneous (through the skin), via laser, radiofrequency ablation (RFA), chemical or other method) without angiography.

- (A) Burns.
- **(B)** Deep vein thrombosis (blood clots in deep veins).
- (C) Hyperpigmentation (darkening of skin).

- **(D)** Skin wound (ulcer).
- (E) Telangiectatic matting (appearance of tiny blood vessels in treated area).
- (F) Paresthesia and dysesthesia (numbress or tingling in the area or limb treated).
- (G) Injury to blood vessel requiring additional procedure to treat.

History

SOURCE:

The provisions of this § 602.2 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.3</u>

This document reflects all regulations in effect as of December 31, 2023

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§ 602.3. Digestive System Treatments and Procedures

- (a) Cholecystectomy with or without common bile duct exploration.
 - (1) Pancreatitis.
 - (2) Injury to the tube between the liver and the bowel.
 - (3) Retained stones in the tube between the liver and the bowel.
 - (4) Narrowing or obstruction of the tube between the liver and the bowel.
 - (5) Injury to the bowel and/or intestinal obstruction.
- (b) Bariatric surgery.
 - (1) Failure of wound to heal or wound dehiscence (separation of wound).
 - (2) Injury to organs.
 - (3) Failure of device requiring additional surgical procedure.
 - (4) Obstructive symptoms requiring additional surgical procedure.
 - (5) Development of gallstones (Roux-En-Y).
 - (6) Development of metabolic and vitamin disorders (Roux-En-Y).
- (c) Pancreatectomy (subtotal or total).
 - (1) Pancreatitis (subtotal).
 - (2) Diabetes (total).
 - (3) Lifelong requirement of enzyme and digestive medication.
 - (4) Anastomotic leaks.
- (d) Total colectomy.
 - (1) Permanent ileostomy.
 - (2) Injury to organs.
 - (3) Infection.
- (e) Subtotal colectomy.

- (1) Anastomotic leaks.
- (2) Temporary colostomy.
- (3) Infection.
- (4) Second surgery.
- (5) Injury to organs.

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

(1) 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).

(2) Pancreatitis (inflammation of the pancreas).

(3) Hemobilia (bleeding into the bile ducts).

(4) Cholangitis, cholecystitis, sepsis (inflammation/infection of the bile ducts, gallbladder or blood).

(5) Pneumothorax (collapsed lung) or other pleural complications (complication involving chest cavity).

- (g) Gastrointestinal tract stenting.
 - (1) Stent migration (stent moves from location in which it was placed).

(2) Esophageal/bowel perforation (creation of a hole or tear in the tube from the throat to the stomach or in the intestines).

- (3) Tumor ingrowth or other obstruction of stent.
- (4) For stent placement in the esophagus (tube from the throat to the stomach).

(A) Tracheal compression (narrowing of windpipe) with resulting or worsening of shortness of breath.

(B) Reflux (stomach contents passing up into esophagus or higher).

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

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

History

SOURCE:

The provisions of this § 602.3 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.4</u>

This document reflects all regulations in effect as of December 31, 2023

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§ 602.4. Ear Treatments and Procedures

- (a) Stapedectomy.
 - (1) Facial paralysis.
 - (2) Diminished or bad taste.
 - (3) Total or partial loss of hearing in the operated ear.
 - (4) Brief or long-standing dizziness.
 - (5) Eardrum hole requiring more surgery.
 - (6) Ringing in the ear.
- (b) Reconstruction of auricle of ear for congenital deformity or trauma.
 - (1) Less satisfactory appearance compared to possible alternative artificial ear.
 - (2) Exposure of implanted material with possible need for removal of material.
- (c) Tympanoplasty with mastoidectomy.
 - (1) Facial paralysis.
 - (2) Altered or loss of taste.
 - (3) Recurrence of original disease process.
 - (4) Total loss of hearing in operated ear.
 - (5) Dizziness.
 - (6) Ringing in the ear.

History

SOURCE:

The provisions of this § 602.4 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.5</u>

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§ 602.5. Endocrine System Treatments and Procedures

- (a) Thyroidectomy.
 - (1) Acute airway obstruction requiring temporary tracheostomy.
 - (2) Injury to nerves resulting in hoarseness or impairment of speech.

(3) 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.

(4) Lifelong requirement of thyroid medication.

- (b) Parathyroidectomy.
 - (1) Acute airway obstruction requiring temporary tracheostomy.
 - (2) Injury to nerves resulting in hoarseness or impairment of speech.

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

- (c) Adrenalectomy.
 - (1) Loss of endocrine functions.
 - (2) Lifelong requirement for hormone replacement therapy and steroid medication.
 - (3) Damage to kidneys.
- (d) Other procedures.

(e) See also Pancreatectomy under § 602.3 of this chapter (relating to Digestive System Treatments and Procedures).

History

SOURCE:

The provisions of this § 602.5 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.6</u>

This document reflects all regulations in effect as of December 31, 2023

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§ 602.6. Eye Treatments and Procedures

- (a) Eye muscle surgery.
 - (1) Additional treatment and/or surgery.
 - (2) Double vision.
 - (3) Partial or total blindness.
- (b) Surgery for cataract with or without implantation of intraocular lens.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Need for glasses or contact lenses.
 - (3) Complications requiring the removal of implanted lens.
 - (4) Partial or total blindness.
- (c) Retinal or vitreous surgery.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Recurrence or spread of disease.
 - (3) Partial or total blindness.

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

- (1) Blindness.
- (2) Nerve damage with loss of use and/or feeling to eye or other areas of face.
- (3) Painful or unattractive scarring.
- (4) Worsening or unsatisfactory appearance.
- **(5)** Dry eye.
- (e) Photocoagulation and/or cryotherapy.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Pain.

- (3) Partial or total blindness.
- (f) Corneal surgery, such as corneal transplant, refractive surgery and pterygium.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Pain.
 - (3) Need for glasses or contact lenses.
 - (4) Partial or total blindness.
- (g) Glaucoma surgery by any method.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Worsening of the glaucoma.
 - (3) Pain.
 - (4) Partial or total blindness.
- (h) Removal of the eye or its contents (enucleation or evisceration).
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Worsening or unsatisfactory appearance.
 - (3) Recurrence or spread of disease.
- (i) Surgery for penetrating ocular injury, including intraocular foreign body.
 - (1) Complications requiring additional treatment and/or surgery.
 - (2) Possible removal of eye.
 - (3) Pain.
 - (4) Partial or total blindness.

History

SOURCE:

The provisions of this § 602.6 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.7</u>

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§ 602.7. Female Genital System Treatments and Procedures

- (a) Hysterectomy (abdominal and vaginal).
 - (1) Uncontrollable leakage of urine.
 - (2) Injury to bladder.
 - (3) Injury to the tube (ureter) between the kidney and the bladder.
 - (4) Injury to the bowel and/or intestinal obstruction.
 - (5) Need to covert to abdominal incision.
 - (6) If laparoscopic surgery is utilized, include the following risks:

(A) Damage during introduction of trocar to adjacent intra-abdominal structures and organs (e.g., bowel, bladder, blood vessels, or nerves) and potential need for additional surgery.

(B) Trocar site complications (e.g., hematoma, bleeding, leakage of fluid, or hernia formation).

- (C) Air embolus (bubble causing heart failure or stroke).
- (D) Change during the procedure to an open procedure.
- (E) If cancer is present, may increase the risk of the spread of cancer.

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

- (1) Injury to the bowel and/or bladder.
- (2) Sterility.
- (3) Failure to obtain fertility (if applicable).
- (4) Failure to obtain sterility (if applicable).

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

(6) If performed with hysterectomy, all associated risks under subsection (a) of this section.

(7) For fallopian tube occlusion (for sterilization with or without hysterectomy), see subsection (n) of this section.

- (c) Removing fibroids (uterine myomectomy).
 - (1) Injury to bladder.
 - (2) Sterility.
 - (3) Injury to the tube (ureter) between the kidney and the bladder.
 - (4) Injury to the bowel and/or intestinal obstruction.
 - (5) May need to convert to hysterectomy.
 - (6) If laparoscopic surgery is utilized, include the following risks:

(A) Damage during introduction of trocar to adjacent intra-abdominal structures and organs (e.g., bowel, bladder, blood vessels, or nerves) and potential need for additional surgery.

(B) Trocar site complications (e.g., hematoma, bleeding, leakage of fluid, or hernia formation).

- (C) Air embolus (bubble causing heart failure or stroke).
- (D) Change during the procedure to an open procedure.
- (E) If cancer is present, may increase the risk of the spread of cancer.
- (d) Uterine suspension.
 - (1) Uncontrollable leakage of urine.
 - (2) Injury to bladder.
 - (3) Injury to the tube (ureter) between the kidney and the bladder.
 - (4) Injury to the bowel and/or intestinal obstruction.
- (e) Removal of the nerves to the uterus (presacral neurectomy).
 - (1) Uncontrollable leakage of urine.
 - (2) Injury to bladder.
 - (3) Injury to the tube (ureter) between the kidney and the bladder.
 - (4) Injury to the bowel and/or intestinal obstruction.
 - (5) Hemorrhage (severe bleeding).
- (f) Removal of the cervix.
 - (1) Uncontrollable leakage of urine.
 - (2) Injury to 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) Need to convert to abdominal incision.

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

- (1) Uncontrollable leakage of urine.
- (2) Injury to 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) Mesh erosion (with damage to vagina and adjacent tissue).
- (h) Abdominal suspension of the bladder (retropubic urethropexy).
 - (1) Uncontrollable leakage of urine.
 - (2) Injury to bladder.
 - (3) Injury to the tube (ureter) between the kidney and the bladder.
 - (4) Injury to the bowel and/or intestinal obstruction.
- (i) Conization of cervix.
 - (1) Hemorrhage (severe bleeding) which may result in hysterectomy.
 - (2) Sterility.
 - (3) Injury to bladder.
 - (4) Injury to rectum.
- (j) Dilation and curettage of uterus (diagnostic/therapeutic).
 - (1) Possible hysterectomy.
 - (2) Perforation (hole) created in the uterus.
 - (3) Sterility.
 - (4) Injury to bowel and/or bladder.
 - (5) Abdominal incision and operation to correct injury.
- (k) Surgical abortion/dilation and curettage/dilation and evacuation.
 - (1) Possible hysterectomy.
 - (2) Perforation (hole) created in the uterus.
 - (3) Sterility.

- (4) Injury to the bowel and/or bladder.
- (5) Abdominal incision and operation to correct injury.
- (6) Failure to remove all products of conception.
- (1) Medical abortion/non-surgical.
 - (1) Hemorrhage with possible need for surgical intervention.
 - (2) Failure to remove all products of conception.
 - (3) Sterility.
- (m) Selective salpingography and tubal reconstruction.
 - (1) Perforation (hole) created in the uterus or Fallopian tube.
 - (2) Future ectopic pregnancy (pregnancy outside of the uterus).
 - (3) Pelvic infection.
- (n) Fallopian tube occlusion (for sterilization with or without hysterectomy).
 - (1) Perforation (hole) created in the uterus or Fallopian tube.
 - (2) Future ectopic pregnancy (pregnancy outside of the uterus).
 - (3) Pelvic infection.
 - (4) Failure to obtain sterility.
- (o) Hysteroscopy.
 - (1) Perforation (hole) created in the uterus.
 - (2) Fluid overload/electrolyte imbalance.
 - (3) Possible hysterectomy.
 - (4) Abdominal incision to correct injury.

History

SOURCE:

The provisions of this § 602.7 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.8</u>

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§ 602.8. Hematic and Lymphatic System Treatments and Procedures

(a) Transfusion of blood and blood components.

(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.
- (b) Splenectomy.
 - (1) Susceptibility to infections and increased severity of infections.
 - (2) Increased immunization requirements.

History

SOURCE:

The provisions of this § 602.8 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.9</u>

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§ 602.9. Breast Surgery (non-cosmetic) Treatments and Procedures

- (a) Radical or modified radical mastectomy.
 - (1) Limitation of movement of shoulder and arm.
 - (2) Permanent swelling of the arm.
 - (3) Loss of the skin of the chest requiring skin graft.
 - (4) Recurrence of malignancy, if present.
 - (5) Decreased sensation or numbress of the inner aspect of the arm and chest wall.
- (b) Simple mastectomy.
 - (1) Loss of skin of the chest requiring skin graft.
 - (2) Recurrence of malignancy, if present.
 - (3) Decreased sensation or numbress of the nipple.
- (c) Lumpectomy.
 - (1) Loss of skin of the chest requiring skin graft.
 - (2) Recurrence of malignancy, if present.
 - (3) Decreased sensation or numbress of the nipple.
- (d) Open biopsy.
 - (1) Loss of skin of the chest requiring skin graft.
 - (2) Recurrence of malignancy, if present.
 - (3) Decreased sensation or numbress of the nipple.

History

SOURCE:

The provisions of this § 602.9 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.10</u>

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§ 602.10. Male Genital System Treatments and Procedures

- (a) Orchidopexy (reposition of testis(es)).
 - (1) Removal of testicle.
 - (2) Atrophy (shriveling) of the testicle with loss of function.
- (b) Orchiectomy (removal of the testis(es)).
 - (1) Decreased sexual desire.
 - (2) Difficulties with penile erection.
 - (3) Permanent sterility (inability to father children) if both testes are removed.
- (c) Vasectomy.
 - (1) Loss of testicle.
 - (2) Failure to produce permanent sterility (inability to father children).
- (d) Circumcision.
 - (1) Injury to penis.
 - (2) Need for further surgery.

History

SOURCE:

The provisions of this § 602.10 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.11</u>

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§ 602.11. Maternity and Related Cases Treatments and Procedures

(a) Delivery (vaginal).

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

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

(3) Sterility (inability to get pregnant).

(4) 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.

- (b) Delivery (cesarean section).
 - (1) Injury to bowel and/or bladder.
 - (2) Sterility (inability to get pregnant).
 - (3) Injury to ureter (tube between kidney and bladder).

(4) 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.

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

- (c) Cerclage.
 - (1) Premature labor.
 - (2) Injury to bowel and/or bladder.
 - (3) Rupture to membranes and possible infection.

History

SOURCE:

The provisions of this § 602.11 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.12</u>

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§ 602.12. Musculoskeletal System Treatments and Procedures

- (a) Arthroplasty of any joints with mechanical device.
 - (1) Impaired function such as stiffness, limp, or change in limb length.
 - (2) Blood vessel or nerve injury.
 - (3) Pain.
 - (4) Blood clot in limb or lung.
 - (5) Failure of bone to heal.
 - (6) Infection.
 - (7) Removal or replacement of any implanted device or material.
 - (8) Dislocation or loosening requiring additional surgery.

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

- (b) Arthroscopy of any joint.
 - (1) Blood vessel or nerve injury.
 - (2) Continued pain.
 - (3) Stiffness of joint.
 - (4) Blood clot in limb or lung.
 - (5) Joint infection.

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

- (c) Open reduction with internal fixation.
 - (1) Impaired function such as stiffness, limp, or change in limb length.
 - (2) Blood vessel or nerve injury.
 - (3) Pain.
 - (4) Blood clot in limb or lung.

(5) Failure of bone to heal.

(6) Infection.

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

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

(d) Osteotomy.

- (1) Impaired function such as stiffness, limp, or change in limb length.
- (2) Blood vessel or nerve injury.
- (3) Pain.
- (4) Blood clot in limb or lung.
- (5) Failure of bone to heal.
- (6) Infection.
- (7) Removal or replacement of any implanted device or material.

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

- (e) Ligamentous reconstruction of joints.
 - (1) Continued instability of the joint.
 - (2) Arthritis.
 - (3) Continued pain.
 - (4) Stiffness of joint.
 - (5) Blood vessel or nerve injury.
 - (6) Impaired function and/or scarring.
 - (7) Blood clot in limb or lung.

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

(f) Vertebroplasty/kyphoplasty.

- (1) Nerve/spinal cord injury.
- (2) Need for emergency surgery.

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

- (4) Collapse of adjacent vertebrae (bones in spine).
- (5) Leak of cerebrospinal fluid (fluid around the brain and spinal cord).

- (6) Pneumothorax (collapsed lung).
- (7) Failure to relieve pain.
- (8) Rib fracture.

(g) 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.

- (1) Arthrotomy (opening of joint).
- (2) Closed reduction with or without pin or external fixation.
- (3) Surgical management of open wound.
- (4) Partial excision or removal of bone.
- (5) Removal of external fixation device.
- (6) Traction or casting with or without manipulation for reduction.
- (h) Amputation of limb.
 - (1) Pain and/or phantom sensation in removed limb.
 - (2) Need for further surgery.
 - (3) Infection.
 - (4) Hemorrhage (severe bleeding).
 - (5) Difficulty with prosthesis fitting.

History

SOURCE:

The provisions of this § 602.12 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.13</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.13. Nervous System Treatments and Procedures

- (a) Craniotomy, craniectomy or cranioplasty.
 - (1) Loss of brain function such as memory and/or ability to speak.

(2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).

- (3) Stroke (damage to brain resulting in loss of one or more functions).
- (4) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
- (5) Weakness, paralysis, loss of coordination.
- (6) Cerebrospinal fluid leak with potential for severe headaches.
- (7) Meningitis (infection of coverings of brain and spinal cord).
- (8) Brain abscess.
- (9) Persistent vegetative state (not able to communicate or interact with others).
- (10) Hydrocephalus (abnormal fluid buildup causing pressure in the brain).
- (11) Seizures (uncontrolled nerve activity).
- (12) Need for permanent breathing tube and/or permanent feeding tube.
- (b) Cranial nerve operations.
 - (1) Weakness, numbness, impaired muscle function or paralysis.
 - (2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).
 - (3) Seizures (uncontrolled nerve activity).
 - (4) New or different pain.
 - (5) Stroke (damage to brain resulting in loss of one or more functions).
 - (6) Persistent vegetative state (not able to communicate or interact with others).
 - (7) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
 - (8) Cerebrospinal fluid leak with potential for severe headaches.

(9) Meningitis (infection of coverings of brain and spinal cord).

(10) Need for prolonged nursing care.

(11) Need for permanent breathing tube and/or permanent feeding tube.

(c) 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).

(1) Weakness, pain, numbness or clumsiness.

(2) Impaired muscle function or paralysis.

(3) Incontinence, impotence or impaired bowel function (loss of bowel/bladder control and/or sexual function).

(4) Migration of implants (movement of implanted devices).

(5) Failure of implants (breaking of implanted devices).

(6) Adjacent level degeneration (breakdown of spine above and/or below the level treated).

(7) Cerebrospinal fluid leak with potential for severe headaches.

(8) Meningitis (infection of coverings of brain and spinal cord).

(9) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).

(10) Unstable spine (abnormal movement between bones and/or soft tissues of the spine).

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

(1) Numbness.

(2) Impaired muscle function.

(3) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).

(4) Continued, increased or different pain.

(5) Weakness.

(e) Transphenoidal hypophysectomy or other pituitary gland operation.

(1) Cerebrospinal fluid leak with potential for severe headaches.

(2) Necessity for hormone replacement.

(3) Recurrence or continuation of the condition that required this operation.

(4) Deformity or perforation of nasal septum (hole in wall between the right and left halves of the nose).

(5) Facial nerve injury resulting in disfigurement (loss of nerve function controlling muscles in face).

- (6) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
- (7) Stroke (damage to brain resulting in loss of one or more functions).
- (8) Persistent vegetative state (not able to communicate or interact with others).
- (9) Headaches.
- (f) Cerebrospinal fluid shunting procedure or revision.
 - (1) Shunt obstruction (blockage of shunt/tubing causing it to stop draining adequately).

(2) Malposition or migration of shunt/tubing (improper positioning or later movement of shunt/tubing causing it to stop draining adequately).

- (3) Seizures (uncontrolled nerve activity).
- (4) Recurrence or continuation of brain dysfunction.
- (5) Injury to internal organs of the chest or abdomen.
- (6) Brain injury.
- (7) Stroke (damage to brain resulting in loss of one or more functions).
- (8) Persistent vegetative state (not able to communicate or interact with others).
- (9) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
- (10) Cerebrospinal fluid leak with potential for severe headaches.
- (11) Meningitis (infection of coverings of brain and spinal cord).
- (12) Need for prolonged nursing care.
- (13) Need for permanent breathing tube and/or permanent feeding tube.
- (g) Elevation of depressed skull fracture.
 - (1) Loss of brain function such as memory and/or ability to speak.

(2) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).

- (3) Loss of senses (blindness, double vision, deafness, smell, numbness, taste).
- (4) Weakness, paralysis, loss of coordination.
- (5) Cerebrospinal fluid leak with potential for severe headaches.
- (6) Meningitis (infection of coverings of brain and spinal cord).
- (7) Brain abscess.
- (8) Persistent vegetative state (not able to communicate or interact with others).
- (9) Seizures (uncontrolled nerve activity).

(10) Need for permanent breathing tube and/or permanent feeding tube.

History

SOURCE:

The provisions of this § 602.13 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.14</u>

This document reflects all regulations in effect as of December 31, 2023

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§ 602.14. Radiology Treatments and Procedures

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

(1) All associated risks as listed under § 602.2(b)(2) of this chapter (relating to Cardiovascular System Treatments and Procedures).

- (2) Injury to the spleen requiring blood transfusion and/or removal of the spleen.
- (b) Chemoembolization.
 - (1) All associated risks as listed under § 602.2(b)(2) of this chapter.

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

- (3) Injury to or failure of liver (or other organ in which tumor is located).
- (4) Risks of the chemotherapeutic agent(s) utilized.

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

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

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

- (c) Radioembolization.
 - (1) All associated risks as listed under \S 602.2(b)(2) of this chapter.

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

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

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

(d) 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).

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

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

(3) Failure to completely treat tumor.

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

- (1) All associated risks as listed under \S 602.2(b)(2)-(4) of this chapter.
- (2) Hepatic encephalopathy (confusion/decreased ability to think).
- (3) Liver failure or injury.
- (4) Gallbladder injury.
- (5) Hemorrhage (severe bleeding).
- (6) Recurrent ascites (fluid building up in abdomen) and/or bleeding.
- (7) Kidney failure.
- (8) Heart failure.
- (9) Death.
- (f) Myelography.
 - (1) Chronic (continuing) pain.
 - (2) Nerve injury with loss of use and/or feeling.
 - (3) Transient (temporary) headache, nausea, and/or vomiting.
 - (4) Numbness.
 - (5) Seizure.

(g) Percutaneous abscess/fluid collection drainage (percutaneous

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

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

- (2) Injury to nearby organs.
- (3) Hemorrhage (severe bleeding).

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

- (h) Procedures utilizing prolonged fluoroscopy.
 - (1) Skin injury (such as epilation (hair loss), burns, or ulcers).
 - (2) Cataracts (for procedures in the region of the head).

History

SOURCE:

The provisions of this § 602.14 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.15</u>

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TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.15. Respiratory System Treatments and Procedures

- (a) Biopsy and/or excision (removal) of lesion of larynx, vocal cords, trachea.
 - (1) Loss or change of voice.
 - (2) Swallowing or breathing difficulties.
 - (3) Perforation (hole) or fistula (connection) in esophagus (tube from throat to stomach).

(b) Rhinoplasty (surgery to change the shape of the nose) or nasal reconstruction with or without nasal septoplasty (surgical procedure to remove blockage in or straighten the bone and cartilage dividing the space between the two nostrils).

(1) Deformity of skin, bone or cartilage.

(2) 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.

(c) Submucous resection of nasal septum or nasal septoplasty (surgery to remove blockage in or straighten the bone and cartilage dividing the space between the two nostrils).

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

(2) Perforation of nasal septum (hole in the bone and/or cartilage dividing the space between the right and left halves of the nose) with dryness and crusting.

(3) External deformity of the nose.

(d) Sinus surgery/endoscopic sinus surgery.

- (1) Spinal fluid leak.
- (2) Visual loss or other eye injury.
- (3) Numbness in front teeth and palate (top of mouth).
- (4) Loss or reduction in sense of taste or smell.
- (5) Recurrence of disease.

(6) Empty Nose Syndrome (sensation of nasal congestion, sensation of not being able to take in adequate air through nose).

(7) Injury to tear duct causing drainage of tears down the cheek.

(8) Brain injury and/or infection.

(9) Injury to nasal septum (the bone and cartilage dividing the space between the two nostrils).

(10) Nasal obstruction.

(e) Lung biopsy (removal of small piece of tissue from inside of lung).

(1) Air leak with pneumothorax (leak of air from lung to inside of chest causing the lung to collapse) with need for insertion of chest tube or repeat surgery.

(2) Hemothorax (blood in the chest around the lung) possibly requiring additional procedures.

(3) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).

(f) Segmental resection of lung (removal of a portion of a lung).

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

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

(3) Air leak with pneumothorax (leak of air from lung inside of chest causing the lung to collapse) with need for insertion of chest drainage tube into space between lung and chest wall or repeat surgery.

(4) Need for additional surgery.

(g) Thoracotomy (surgery to reach the inside of the chest).

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

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

(3) Air leak with pneumothorax (leak of air from lung inside of chest causing the lung to collapse) with need for insertion of chest drainage tube into space between lung and chest wall or repeat surgery.

(4) Need for additional surgery.

(h) VATS - video-assisted thoracoscopic surgery (camera-assisted surgery to reach the inside of the chest through small incisions).

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

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

(3) Air leak with pneumothorax (leak of air from lung inside of chest causing the lung to collapse) with need for insertion of chest drainage tube into space between lung and chest wall or repeat surgery.

(4) Need for additional surgery.

(5) Need to convert to open surgery.

(i) Percutaneous (puncture through the skin instead of incision) or Open (surgical incision) tracheostomy.

(1) Loss of voice.

(2) Breathing difficulties.

(3) Pneumothorax (collapsed lung) with need for insertion of chest tube.

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

(5) Scarring in trachea (windpipe).

(6) Fistula (connection) between trachea into esophagus (tube from throat to stomach) or great vessels.

(7) Bronchospasm (constriction of the airways leading to trouble breathing).

(8) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).

(j) Bronchoscopy (insertion of a camera into the airways of the neck and chest).

(1) Mucosal injury (damage to lining of airways) including perforation (hole in the airway).

(2) Pneumothorax (collapsed lung) with need for insertion of chest tube.

(3) Pneumomediastinum (air enters the space around the airways including the space around the heart).

(4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords).

(5) Bronchospasm (constriction of the airways leading to trouble breathing).

(6) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).

(k) Endobronchial valve placement (device inserted into airways in the lung that controls air movement into and out of abnormal portions of a lung).

(1) Mucosal injury (damage to lining of airways) including perforation (hole in the airway).

(2) Pneumothorax (collapsed lung) with need for insertion of chest tube.

(3) Pneumomediastinum (air enters the space around the airways including the space around the heart).

(4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords).

(5) Migration (movement) of the stent from its original position.

(6) Airway blockage, potentially life threatening.

(7) Stent blockage.

(8) Worsening of chronic obstructive pulmonary disease (worsening of emphysema).

(9) Respiratory failure (need for breathing tube placement with ventilator support).

(10) Bronchospasm (constriction of the airways leading to trouble breathing).

(11) Hemoptysis (coughing up blood which can result in trouble breathing and the need to be placed on a ventilator or breathing machine and oxygen).

(12) Recurrent infections.

(1) Endobronchial balloon dilatation with or without stent placement (placement of tube to keep airway open).

(1) Bronchial rupture (tearing of the airway) with need for additional surgery.

(2) Pneumothorax (collapsed lung) with need for insertion of chest tube.

(3) Pneumomediastinum (air enters the space around the airways including the space around the heart).

(4) Injury to vocal cords, laryngospasm (irritation/spasm of the vocal cords) or laryngeal edema (swelling of the vocal cords).

(5) Migration (movement) of the stent from its original position.

- (6) Airway blockage, potentially life threatening.
- (7) Stent blockage.
- (8) Stent fracture (broken stent).
- (9) Recurrent infections.

(10) Stent erosion into adjacent structures (stent wears a hole through the airway and injures nearby tissues).

(11) Hemoptysis (coughing up blood which can result in respiratory distress and the need to be placed on a ventilator or breathing machine and oxygen).

(m) Mediastinoscopy (insertion of a camera into the space behind the breastbone and between the lungs) with or without biopsy (removal of tissue).

(1) Hemorrhage (severe bleeding) requiring open surgery.

(2) Nerve injury causing vocal cord paralysis or poor function.

(3) Pneumothorax (collapsed lung).

(4) Tracheal injury (damage to the airway/windpipe).

(n) Pleurodesis (procedure to prevent fluid build-up in space between the lung and chest wall).

- (1) Respiratory failure (need for breathing tube placement).
- (2) Empyema (infection/pus in the space around the lung).

History

SOURCE:

The provisions of this § 602.15 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.16</u>

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§ 602.16. Urinary System Treatments and Procedures

- (a) Partial nephrectomy (removal of part of the kidney).
 - (1) Incomplete removal of stone(s) or tumor, if present.
 - (2) Blockage of urine.
 - (3) Leakage of urine at surgical site.
 - (4) Injury to or loss of the kidney.
 - (5) Damage to organs next to kidney.
- (b) Radical nephrectomy (removal of kidney and adrenal gland for cancer).

(1) Loss of the adrenal gland (gland on top of kidney that makes certain hormones/chemicals the body needs).

- (2) Incomplete removal of tumor.
- (3) Damage to organs next to kidney.
- (c) Nephrectomy (removal of kidney).
 - (1) Incomplete removal of tumor if present.
 - (2) Damage to organs next to kidney.
 - (3) Injury to or loss of the kidney.
- (d) Nephrolithotomy and pyelolithotomy (removal of kidney stone(s)).
 - (1) Incomplete removal of stone(s).
 - (2) Blockage of urine.
 - (3) Leakage of urine at surgical site.
 - (4) Injury or loss of the kidney.
 - (5) Damage to organs next to kidney.
- (e) Pyeloureteroplasty (pyeloplasty or reconstruction of the kidney drainage system).
 - (1) Blockage of urine.

- (2) Leakage of urine at surgical site.
- (3) Injury to or loss of the kidney.
- (4) Damage to organs next to kidney.
- (f) Exploration of kidney or perinephric mass.
 - (1) Incomplete removal of stone(s) or tumor, if present.
 - (2) Leakage of urine at surgical site.
 - (3) Injury to or loss of the kidney.
 - (4) Damage to organs next to kidney.
- (g) Ureteroplasty (reconstruction of ureter (tube between kidney and bladder)).
 - (1) Leakage of urine at surgical site.
 - (2) Incomplete removal of the stone or tumor (when applicable).
 - (3) Blockage of urine.
 - (4) Damage to organs next to ureter.
 - (5) Damage to or loss of the ureter.

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

- (1) Leakage of urine at surgical site.
- (2) Incomplete removal of stone.
- (3) Blockage of urine.
- (4) Damage to organs next to ureter.
- (5) Damage to or loss of ureter.
- (i) Ureterectomy (partial/complete removal of ureter (tube between kidney and bladder)).
 - (1) Leakage of urine at surgical site.
 - (2) Incomplete removal of stone.
 - (3) Blockage of urine.
 - (4) Damage to organs next to ureter.

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

- (1) Leakage of urine at surgical site.
- (2) Blockage of urine.
- (3) Damage to organs next to ureter.
- (4) Damage to or loss of ureter.

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

- (1) Leakage of urine at surgical site.
- (2) Blockage of urine.
- (3) Damage to or loss of ureter.
- (4) Backward flow of urine from bladder into ureter.
- (5) Damage to organs next to ureter.
- (1) Prostatectomy (partial or total removal of prostate).
 - (1) Leakage of urine at surgical site.
 - (2) Blockage of urine.
 - (3) Incontinence (difficulty with control of urine flow).
 - (4) Semen passing backward into bladder.

(5) Difficulty with penile erection (possible with partial and probable with total prostatectomy).

- (m) Total cystectomy (removal of bladder).
 - (1) Probable loss of penile erection and ejaculation in the male.
 - (2) Damage to organs next to bladder.
 - (3) This procedure will require an alternate method of urinary drainage.
- (n) Radical cystectomy.
 - (1) Probable loss of penile erection and ejaculation in the male.
 - (2) Damage to organs next to bladder.
 - (3) This procedure will require an alternate method of urinary drainage.
 - (4) Chronic (continuing) swelling of thighs, legs and feet.
 - (5) Recurrence or spread of cancer if present.
- (o) Partial cystectomy (partial removal of bladder).
 - (1) Leakage of urine at surgical site.
 - (2) Incontinence (difficulty with control of urine flow).
 - (3) Backward flow of urine from bladder into ureter (tube between kidney and bladder).
 - (4) Blockage of urine.
 - (5) Damage to organs next to bladder.
- (p) Urinary diversion (ileal conduit, colon conduit).
 - (1) Blood chemistry abnormalities requiring medication.

(2) Development of stones, strictures or infection in the kidneys, ureter or bowel (intestine).

(3) Leakage of urine at surgical site.

(4) This procedure will require an alternate method of urinary drainage.

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

(1) Blood chemistry abnormalities requiring medication.

(2) Development of stones, strictures or infection in the kidneys, ureter or bowel (intestine).

- (3) Leakage of urine at surgical site.
- (4) Difficulty in holding urine in the rectum.
- (r) Urethroplasty (construction/reconstruction of drainage tube from bladder).
 - (1) Leakage of urine at surgical site.
 - (2) Stricture formation (narrowing of urethra (tube from bladder to outside)).
 - (3) Need for additional surgery.
- (s) Percutaneous nephrostomy/stenting/stone removal.

(1) Pneumothorax or other pleural complications (collapsed lung or filling of the chest cavity on the same side with fluid).

(2) Septic shock/bacteremia (infection of the blood stream with possible shock/severe lowering of blood pressure) when pyonephrosis (infected urine in the kidney) present.

- (3) Bowel (intestinal) injury.
- (4) Blood vessel injury with or without significant bleeding.
- (t) Dialysis (technique to replace functions of kidney and clean blood of toxins).
 - (1) Hemodialysis.
 - (A) Hypotension (low blood pressure).
 - **(B)** Hypertension (high blood pressure).
 - (C) Air embolism (air bubble in blood vessel) resulting in possible death or paralysis.
 - **(D)** Cardiac arrhythmias (irregular heart rhythms).

(E) Infections of blood stream, access site, or blood borne (for example: Hepatitis B, C, or HIV).

(F) Hemorrhage (severe bleeding as a result of clotting problems or due to disconnection of the bloodline).

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

(H) Allergic reactions.

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

(J) Pyrogenic reactions (fever).

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

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

(2) Peritoneal dialysis.

(A) 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.

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

(C) Hypertension (high blood pressure).

(D) Hypotension (low blood pressure).

(E) Hydrothorax (fluid in chest cavity).

(F) Arrhythmia (irregular heart rhythm).

(G) Perforation of the bowel.

(H) Sclerosis or scarring of the peritoneum.

(I) Weight gain leading to obesity.

(J) Abdominal discomfort/distension.

(K) Heartburn or reflux.

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

(M) Muscle weakness.

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

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

(P) Allergic reactions.

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

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§ 602.17. Psychiatric Treatments and Procedures

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

- (1) Memory changes of events prior to, during, and immediately following the treatment.
- (2) Fractures or dislocations of bones.
- (3) Significant temporary confusion requiring special care.
- (b) Other Procedures. No other procedures are assigned at this time.

History

SOURCE:

The provisions of this § 602.17 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.18</u>

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§ 602.18. Radiation Therapy Treatments and Procedures

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

(b) Head and neck.

- (1) Early reactions.
 - (A) Reduced and sticky saliva, loss of taste and appetite, altered sense of smell, nausea.

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

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

- (D) Hoarseness, cough, loss of voice, and swelling of airway.
- (E) Blockage and crusting of nasal passages.
- (F) Inflammation of ear canal, feeling of "stopped up" ear, hearing loss, dizziness.

(G) Dry and irritable eye(s).

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

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

(2) Late reactions.

- (A) Dry mouth and altered sense, or loss, of taste.
- **(B)** Tooth decay and gum changes.
- (C) Bone damage, especially in jaws.
- (D) Stiffness and limitation of jaw movement.

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

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

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

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

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

(J) 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.

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

(L) 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.

(c) Central nervous system.

(1) Early reactions.

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

(B) Nausea, vomiting, headaches.

(C) Fatigue, drowsiness.

(D) Altered sense of taste or smell.

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

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

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

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

(2) Late reactions.

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

(B) Persistent drowsiness and tiredness.

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

(D) Scarring of skin.

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

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

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

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

(I) 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.

- (d) Thorax.
 - (1) Early reactions.

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

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

(C) Loss of appetite, nausea, vomiting.

(D) Weight loss, weakness, vomiting.

- (E) Inflammation of the lung with pain, fever and cough.
- (F) Inflammation of the heart sac with chest pain and palpitations.
- (G) Bleeding or creation of a fistula resulting from tumor destruction.

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

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

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

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

(2) Late reactions.

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

- (B) Lung scarring or shrinkage causing shortness of breath.
- (C) Narrowing of esophagus causing swallowing problems.
- (D) Constriction of heart sac which may require surgical correction.

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

(F) Fracture of ribs.

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

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

(I) 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.

(e) Breast.

(1) Early reactions.

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

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

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

- (D) Lung inflammation with cough.
- (E) Inflammation of heart sac with chest pain and palpitations.
- (2) Late reactions.
 - (A) Changes in skin texture and/or coloration, permanent hair loss, scarring of skin.
 - (B) Breast changes including thickening, firmness, tenderness, shrinkage.
 - (C) Swelling of arm.
 - (D) Stiffness and discomfort in shoulder joint.
 - (E) Rib or lung damage causing pain, fracture, cough, shortness of breath.
 - (F) Nerve damage causing pain, loss of strength or feeling in arm.
 - (G) Damage to heart muscle or arteries or heart sac leading to heart failure.

(f) Abdomen.

(1) Early reactions.

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

- (B) Loss of appetite, nausea, vomiting.
- (C) Weight loss, weakness, fatigue.
- (D) Inflammation of stomach causing indigestion, heartburn, and ulcers.

(E) Inflammation of bowel causing cramping and diarrhea.

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

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

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

(2) Late reactions.

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

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

(C) 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.

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

(E) Liver damage leading to liver failure.

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

(G) 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.

(g) Female pelvis.

- (1) Early reactions.
 - (A) Inflammation of bowel causing cramping and diarrhea.
 - (B) Inflammation of rectum and anus causing pain, spasm, discharge, bleeding.
 - (C) Bladder inflammation causing burning, frequency, spasm, pain, bleeding.

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

(E) Disturbance of menstrual cycle.

(F) Vaginal discharge, pain, irritation, bleeding.

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

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

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

(2) Late reactions.

(A) 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.

(B) 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.

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

(D) Bone damage leading to fractures.

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

(F) Vaginal damage leading to dryness, shrinkage, pain, bleeding, or sexual dysfunction.

(G) Swelling of the genitalia or legs.

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

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

(J) 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.

(h) Male pelvis.

(1) Early reactions.

(A) Inflammation of bowel causing cramping and diarrhea.

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

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

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

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

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

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

(2) Late reactions.

(A) 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.

(B) 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.

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

(D) Bone damage leading to fractures.

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

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

(G) Swelling of the genitalia or legs.

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

(I) Fistula between the bowel and other organs.

(J) 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.

(i) Skin.

- (1) Early reactions.
 - (A) Redness, irritation, or soreness.
 - (B) Scaliness, ulceration, crusting, oozing, discharge.
 - (C) Hair loss.
 - (D) These reactions are likely to be intensified by chemotherapy.
- (2) Late reactions.

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

- (B) Changes in skin color.
- (C) Prominent dilated small blood vessels.
- (D) Permanent hair loss.
- (E) Chronic or recurrent ulcerations.
- (F) Damage to adjacent tissues including underlying bone or cartilage.
- (G) In children, second cancers may develop in the irradiated area.

(j) Extremities.

(1) Early reactions.

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

(B) Inflammation of soft tissues causing tenderness, swelling, and interference with movement.

(C) Inflammation of joints causing pain, swelling and limitation of joint motion.

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

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

(2) Late reactions.

(A) Changes in skin reaction and/or coloration, permanent hair loss and scarring of the skin.

(B) Scarring or shrinkage of soft tissues and muscle causing loss of flexibility and movement, swelling of the limb.

(C) Nerve damage causing loss of strength, feeling or coordination.

(D) Bone damage causing fracture.

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

(F) Swelling of limb below the area treated.

(G) 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.

(k) Total body irradiation.

(1) Early reactions.

(A) Loss of appetite, nausea, vomiting.

(B) Diarrhea.

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

(D) Hair loss.

(E) Sore mouth and throat, difficulty swallowing.

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

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

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

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

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

- (2) Late reactions.
 - (A) Lung scarring causing shortness of breath, infection, and fatal lung failure.
 - (B) Cataract formation in the eyes, possible loss of vision.
 - (C) Testicular damage in males causing sterility.
 - (D) Ovarian damage in females causing premature menopause and sterility.
 - (E) Increased risk of second cancer.

History

SOURCE:

The provisions of this § 602.18 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.19</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.19. Laparoscopic, Thoracoscopic and Robotic Surgery Treatments and Procedures

The following shall be in addition to risks and hazards of the same surgery when done as an open procedure.

(1) Damage during introduction of trocar to adjacent intra-abdominal structures (e.g., organs, blood vessels, or other vital tissues) and potential need for additional surgery.

(2) Trocar site complications (e.g., hematoma/bleeding, leakage of fluid, or hernia formation).

- (3) Air embolus (bubble causing heart failure or stroke).
- (4) Postoperative pneumothorax (collapsed lung).
- (5) Subcutaneous emphysema (air in between skin layers).
- (6) Change during the procedure to an open procedure.
- (7) If cancer is present, may increase the risk of the spread of cancer.

History

SOURCE:

The provisions of this § 602.19 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.20</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.20. Pain Management Treatments and Procedures

- (a) Neuroaxial procedures (injections into or around spine).
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Nerve damage including paralysis (inability to move).
 - (3) Epidural hematoma (bleeding in or around spinal canal).
 - (4) Infection.
 - (5) Seizure.
 - (6) Persistent leak of spinal fluid which may require surgery.
 - (7) Breathing and/or heart problems including cardiac arrest (heart stops beating).
 - (8) Loss of vision.
 - (9) Stroke.
- (b) Peripheral and visceral nerve blocks and/or ablations.
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Bleeding.
 - (3) Nerve damage including paralysis (inability to move).
 - (4) Infection.
 - (5) Damage to nearby organ or structure.
 - (6) Seizure.
- (c) Implantation of pain control devices.
 - (1) Failure to reduce pain or worsening of pain.
 - (2) Nerve damage including paralysis (inability to move).
 - (3) Epidural hematoma (bleeding in or around spinal canal).
 - (4) Infection.
 - (5) Persistent leak of spinal fluid which may require surgery.

History

SOURCE:

The provisions of this § 602.20 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.21</u>

This document reflects all regulations in effect as of December 31, 2023

TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.21. Dental Surgery Treatments and Procedures

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

(D) 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).

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

(F) Fracture or loss of tooth.

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

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

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

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

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

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

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

(3) 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)).

(A) Permanent or temporary numbress or altered sensation.

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

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

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

(A) Permanent or temporary numbress or altered sensation.

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

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

(A) Permanent or temporary numbress or altered sensation.

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

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

(A) Permanent or temporary numbress or altered sensation.

- (B) Tooth sensitivity to hot, cold, sweet, or acid foods.
- (C) Loss of tooth.

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

- (7) Guided tissue regeneration-resorbable barrier.
 - (A) Permanent or temporary numbress or altered sensation.
 - **(B)** Accidental aspiration (into the lungs) of foreign matter.
 - (C) Rejection of donor materials.
- (8) Guided tissue regeneration-nonresorbable barrier (includes membrane removal).
 - (A) Permanent or temporary numbress or altered sensation.

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

- (C) Accidental aspiration (into the lungs) of foreign matter.
- **(D)** Rejection of donor materials.

(9) Pedicle soft tissue graft procedure.

(A) Permanent or temporary numbress or altered sensation.

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

(C) Rejection of donor materials.

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

(A) Permanent or temporary numbress or altered sensation.

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

(C) Rejection of graft.

(11) Sub epithelial connective tissue graft procedures.

(A) Permanent or temporary numbress or altered sensation.

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

(C) Rejection of graft.

(12) 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.

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

(A) Permanent or temporary numbress or altered sensation.

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

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

- (d) Implant procedures.
 - (1) Bone grafting (replacing missing bone).
 - (A) Permanent or temporary numbress or altered sensation.
 - (B) Rejection of bone particles or graft from donor or recipient sites.
 - **(C)** Damage to adjacent teeth or bone.
 - (2) Surgical placement of implant body.
 - (A) Blood vessel or nerve injury.
 - (B) Damage to adjacent teeth or bone fracture.
 - (C) Sinus communication (opening from tooth socket into the sinus cavity).
 - **(D)** Failure of implant requiring corrective surgery.
 - (E) Cyst formation, bone loss, or gum disease around the implant.

History

SOURCE:

The provisions of this § 602.21 adopted to be effective December 26, 2023, 48 TexReg 7985

TEXAS ADMINISTRATIVE CODETEXAS ADMINISTRATIVE CODE

<u>25 TAC § 602.22</u>

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TX - Texas Administrative Code > TITLE 25. HEALTH SERVICES > PART 7. TEXAS MEDICAL DISCLOSURE PANEL > CHAPTER 602. PROCEDURE REQUIRING FULL DISCLOSURE OF SPECIFIC RISKS AND HAZARDS--LIST A

§ 602.22. Plastic Surgery and Surgery of the Integumentary System Treatments and Procedures

- (a) Augmentation mammoplasty (breast enlargement with implant).
 - (1) Bleeding around implant.
 - (2) Sensory changes or loss of nipple sensitivity.
 - (3) Failure, deflation, or leaking of implant requiring replacement.
 - (4) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).
 - (5) Problems with or the inability to breastfeed.
 - (6) Capsular contracture (hardening of breast).
- (b) Bilateral breast reduction.
 - (1) Skin flap or fat necrosis (injury or death of skin and fat).
 - (2) Loss of nipple or areola.
 - (3) Sensory changes or loss of nipple sensitivity.
 - (4) Problems with or the inability to breastfeed.

(5) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape or not desired size).

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

(1) 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.

- (2) Spinal fluid leak.
- (3) Worsening or unsatisfactory appearance.
- (d) Reconstruction and/or plastic surgery operations of the face and neck.
 - (1) Impairment of regional organs, such as eye or lip function.
 - (2) Recurrence of the original condition.

- (3) Worsening or unsatisfactory appearance.
- (e) Liposuction (removal of fat by suction).
 - (1) Shock.
 - (2) Pulmonary fat embolism (fat escaping with possible damage to vital organs).
 - (3) Damage to skin with possible skin loss.
 - (4) Loose skin.
 - (5) Worsening or unsatisfactory appearance.
- (f) Breast reconstruction with other flaps and/or implants.
 - (1) Bleeding around implant.
 - (2) Sensory changes or loss of nipple sensitivity.
 - (3) Failure, deflation, or leaking of implant requiring replacement.
 - (4) Damage to internal organs.
 - (5) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).
- (g) Nipple Areolar Reconstruction.
 - (1) Loss of graft.
 - (2) Unsatisfactory appearance.
- (h) Panniculecotomy (removal of skin and fat).
 - (1) Persistent swelling in the legs.
 - (2) Nerve damage.
 - (3) Worsening or unsatisfactory appearance.
- (i) Tendonitis, tendon release, and trigger releases.
 - (1) Recurrence of symptoms.
 - (2) Damage to blood vessels, nerves, tendons, or muscles.
 - (3) Worsening function.
- (j) Breast reconstruction with flaps.
 - (1) Damage to blood vessels, nerves, or muscles.
 - (2) Loss of flap possibly requiring additional surgery.
 - (3) Damage to internal organs.
 - (4) Increased risk of abdominal wall complications with pregnancy.
 - (5) Abdominal hernias with abdominal flaps.
 - (6) Chronic abdominal pain with abdominal flaps.

§ 602.22. Plastic Surgery and Surgery of the Integumentary System Treatments and Procedures

- (7) Worsening or unsatisfactory appearance including asymmetry (unequal size or shape).
- (k) Flap or graft surgery.
 - (1) Damage to blood vessels, nerves, or muscles.
 - (2) Deep vein thrombosis (blood clot in legs or arms).
 - (3) Loss of flap possibly requiring additional surgery.
 - (4) Worsening or unsatisfactory appearance.
- (1) Tendons, nerves, or blood vessel repair.
 - (1) Damage to nerves.
 - (2) Deep vein thrombosis (blood clot in legs or arms).
 - (3) Rupture of repair.
 - (4) Worsening of function.

(m) Reconstructive and/or plastic surgical procedures of the eye and eye region, such as blepharoplasty, tumor, fracture, lacrimal surgery, foreign body, abscess, or trauma. See § 602.6(d) of this chapter (relating to Eye Treatments and Procedures).

History

SOURCE:

The provisions of this § 602.22 adopted to be effective December 26, 2023, 48 TexReg 7985

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