

Minutes LOUISIANA MEDICAL DISCLOSURE PANEL Friday, March 27, 2015 1:00 pm- 3:00 pm Bienville Building Room 173 (unapproved)

- I. Welcome
- II. Roll Call/ Establish Quorum
 - Quorum established at 1:15 p.m.
 - Attendees:
 - i. Dr. Leo Regan
 - ii. Dr. Nelson Daly
 - iii. Charles W. "Bill" Bradley LA Association of Defense Counsel
 - iv. Benjamin Mouton
 - v. Kara Samuels
 - vi. Dr. Geoffrey Garrett
 - vii. Dr. Katherine Williams
 - viii. Dr. Patrick Hall
 - ix. Dr. Devjani Lahiri-Munir Optometry Association of LA
 - x. Dr. Debra Berger
 - Also in attendance:
 - i. Dr. Mark Dotson
 - ii. Dr. Hanemann
 - iii. Dr. Hubble
 - iv. Dr. Larry Simon, Head of Otolaryngology (Lafayette, LA)

Opening:	
The regular meeting of the Medical Disclosure Par	nel was called to order at 1:11 p.m. on 3/27/2015
in Baton Rouge by Dr. Katherine Williams. Quoru	m established at 1:15 p.m.
Review of Minutes:	
Motion by, seconded by	to approve the minutes from the March 28.
2014 meeting. Motion carried.	
Rulemaking Strategy:	
Motion by Dr. Devjani Lahiri, seconded by Dr. Go	eoffrey Garrett to repeal current rule and replace
with new/updated documentation in a new rule.	

Review of Specialties:

Anesthesiology – approval of definition of compartment syndrome

Motion by Dr. Geoffrey Garrett and seconded by Dr. Devjani Lahiri to accept the Anesthesiology Specialty definition of compartment syndrome: A buildup of pressure within muscles which can lead to decreased blood flow, nerve and muscle damage. Motion Carried.

Surgery list of procedures that do not require consent

Motion by Dr. Debra Berger and seconded by Dr. Devjani Lahiri to accept the Surgery list of procedures that do not require consent with the inclusion of Minor excisions and I and D.

Suture removal

Staple removal

Drain removal

Central line removal

Dressing removal (including packing)

Dressing placement (including packing)

Wound vac placement or removal

Motion Carried.

Podiatry presented by Dr. Patrick Hall

Discussion held regarding submission by Dr. Hall. Dr. Hall will update documentation pursuant to discussion and present at the next meeting.

Otolaryngology presented by Dr. Debra Berger with Dr. Larry Simon, Head of Otolaryngology Motion by Dr. Debra Berger and seconded by Dr. Devjani Lahiri to accept the Otolaryngology procedures as presented. Will add a list of Exclusions at the next meeting. Motion Carried.

Radiology presented by Dr. J. Douglass Hanemann

Motion by Ben Mouton and seconded by Dr. Debra Berger to accept the Radiology Section 2430 as is and add Intravenous Injection of Radiopaque Contrast Media (ionic and nonionic) to the list of procedures that do not require consent. Motion Carried.

Ophthalmology presented by Dr. Geoffrey Garrett

Motion by Ben Mouton to resubmit/represent Ophthalmology procedures at next meeting with changes suggested.

Orthopedics (Presented by Dr. Mark Dodson/Louisiana Orthopeadic Association)

Motion by Ben Mouton and seconded by Dr. Debra Berger to accept the orthopedic procedures, Section 2339 to remain as is and add the list of procedures that do not require consent as presented by Dr. Dodson:

- (1) Arthrotomy, arthrocentesis, or joint injection.
- (2) Closed reduction without internal fixation.
- (3) Wound debridement.
- (4) Needle biopsy or aspiration, bone marrow.
- (5) Partial excision of bone.
- (6) Removal of external fixation device.
- (7) Traction or fixation without manipulation for reduction.

- (8) Removal of sutures
 - (9) Removal of percutaneous pins Motion Carried.

Gastroenterology/Digestive System (Dr. Hobley/Information by Dr. Kelly Finan)
Motion by Dr. Geoffrey Garrett and seconded by Dr. Berger to accept the
Gastroenterology/Digestive System changes as presented with a Digestive System Category and A.
Gastroenterology Section and B. Colorectal Surgery Section. Motion Carried.

Pain Management (Dr. Paul Hubble) -

Draft reviewed along with discussion regarding Botox and placing Pain Management under the Nervous System. Dr. Hubble will continue to work on the document and present at the next meeting.

New Business:

Finalize Meeting Topics for Next Meeting

- Podiatry complex excision and debridement complete with list of exclusions (Dr. Patrick Hall)
- Otolaryngology will bring list of exclusions (Dr. Berger with Dr. Simon)
- Ophthalmology make changes (Dr. Garrett with the Louisiana Ophthalmology Association)
- Optometry (Dr. Lahiri)
- Thoracic Surgery Dr. Blaine Borders (Cindy Bishop, Society of Thoracic Surgeons)
- Radiation Oncology Dr. Hanemann and LRS to review and discuss at annual meeting weekend of 3/27/15
- Neurosurgery (Dr. Hanemann locating Neurosurgeon to review)
- Pain Management represent add devices/exceptions
- Botox (Dr. Williams)
- Urology

Dr. Williams recommended for specialties that have not submitted updated documentation that the Panel submits the Texas Rule changes to them for approval and/or comment. Should the Panel receive no comment the Panel may then vote to accept/adopt the Texas Rules for those specialties at the next meeting. Motion to accept Dr. Geoffrey Garrett

Bill Bradley - we would want as comprehensive a list as possible.

Gastroenterology – camera question from Dr. Berger

Dr. Hubble has a recommendation for the Consent form. Carol to forward to the lawyers to review.

Page 2, Consent Form, first paragraph 2nd or 3rd line. I will forward this to the Panel within the next few weeks. Would like amendment added to consent form

Announcements:

Next Meeting:

Friday, August 21, 2015

1pm - 3pm

DHH, Bienville Building, Room 173

Baton Rouge, LA 70802

Adjournment:

Motion to Adjourn was made by Dr. Williams. No objection. Panel adjourned at 2:21 p.m.

OTOLARYNGOLOGY

EAR PROCEDURES and SURGERIES (This would replace § 2313, or be assigned a new § number)

A. Tubes in ears (formerly §2371)

- 1. Pain
- 2. Bleeding which may require transfusion
- 3. Infection or failure of wound to heal, requiring further treatment or surgery
- 4. Injury to surrounding structures
- 5. Hearing loss that may be temporary or permanent
- 6. Otorrhea (drainage from the ears)
- 7. Persistent Infection, that may require further treatment or surgery
- 8. Perforation of Eardrum or Cyst behind the Eardrum Requiring Surgical Repair
- 9. Need to Surgically Remove Tubes
- 10. Death

B. Preauricular pit removal

- 1. Pain
- 2. Bleeding which may require transfusion
- 3. Infection or failure of wound to heal requiring further treatment or surgery
- 4. Injury to surrounding structures
- 5. Need for further surgery
- 6. Recurrence
- 7. Injury to external ear which may require further or additional surgery
- 8. Injury to ear canal which may require surgery
- 9. Death

C. Removal of acoustic neuroma/ vestibular schwannoma or other skull base tumor, or craniotomy for ear disease

- 1. Pain
- 2. Bleeding which may require transfusion
- 3. Infection or failure of wound to heal requiring further treatment or surgery
- 4. Injury to surrounding structures
- 5. Need for further surgery
- 6. Stroke
- 7. Paralysis that may be temporary or permanent
- 8. Visual loss that may be temporary or permanent
- 9. Prolonged vegetative state that may be temporary or permanent
- 10. Hearing loss
- 11. Prolonged dizziness or imbalance
- 12. Facial paralysis or weakness
- 13. Leakage of brain fluid and leakage of spinal fluid, which may lead to brain infection (meningitis) and require surgery

- 14. Meningitis
- 15. Additional surgery
- 16. Tracheostomy (a breathing tube surgically placed in the neck)
- 17. Surgically placed feeding tube (temporary or permanent)
- 18. Tumor recurrence
- 19. Blindness in one or both eyes (temporary or permanent)
- 20. Loss of smell (temporary or permanent)
- 21. Loss of facial sensation (permanent or temporary)
- 22. Tinnitus (ringing in the ears) (permanent, temporary, or intermittent)
- 23. Death

D. Semicircular Canal Occlusion or labyrinthectomy

- 1. Pain
- 2. Bleeding which may require transfusion
- 3. Infection or failure of wound to heal requiring further treatment or surgery
- 4. Injury to surrounding structures
- 5. Total hearing loss that may be temporary or permanent
- 6. Worsening of dizziness that may be temporary or permanent
- 7. Tinnitus that may be temporary or permanent
- 8. Facial paralysis that may be temporary or permanent
- 9. Brain fluid leak or spinal fluid leak, which can lead to brain infection (meningitis) and require surgical repair
- 10. Need for additional surgery
- 11. Death

E. Cochlear implant

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Permanent and disfiguring scarring
- 6. Loss of residual hearing that may be temporary or permanent
- 7. Non function of the device requiring another operation or removal of the device
- 8. Facial paralysis that may be temporary or permanent
- 9. Dizziness that may be temporary or permanent
- 10. Brain fluid leak or spinal fluid leak, which could lead to brain infection (meningitis) and require surgical repair
- 11. Need for additional surgery
- 12. Alteration of sense of taste that may be temporary or permanent
- 13. Failure to improve hearing
- 14. Tinnitus that may be temporary or permanent
- 15. Facial swelling that may be temporary or permanent
- 16. Death

F. Surgical Placement of Bone Integrated Hearing Device

1. Bleeding that might require transfusion

- 2. Infection that may require further treatment or surgery
- 3. Brain fluid leak or spinal fluid leak, which could lead to brain infection (meningitis) and require surgical repair.
- 4. Nonfunctioning of the device requiring reoperation or removal of the device
- 5. Permanent and disfiguring scarring
- 6. Failure to improve hearing
- 7. Extrusion of device from the skull (possibly requiring surgical repair or revision)
- 8. Injury to surrounding structures
- 9. Need for additional surgery
- 10. Death

G. Stapedectomy or middle ear exploration

- 1. Bleeding that may require transfusion
- 2. Total hearing loss that may be temporary or permanent
- 3. Perforation of the tympanic membrane (hole in the eardrum)
- 4. Infection that may require further treatment or surgery
- 5. Drainage from the ear that may be temporary or permanent
- 6. Brain or spinal fluid leak, which may lead to brain infection (meningitis) and require surgery
- 7. Facial paralysis that may be temporary or permanent
- 8. Tinnitus that may be temporary or permanent
- 9. Dizziness that may be temporary or permanent
- 10. Alteration or loss of sense of taste that may be temporary or permanent
- 11. Failure to improve hearing
- 12. Injury to surrounding structures
- 13. Need for additional surgery
- 14. Death

H. Tympanoplasty with ossicular chain reconstruction

- 1. Infection that may require further treatment or surgery
- 2. Bleeding
- 3. Injury to facial nerve causing weakness or paralysis of the face (Permanent or Temporary)
- 4. Injury to nerves of tongue causing alteration of taste or loss of taste (Permanent or Temporary)
- 5. Ringing in the ears (Permanent or Temporary)
- 6. Dizziness (Permanent or Temporary)
- 7. Hole in the eardrum, which may require surgery to repair.
- 8. Leakage of brain fluid which may require surgery and which may lead to brain injection (meningitis)
- 9. Recurrence of the original problem
- 10. Failure of hearing to improve or loss of hearing
- 11. Graft Failure
- 12. Damage to the skull base, which may require surgery to repair
- 13. Stroke

14. Injury to the nerves of the arm with weakness and/or numbness of the arm and hand (Permanent or Temporary)

I. Tympanoplasty without ossicular chain reconstruction

- 1. Infection that may require further treatment or surgery
- 2. Bleeding
- 3. Injury to facial nerve causing weakness or paralysis of the face (Permanent or Temporary)
- 4. Injury to nerves of tongue causing alteration of taste or loss of taste (Permanent or Temporary)
- 5. Ringing in the ears (Permanent or Temporary)
- 6. Dizziness (Permanent or Temporary)
- 7. Hole in the eardrum, which may require surgery to repair.
- 8. Leakage of brain fluid which may require surgery and which may lead to brain injection (meningitis)
- 9. Recurrence of the original problem
- 10. Failure of hearing to improve or loss of hearing
- 11. Graft Failure
- 12. Damage to the skull base, which may require surgery to repair
- 13. Stroke
- 14. Injury to the nerves of the arm with weakness and/or numbness of the arm and hand (Permanent or Temporary)

J. Tympanoplasty with Mastoidectomy, with ossicular chain reconstruction

- 1. Infection that may require further treatment or surgery
- 2. Bleeding, which may require transfusion
- 3. Injury to facial nerve causing weakness or paralysis of the face (Permanent or Temporary)
- 4. Injury to nerves of tongue causing alteration of taste or loss of taste (Permanent or Temporary)
- 5. Ringing in the ears (Permanent or Temporary)
- 6. Dizziness (Permanent or Temporary)
- 7. Hole in the eardrum
- 8. Leakage of brain fluid which may require surgery and which may lead to brain injection (meningitis)
- 9. Recurrence of the original problem
- 10. Failure of hearing to improve or loss of hearing
- 11. Graft Failure
- 12. Damage to the skull base, which may require surgery to repair
- 13. Stroke
- 14. Injury to the nerves of the arm with weakness and/or numbness of the arm and hand (Permanent or Temporary)

K. Tympanoplasty with Mastoidectomy, without ossicular chain reconstruction

- 1. Infection that may require further treatment or surgery
- 2. Bleeding, which may require transfusion
- 3. Injury to facial nerve causing weakness or paralysis of the face (Permanent or Temporary)
- 4. Injury to nerves of tongue causing alteration of taste or loss of taste (Permanent or Temporary)
- 5. Ringing in the ears (Permanent or Temporary)
- 6. Dizziness (Permanent or Temporary)
- 7. Hole in the eardrum
- 8. Leakage of brain fluid which may require surgery and which may lead to brain injection (meningitis)
- 9. Recurrence of the original problem
- 10. Damage to the skull base, which may require surgery to repair
- 11. Failure of hearing to improve or loss of hearing
- 12. Graft Failure
- 13. Stroke
- 14. Injury to the nerves of the arm with weakness and/or numbness of the arm and hand (Permanent or Temporary)

(assign NEW § number) NOSE PROCEDURES and SURGERIES

A. Balloon Sinus Ostial Dilation (any sinus)

- 1. Pain
- 2. Permanent and disfiguring scarring
- 3. Infection or failure of wound to heal requiring further treatment or surgery
- 4. Bleeding which may require transfusion
- 5. Injury to surrounding structures
- 6. Need for further surgery
- 7. Injury to sense of smell that may be temporary or permanent
- 8. Leakage of brain fluid which may require surgery and which may lead to brain injection (meningitis)
- 9. Injury to skull base which may require surgery
- 10. Injury to eye which may require surgery or result in permanent or temporary blindness and/or double vision
- 11. Death

B. Inferior Turbinate Reduction

- 1. Pain
- 2. Permanent and disfiguring scarring
- 3. Infection or failure of wound to heal requiring further treatment or surgery
- 4. Injury to surrounding structures

- 5. Need for further and/or revision surgery
- 6. Dryness and crusting of nose which may be permanent
- 7. Loss of sense of smell, which may be permanent
- 8. Significant bleeding which may require further surgery or blood transfusion
- 9. Nasal obstruction which may require surgery
- 10. Death

C. Septoplasty (formerly §2377)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding requiring surgery and/or transfusion which may be fatal
- 4. Injury to sense of smell which may be temporary or permanent
- 5. Nasal obstruction
- 6. Nasal deformity which may be permanent or require additional surgery
- 7. Injury to nerves of upper teeth
- 8. Septal perforation
- 9. Spinal fluid leak
- 10. Permanent disfiguring or scarring
- 11. Injury to surrounding structures
- 12. Death
- 13. Dryness and crusting of the nose, which may be permanent

D. Nasal Cautery (formerly §2379)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding requiring surgery and/or transfusion which may be fatal
- 4. Scarring with obstruction of breathing which may be permanent
- 5. Dryness of nose (temporary or permanent)
- 6. Injury to sense of smell (temporary or permanent)
- 7. Nasal obstruction, which may be permanent
- 8. Nasal deformity which may require additional surgery
- 9. Injury to surrounding structures
- 10. Need for further surgery
- 11. Death
- 12. Staining of the skin of the upper lip/skin under the nose, which may be permanent or temporary

E. Rhinoplasty (Formerly §2381)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding requiring surgery and/or transfusion which may be fatal
- 4. Failure to achieve desired facial appearance
- 5. Possible need for corrective surgery
- 6. Temporary Skin discoloration and swelling
- 7 Bleeding or hematoma
- 8. Poor wound healing or permanent disfiguring or scarring

- 9. Change in skin sensation with numbness, tingling, and pain
- 10. Difficulty breathing, which may be permanent
- 11. Possible perforation of septum (hole in the septum). Corrective surgery may be required, but it may be impossible to correct this complication.
- 12. Injury to surrounding structures
- 13. Need for further surgery
- 14. Death

F. Endoscopic Nasal Surgery- includes Polypectomy, Biopsy, Debridement, and Endoscopic Sinus Surgery – any Sinus (Formerly §2383)

- 1. Pain
- 2. Bleeding
- 3. Infection that may require further treatment or surgery
- 4. Scar formation
- 5. Injury to eye, including blindness and/or double vision, which may be permanent
- 6. Injury to sense of smell (temporary or permanent)
- 7. Injury to tear duct drainage (temporary or permanent)
- 8. Nasal obstructions
- 9. Injury to skull base which may require additional surgery
- 10. Leakage of brain or spinal fluid, which may lead to brain infection (meningitis) and require surgery
- 11. Injury to any surrounding structures
- 12. Need for further surgery
- 13. Death

(assign NEW § number)

<u>NECK PROCEDURES</u> and SURGERIES (Formerly §2385 Radical Neck – Extensive Neck Surgery)

A. Removal of Thyroglossal Duct Cyst

- 1. Pain
- 2. Bleeding requiring further treatment or transfusion
- 3. Infection requiring further treatment or surgery
- 4. Injury to the nerve that moves the tongue that may be permanent
- 5. Tongue weakness or paralysis that may be permanent
- 6. Difficulty speaking that may be permanent
- 7. Difficulty swallowing that may be permanent
- 8. Perforation of the throat
- 9. Injury to airway structures
- 10. Altered taste that may be permanent
- 11. Recurrence of the cyst with need for additional surgery
- 12. Injury to any surrounding structures
- 13. Need for further surgery
- 14. Death

B. Brachial Cleft Excision

- 1. Pain
- 1. Bleeding requiring further treatment or surgery
- 2. Infection requiring further treatment or surgery
- 3. Carotid artery injury with significant blood loss and possible stroke
- 4. Jugular vein injury with significant blood loss
- 5. Injury to cranial nerves
- 6. Facial paralysis or weakness (may be temporary or permanent)
- 7. Numbness of ear and or neck (may be temporary or permanent)
- 8. Shoulder weakness (may be temporary or permanent)
- 9. Injury to the nerve that moves the tongue and difficulty speaking, that may result in a permanent deficit
- 10. Altered taste that may be permanent
- 11. Injury to surrounding structures
- 12. Need for further surgery
- 13. Death

C. Deep Cervical Node Biopsy

- 1. Pain
- 2. Infection requiring further treatment and surgery
- 3. Bleeeding that may require transfusion and may be fatal
- 4. Injury to surrounding structures
- 5. Permanent and disfiguring scarring
- 6. Carotid artery injury with significant blood loss and possible stroke
- 7. Jugular vein injury with significant blood loss requiring transfusion
- 8. Injury to cranial nerves leading to temporary or permanent deficits
- 9. Facial paralysis or weakness (may be temporary or permanent)
- 10. Numbness of ear and/or neck (may be temporary or permanent)
- 11. Shoulder weakness (may be temporary or permanent)
- 12. Need for additional surgery
- 13. Death

D. Rigid Esophagoscopy with Foreign Body Removal

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal
- 4. Permanent disfiguring or scarring
- 5. Injury to surrounding structures
- 6. Injuring to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 7. Cardiac arrhythmias (irregular heartbeats)
- 8. Perforation of throat, pharynx, or esophagus which may require surgery

- 9. Difficulty swallowing (may be temporary or permanent)
- 10. Esophageal obstruction which may require surgery
- 11. Failure to retrieve foreign body
- 12. Airway obstruction which could require surgery and which could be fatal
- 13. Need for further surgery
- 14. Death

E. Wide Local Excision of Facial Skin Lesion

- 1. Failure to remove entire lesion
- 2. Permanent and disfiguring scar
- 3. Recurrence of the original lesion

F. Thyroid Surgery

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal
- 4. Injury to any surrounding structures
- 5. Injury to the nerves resulting in hoarseness or impairment of speech, which could be temporary or permanent and which might require additional treatment or surgery
- 6. Hoarseness or weak voice which could require additional surgery
- 7. Injury to the airway which may require additional surgery and/or tracheostomy
- 8. In jury to the laryngeal nerve (may be temporary or permanent)
- 9. Hypothyroidism with need for lifelong medication
- 10. Injury to parathyroid glands
- 11. Low blood calcium which may lead to cardiac arrhythmias (irregular heartbeats) and which may require lifelong medication
- 12. Airway obstruction which may require additional surgery and which may be fatal
- 13. Need for a tracheostomy (breathing tube in the neck)
- 14. Permanent disfiguring or scarring
- 15. Need for further surgery
- 16. Death

G. Tracheostomy

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Injury to any surrounding structures
- 4. Difficulty swallowing (temporary or permanent)
- 5. Difficulty speaking (temporary or permanent)
- 6. Injury to airway
- 7. Significant bleeding which may require surgery and /or transfusion

- 8. Hoarseness or weak voice which could require additional surgery
- 9. In jury to the laryngeal nerve (temporary or permanent)
- 10. Injury to the esophagus which may require additional surgery
- 11. Dislodgement of tracheostomy tube with inability to breathe which may lead to hypoxic (low oxygen) injury (such as brain injury or stroke)
- 12. Obstruction of tracheostomy tube that may lead to need additional surgery and which may be fatal
- 13. Brain injury and stroke
- 14. Need for further surgery
- 15. Death

H. Reconstruction of Facial Defects Using Local or Regional Flaps

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal]
- 4. Disfigurement requiring further surgery
- 5. Failure of or loss of flap requiring further surgery
- 6. Injury to tissue at flap donor site with need for further surgery
- 7. Unsatisfactory cosmetic outcome
- 8. Permanent disfiguring or scarring
- 9. Injury to surrounding structures
- 10. Need for further surgery
- 11. Death

I. Parotidectomy

(Formerly §2395 Parotidectomy (Removal of Salivary Gland near the Ear))

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding which may require surgery and /or transfusion
- 4. Irregular, unususal, and unpredicatable facial swelling
- 5. Disfigurement of face, neck, or ear
- 6. Fluid collection in area of gland removal which may require further surgery
- 7. Depression of skin in area of gland removal
- 8. Damage to nerves working muscles of forehead, eye, cheek, lower lip of same side of face (temporary or permanent paralysis)
- 9. Numbness (temporary or permanent) of area around the ear
- 10. Sweating of skin when eating over the previous area of gland
- 11. Prolonged lumpiness in area of excision
- 12. Injury to facial nerve causing weakness or paralysis of the face
- 13. Injury to surrounding structures

- 14. Need for further surgery
- 15. Death

J. Submandibular Gland Surgery (Formerly §2387)

- 1. Pain
- 2.Infection requiring further treatment or surgery
- 3. Bleeding, which may require transfusion and which may be fatal
- 4. Alteration of taste (may be temporary or permanent)
- 5. Loss of sensation of tongue and mouth (may be temporary or permanent)
- 6. Fluid collection in area of gland removal which may require further surgery
- 7. Permanent and disfiguring scarring
- 8. Injury to surrounding structures
- 9. Injury of nerve that moves the tongue (may be temporary or permanent)
- 10. Injury of nerve that moves the lip and mouth (may be temporary or permanent)
- 11. Difficulty speaking (may be temporary or permanent)
- 12. Difficulty swallowing (may be temporary or permanent)
- 13. Hearing loss (may be temporary or permanent)
- 14. Ringing in the ears (may be temporary or permanent)
- 15. Dizziness (may be temporary or permanent)
- 16. Graft failure
- 17. Need for further surgery
- 18. Death

K. Neck Dissection (Formerly §2385 Radical Neck (Extensive Neck Surgery)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding, which may require transfusion and which may be fatal
- 4. Injury to nerves of shoulder resulting in temporary or permanent numbness, pain, or loss of function
- 5. Injury to voice box resulting in temporary or permanent hoarseness or speech impairment
- 6. Injury to nerve of tongue resulting in temporary or permanent loss of sensation, loss or alteration of sense of taste, or possible speech impairment
- 7. Injury to mandibular branch of facial nerve resulting in temporary or permanent loss of function of lip or cheek
- 8. Chyle leak possibly requiring treatment with medicine, diet modification, or surgery
- 9. Cardiac arrhythmias (irregular heartbeat)
- 10. Injury to surrounding structures
- 11. Need for further surgery
- 12. Death

L. Laryngectomy

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding, which may require transfusion and which may be fatal
- 4. Permanent scars or disfigurement
- 5. Breathing or swallowing difficulties
- 6. Fistula (opening from skin into throat or food pipe allowing drainage of saliva and needing packing or additional surgery)
- 7. Vocal changes or total loss of voice, requiring
 - a. prolonged speech therapy
 - b. esophageal speech by use of an electronic device
 - c. additional surgery of insertion of a Bloom-Singer type valve
- 8. Loss of smell, which may be permanent
- 9. Weakness or alteration in lifting or straining ability
- 10. Permanent breathing hole in the neck
- 11. Inability to swim due to aspiration of water into the breathing hole in the neck
- 12. Injury to nerves of shoulder causing numbness, pain, or loss of function
- 13. Injury to nerves of tongue causing numbness, loss of sensation and movement, and impairment of speech
- 14. Injury to nerve that moves lower lip or cheeks
- 15. Leakage of lymph fluid, which may require treatment with medicine, diet modification or surgery
- 16. Additional risks associated, due to any complicating medical condition of the patient
- 17. Persistence of the cancer
- 18. Recurrence of the cancer
- 19. Low blood calcium which may lead to cardiac arrhythmias (irregular heartbeats) and which may require lifelong medication
- 20. Carotid artery injury with significant blood loss and possible stroke
- 21. Jugular vein injury with significant blood loss
- 22. Stroke
- 23. Injury to surrounding structures
- 24. Need for further surgery
- 25. Death

(assign NEW § number)

THROAT PROCEDURES and SURGERIES

- A. Tonsillectomy (formerly §2375)
 - 1. Pain

- 2. Infection requiring further treatment or surgery
- 3. Alteration of voice, which may be temporary or permanent.
- 4. Injury to nerves of tongue, which may produce temporary or permanent drooling and/or difficulty with speech and/or swallowing
- 5. Pharyngeal stenosis (narrowing of upper airway) which may require multiple surgeries to treat
- 6. Bleeding, which may require surgery and/or transfusion and which may be fatal
- 7. Regrowth of tonsil tissue
- 8. Nasal speech that may be temporary or permanent
- 9. Injury to surrounding structures
- 10. Need for further surgery
- 11. Death

B. Adenoidectomy (formerly §2373)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding which may require surgery and/or transfusion and which may be fatal
- 4. Nasal speech which may be temporary or permanent
- 5. Nasal regurgitation of foods or liquids which may be temporary or permanent
- 6. Injury to surrounding structures
- 7. Need for further surgery
- 8. Injury to nerves of tongue, which may produce temporary or permanent drooling and/or difficulty with speech and/or swallowing
- 9. Death

C. Uvuloparatopharyngoplasty (UPPP)

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Persistence of sleep apnea
- 6. Alteration of voice (temporary or permanent)
- 7. Nasal speech (temporary or permanent)
- 8. Nasal regurgitation of foods (temporary or permanent)
- 9. Injury to nerves of tongue, which may produce temporary or permanent drooling and/or difficulty with speech and/or swallowing
- 10. Pharyngeal stenosis (narrowing or obstruction of the upper airway) which may require additional surgeries to correct.
- 11. Bleeding which may require blood transfusions and which could be fatal
- 12. Carotid artery injury with significant blood loss and possible stroke
- 13. Need for other further surgery

14. Death

D. Direct Laryngoscopy and Bronchoscopy (Formerly §2393 – Direct Laryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal
- 4. Injury to surrounding structures
- 5. Difficulty swallowing (temporary or permanent)
- 6. Peristent hoarseness
- 7. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 8. Cardiac arrhythmias (irregular heartbeats)
- 9. Need for tracheostomy
- 10. Change in or loss of voice (temporary or permanent)
- 11. Injury to larynx which may require surgery
- 12. Perforation of throat, pharynx, or esophagus which may require surgery
- 13. Obstruction of airway which may require surgery and which may be fatal
- 14. Perforation of airway which may require surgery and which may be fatal
- 15. Disfiguring or scarring of surrounding structures
- 16. Need for surgery
- 17. Death

E. Direct Laryngoscopy and Bronchoscopy with Excision of Tumor/Lesion

(Formerly §2393 – Direct Laryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal
- 4. Injury to surrounding structures
- 5. Difficulty swallowing (temporary or permanent)
- 6. Peristent hoarseness
- 7. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 8. Cardiac arrhythmias (irregular heartbeats)
- 9. Recurrence of original problem with need for further surgery
- 10. Need for tracheostomy
- 11. Change in or loss of voice (temporary or permanent)
- 12. Injury to larynx which may require surgery
- 13. Perforation of throat, pharynx, or esophagus which may require surgery

- 14. Obstruction of airway which may require surgery and which may be fatal
- 15. Perforation of airway which may require surgery and which may be fatal
- 16. Disfiguring or scarring of surrounding structures
- 17. Need for surgery
- 18. Death

F. Direct Laryngoscopy and Bronchoscopy with Foreign Body Removal (Formerly §2393 – Direct Laryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection requiring further treatment or surgery
- 3. Bleeding that may require transfusion or may be fatal
- 4. Injury to surrounding structures
- 5. Difficulty swallowing (temporary or permanent)
- 6. Peristent hoarseness
- 7. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 8. Cardiac arrhythmias (irregular heartbeats)
- 9. Failure to retrieve the foreign body
- 10. Need for tracheostomy
- 11. Change in or loss of voice (temporary or permanent)
- 12. Injury to larynx which may require surgery
- 13. Perforation of throat, pharynx, or esophagus which may require surgery
- 14. Obstruction of airway which may require surgery and which may be fatal
- 15. Perforation of airway which may require surgery and which may be fatal
- 16. Disfiguring or scarring of surrounding structures
- 17. Need for surgery
- 18. Death

G. Direct Laryngoscopy with Dilation (Formerly §2393 – Direct Laryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 5. Cardiac arrhythmias (irregular heartbeats)

- 6. Airway fire if laser is being used, which may result in extensive airway damage and which may require surgery, prolonged hospitalization, and/or tracheostomy, and which may be fatal
- 7. Difficulty swallowing (temporary or permanent)
- 8. Change in or loss of voice (temporary or permanent)
- 9. Injury or scarring of surrounding structures
- 10. Injury to larynx which may require surgery
- 11. Need for tracheostomy
- 12. Perforation of throat, pharynx, or esophagus which may require surgery
- 13. Obstruction of airway which may require surgery and which may be fatal
- 14. Perforation of airway which may require surgery and which may be fatal
- 15. Need for further surgery
- 16. Death

H. Direct Laryngoscopy with Removal of Neoplasm (Formerly §2393 –

DirectLaryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Recurrence of neoplasm
- 6. Change in or loss of voice
- 7. Difficulty swallowing
- 8. Injury to larynx which may require surgery
- 9. Change in voice (temporary or permanent)
- 10. Persistent hoarseness
- 11. Loss of voice (temporary or permanent)
- 12. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 13. Cardiac arrhythmias (irregular heartbeats)
- 14. Airway fire if laser is being used
- 15. Need for tracheostomy (temporary or permanent)
- 16. Perforation of throat, pharynx, or esophagus which may require surgery
- 17. Obstruction of airway which may require surgery and which may be fatal
- 18. Perforation of airway which may require surgery and which may be fatal
- 19. Need for other surgery
- 20. Death

I Direct Laryngoscopy with or without Bronchoscopy (Formerly §2393 – Direct Laryngoscopy (Passage of Lighted Tube in Voice Box)

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 6. Injury to larynx which may require surgery
- 7. Change in voice (temporary or permanent)
- 8. Persistent hoarseness
- 9. Loss of voice (temporary or permanent)
- 10. Cardiac arrhythmias (irregular heartbeats)
- 11. Need for tracheostomy (temporary or permanent)
- 12. Perforation of throat, pharynx, or esophagus which may require surgery
- 13. Obstruction of airway which may require surgery and which may be fatal
- 14. Perforation of airway which may require surgery and which may be fatal
- 15. Need for other surgery
- 16. Death

J. Bronchoscopy with Dilation

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Injury to teeth, with possible aspiration of teeth and possible need for repair of teeth
- 6. Cardiac arrhythmias (irregular heartbeats)
- 7. Airway fire if laser is being used, which may result in extensive airway damage and which may require surgery, prolonged hospitalization, and/or tracheostomy, and which may be fatal
- 8. Difficulty swallowing (temporary or permanent)
- 9. Change in voice (temporary or permanent)
- 10. Persistent hoarseness
- 11. Loss of voice (temporary or permanent)
- 12. Injury to larynx which may require surgery
- 13. Need for tracheostomy (temporary or permanent)
- 14. Perforation of throat, pharynx, or esophagus which may require surgery
- 15. Obstruction of airway which may require surgery and which may be fatal
- 16. Perforation of airway which may require surgery and which may be fatal

K. Incision of Lingual (tongue) Frenulum or Removal of Lingual Frenulum

- 1. Pain
- 2. Infection or failure of wound to heal requiring further treatment or surgery
- 3. Bleeding which may require transfusion
- 4. Injury to surrounding structures
- 5. Impairment of tongue movement (temporary or permanent)
- 6. Speech impediment (temporary or permanent)
- 7. Difficulty swallowing (temporary or permanent)
- 8. Injury to tongue which may require surgery
- 9. Need for other further surgery
- 10. Death

Digestive System treatments and Procedures (Formerly 2319) Procedures Requiring Full Disclosure of Specific Risks and Hazards—List A a. Endoscopic Procedures (1) Diagnostic and Therapeutic ERCP (Endoscopic Retrograde Cholangio Pancreatogram) (formerly 2404)

- (a) Infection
- (b) Bleeding which may Require Transfusion
- (c) Perforation of Esophagus, Stomach, Intestinal Wall or Ducts which May Require Surgery
- (d) Cardiac Arrhythmias (Irregular Heartbeats)
- (e) Pancreatic Inflammation

(2) Esophageal Manometry (formerly 2410)

- (a) Esophageal Perforation which may Require Surgery
- (b) Aspiration Pneumonia
- (c) Cardiac Arrhythmias (irregular heartbeats)

(3) Percutaneous Needle Biopsy of the Liver (formerly 2412)

- (a) Bleeding Requiring Transfusion and/or Surgery
- (b) Lung Collapse which may Require Surgery
- (c) Internal Leakage of Bile which may Require Surgery
- (d) Puncture of other Organs which may Require Surgery
- (e) Aspiration Pneumonia

(4) 24-Hour PH Monitoring (2414)

- (a) Aspiration Pneumonia
- (b) Cardiac Arrhythmias (Irregular Heartbeats)

(5) Endoscopic Ultrasonagraphy (EUS) with/without Fine needle aspiration

(Same risks as ERCP)

- (a) Infection
- (b) Bleeding which may Require Transfusion
- (c) Perforation of Esophagus, Stomach, Intestinal Wall or Ducts which May Require Surgery
- (d) Cardiac Arrhythmias (Irregular Heartbeats)
- (e) Pancreatic Inflammation

(6) Moderate Sedation

- (a) IV site infection
- (b) Cardac Arrhythmias
- (c) Respiratory Arrest
- (d) Aspiration
- (e) Memory loss

(7) Percutaneous Endoscopic Gastrostomy (PEG)

- (a) PEG site infection
- (b) Perforation of Esphagus, Stomach or duodenum
- (c) Bleeding which may require transfusion
- (d) Perforation of small or large intestine
- (e) Aspiraration.

(8) Fundoplication, hiatal hernia, Heller myotomy

- (a) Reflux or recurrent reflux
- (b) Hiatal hernia or recurrent hiatal hernia
- (c) Inability to vomit or burp
- (d) Difficulty swallowing
- (e) Increased flatulence
- (f) floating

b. General Surgery Procedures

(1) Botox Chemodenervation of Internal anal sphincter

- (a) Pain or bleeding at injection site
- (b) Bleeding at injection site
- (c) Bowel dysfunction
- (d) Failure of fissure to heal

Anorectal Exam Under Anesthesia **(2)** Bleeding (a) (b) Post-operative pain **Bowel dysfunction** (c) Urinary retention (d) (e) Infection **(3)** Treatment of Perirectal abscess or fistula in ano (a) Bleeding at operative site (b) Post-operative pain, especially with bowel movement Temporary/permanent difficulty controlling bowel movements or passage of gas (c) (d) Recurrence or development of a subsequent abscess or fistula (e) Narrowing of anal opening requiring additional surgery or repeated anal dilations (f) Urinary retention Infection which could require additional surgery, prolonged healing (g) Transabdominal proctectomy/anterior resection **(4)** (a) Post-operative bleeding Abdominal pain (b) (c) Intra-abdominal infection or infection at the incision site that may require additional hospitalization or surgery Change in bowel function (d) (e) Injury to other organs or blood vessels (f) Hernia at incision site Leakage or narrowing at bowel anastomosis that may require additional surgery with (g) possible need for an ostomy. (h) Urinary infection (i) Deep vein thrombosis with or without pulmonary embolism Adhesions or scar tissue that could cause a bowel obstruction (j) (k) Recurrence of disease (1) Risk of temporary or permanent sexual or bladder dysfunction, and ifof reproductive age, risk of infertility. (m) If robotic or laparoscopic surgery, risk conversion to an open procedure Collapse of lung tissue (atelectasis) or infections (pneumonia) in the lungs (n) Ileoanal J. Pouch **(5)** Post-operative bleeding (a) (b) Abdominal pain (c) Intra-abdominal infection or infection at the incision site that may require additional hospitalization or surgery Change in bowel function (d) Injury to other organs or blood vessels (e) Hernia at incision site (f) Leakage or narrowing at bowel anastomosis that may require additional surgery with (g) possible need for an ostomy Urinary infection (h) (i) Deep vein thrombosis with or without pulmonary embolism Adhesions or scar tissue that could cause a bowel obstruction (i) (k) Recurrence of disease Risk of temporary or permanent sexual or bladder dysfunction, and if of reproductive **(1)**

If robotic or laparoscopic surgery, risk conversion to an open procedure Collapse of lung tissue (atelectasis) or infection (pneumonia) in the lungs

Pouch dysfunction including pouchitis, incontinence or fecal seepage

Pouch failure requiring future surgery

age, risk of infertility (m) If rob

(n)

(o)

(p)

(a)

(b)

(6)

Loop Ileostomy Closure

Pain at operative site

Post-operative bleeding

(c) Infection at incision or intraabdominal infection that may require additional hospitalization or surgery Leak at anastomosis (d) (e) Adhesions or scarring Hernia at incision site (f) (g) Slow recovery of intestinal function (ileus) Complications with distal bowel anastomosis unrecognized before time of ileostomy (h) closure Change in future bowel function (i) Mediport Placement under Flouroscopic Guidence **(7)** (a) Pain at site of insertion Pneumothoras (accumulation of air or gas in the pleural (lung) space, requiring further (b) treatment Blood clot around catheter (c) Infection (d) (e) Vascular injury Cardiac arrhythmia (irregular heartbeat) (f) Pilonidal Disease **(8)** Wound dehiscence (a) (b) Infection (c) Delayed healing (d) Recurrent disease requiring reoperation (e) Bleeding (f). **Colon Resection (9)** Post-operative bleeding (a) Abdominal pain (b) Infection in the incision (c) (d) Intra-abdominal infection (abscess) or infection at the incision site that may require additional hospitalization or surgery Change in bowel function (Diarrhea, sometimes permanent) (e) (f) Injury to other organs or blood vessels requiring additional surgery or blood transfusion Hernia at incision site (Hernia in incision requiring additional surgery for repair) (g) (h) Risk of temporary or permanent sexual or bladder dysfunction, if of reproductive age risk of infertility Urinary infection (i) Deep vein thrombosis with or without pulmonary embolism (j) Adhesions or scar tissue that could cause a bowel obstruction (k) Recurrence of disease (cancer) (if surgery is done for cancer) (1) If robotic or laparoscopic surgery, risk conversion to an open procedure (m) Collapse of lung tissue (atelectasis) or infection (pneumonia) in the lungs (n) Leakage from Colon (Fistula) Requiring Additional Surgery and Possible Colostomy (o) (Colon Empties into Bag Worn on the Abdomen) (p) Incomplete resection of disease Malfunctioning of Stoma (if performed) (q) (10)**Proctoscopy** Pain (a) Bleeding (b) (c) Infection Damage bowel wall (d) Rubber Band Ligation of Internal Hemorrhoids/Infrared coagulation of Internal (11)Hemorrhoids/Sclerotherapy of Internal Hemorrhoids Severe pain that does not respond to the methods of pain relief used after this procedure (a) that may require additional intervention Bleeding from the anus (b)

Inability to pass urine (urinary retention)

(c)

- (d) Infection in the anal area Worsening of symptoms from hemorrhoids (e) (12)**Sacral Nerve Stimulation** Pain at the implant site (a) Lead migration requiring dysfunction of the stimulator (b) (c) Infection or skin irritation (d) Technical problems Jolting or shocking stimulation (e) Adverse changes in bowel function (f) Numbness at the neuro stimulator site (g) (h) Undesirable stimulation or sensations (i) Persistent or recurrent GI symptoms **Internal anal Sphincterotomy** (13)Risk of Bleeding at operative site (a) (b) Fecal incontinence or seepage that may be temporary or permanent (c) Inability to urinate (d) Infection Risk of Abscess or fistula (e) **(f)** Risk of bleeding at operative site Fecal incontinence or seepage that may be temporary or permanent (g) (h) Inability to urinate (i) Infection (j) Risk of abscess or fistula Post-operative pain (k) (1) Failure of fissure to heal (14)Transanal Endoscopic Surgery Anorectal pain (Post-operative pain, especially with bowel movements) (a) (b) Infection (c) Bleeding (at Operative Site) (d) Urinary retention or urinary tract infection Vaginal mucosal injury in females (e) Fecal incontinence (Temporary/Permanent difficulty controlling bowel movements or (f) passage of gas.) Scars or narrowing of bowel wall (Narrowing of Anal Opening requiring additional (g) surgery or repeated anal dilations) (h) Need conversion to and abdominal surgery Recurrence of lesions or need further surgery after review of final pathology. (i) (j) Recurrence of hemorrhoids or fistula or fissure (k) Incomplete resection of disease (15)Colonoscopy (a) Infection (b) Bleeding which may require transfusion and/or surgery (c) Perforation of colon or rectal wall which may require surgery (d) Cardiac Arrhythmias (irregular Heartbeats)

Flexible Sigmoidoscopy (Sigmoidoscopy/Proctoscopy) (16)

- (a) Infection
- (b) Bleeding which may require transfusion and/or surgery
- (c) Perforation of colon or rectal wall which may require surgery
- Cardiac arrhythmia (irregular heartbeats) (d)

(17)Mediport Removal

- Bleeding, pain, and air embolus (a)
- (b) Blood clots
- Infection (c)
- (d) Fracture of catheter requiring further treatment

(18)Proctoscopy and transrectal ultrasound

(a) Pain or discomfort during procedure

Bleeding (b) Infection (c) (d) Damage bowel wall (19)Esophagogastroduodenoscopy (Esophageal Dilation/Esophagogastroduodenoscopy) Infection (a) (b) Bleeding which may require transfusion and/or surgery Perforation of gastric or duodenal wall which may require surgery (c) (d) Respiratory Arrest Cardiac Arrhythmias (irregular heartbeat) (e) Cholecystectomy (Removal of the Gallbladder) with or without Common Bile Duct (20)**Exploration** Pancreatitis (inflammation of the gland that produces insulin) (a) Injury to the tube (common bile duct) between the liver and the bowel; (b) Retained stones in the tube (common bile duct) between the liver and the bowel; (c) Narrowing or obstruction of the tube (common bile duct) between the liver and the (d) bowel; Injury to the bowel and/or intestinal obstruction. (e) (f) Bile leak Contrast reaction (g) Gastrectomy or Vagotomy and Pyloroplasty (formerly 2416) (21) (a) Infection in Incision or Inside Abdomen Bleeding which may Require Transfusion (b) Leakage from Stomach (Fistula) (c) (d) Inability to Maintain Weight (e) "Dumping Syndrome" (Chronic Vomiting after Eating) (f) Inability to eat Large Amount of Food, Especially Early after Surger (g) Diarrhea (h) Need for Vitamin B-12 Injections for Life if Total Gastrectomy is Needed Recurrence of Condition for which Surgery was Originally Done (i) **Appendectomy (formerly 2420)** (22)(a) Infection in the Incision (b) Bleeding from or into Incision (c) Intra-Abdominal Infection (Abscess) Requiring Additional Surgery and Prolonged Hospitalization Leakage from the Colon (Fistula) Requiring Additional Surgery and/or Colostomy (Colon (d) Empties into Bag Worn on the Abdomen) Hernia in the Incision Hemorrhoidectomy or Excision of Anal Fistula or Fissure (formerly 2424) (28)Bleeding at Operative Site (a) Post-Operative Pain, Especially with Bowel Movements (b) (c) Temporary/Permanent Difficulty Controlling Bowel Movements or Passage of Gas Recurrence of Hemorrhoids or Fistula or Fissure (d) Narrowing of Anal Opening Requiring Additional Surgery or Repeated anal Dilatations (e) Urinary retention (f) Pancreatic Resection (Add blank for location or type of resection) (29)Leakage of bowel (a) Leakage or Spillage of Pancreas or liver secretions (b) Development of diabetes (c) Prolonged O2 Requirement (d) Arrhythmia (e) (30)Liver Resection (Add blank for location or type of resection) Liver Failure (a) Bile Leak (b) Prolonged O2 requirement (c) Arrhythmia (d) Recurrent disease (e)

- (f) Failure to remove all Disease
- (g) Misdiagnosis of disease

c. Bariatric Surgery Procedures

(1) Gastric Lap Band for Obesity (formerly 2451)

- (a) Risks of Surgery
 - i. Damage to surrounding organs:
 - ii. Bowel, pancreas, liver, requiring more surgery;
 - iii. Blood vessels and/or spleen with bleeding requiring transfusion;
 - iv. With removal of spleen.
- (b) Risks of Recovery Period
 - i. Abdominal wound problems:
 - ii. Infection, failure to heal, severe scarring, hernia.
 - iii. Blood clots in the legs and/or pulmonary embolism (clots moving to lungs).
- iv. Pneumonia or other breathing problems requiring prolonged need for ventilator (breathing machine).
- (c) Need for additional surgery due to:
 - i. Gallstones with possible inflammation of the liver and/or pancreas;
 - ii. Stomach or intestinal blockage from trapped food or scarring;
 - iii. Abdominal infection with abscess;
 - iv. Bleeding;
 - v. Band slippage and/or movement of band position on stomach;
 - vi. Band Erosion;
 - vii. Reflux and/or inflammation of the esophagus;
 - viii. Enlargement and/or dysfunction of the esophagus;
 - ix. Malfunction of band device.
- (d) Other long term risks:
 - i. Extreme weight loss;
 - ii. Inadequate weight loss;
 - iii. Large folds of loose skin;
 - iv. Depression as a result of weight loss, required diet change, or complications of

surgery;

- v. Failure of the procedure;
- vi. Vitamin and/or mineral deficiency, possible requiring lifelong injections;
- vii. Band slippage and/or movement of band position on stomach;
- viii. Band Erosion;
- ix. Reflux and/or inflammation of the esophagus;
- x. Enlargement and/or dysfunction of the esophagus.

(2) Gastric Bypass with or without Liver Biopsy for Obesity (formerly 2453)

- (a) Risks of Surgery:
 - i. Damage to surrounding organs;
 - ii. Bowel, Pancreas, liver, requiring more surgery;
 - iii. Blood vessels and/or spleen with bleeding requiring transfusion;
 - iv. With removal of spleen.
- (b) Risks of Recovery Period:
 - i. Abdominal wound problems;
 - ii. Infection, failure to heal, severe scarring, hernia;
 - iii. Blood clots in the legs and/or pulmonary embolism (clots moving to lungs);
- iv. Pneumonia or other breathing problems requiring prolonged need for ventilator (breathing machine);
- (c) Need for additional surgery due to:
 - i. Gallstones with possible inflammation of the liver and/or pancreas;
 - ii. Stomach or intestinal blockage from trapped food or scarring;
 - iii. Abdominal infection with abscess;
 - iv. Bleeding.
 - v. Leakage of stomach and/or intestinal fluids;

- vi. Strictures at anastomosis (areas where bowel and/or stomach are joined);
- vii. Persistent ulcers.
- (d) Other long term risks:
 - i. Extreme weight loss;
 - ii. Inadequate weight loss;
 - iii. Large folds of loose skin;
- iv. Depression as a result of weight loss, required diet change, or complications of surgery;
 - v. Failure of the procedure;
 - vi. Excessive flatulence (passing bowel gas);
 - vii. Severe, persistent diarrhea;
 - viii. Vitamin and/or mineral deficiency, possibly requiring lifelong injections;
 - ix. Hair loss:
 - x. Sensitivity to alcoholic beverages.

(3) Sleeve Gastrectomy with or without Liver Biopsy for Obesity

- (a) Risks of Surgery:
 - i. Damage to surrounding organs;
 - ii. Bowel, Pancreas, liver, requiring more surgery;
 - iii. Blood vessels and/or spleen with bleeding requiring transfusion;
 - iv. With removal of spleen.
- (b) Risks of Recovery Period:
 - i. Abdominal wound problems;
 - ii. Infection, failure to heal, severe scarring, hernia;
- iii. Blood clots in the legs and/or pulmonary embolism (clots moving to lungs), and/or blood clots in intestinal vessels;
- iv. Pneumonia or other breathing problems requiring prolonged need for ventilator (breathing machine);
- (c) Need for additional surgery due to:
 - i. Gallstones with possible inflammation of the liver and/or pancreas;
 - ii. Stomach or intestinal blockage from trapped food or scarring;
 - iii. Abdominal infection with abscess;
 - iv. Bleeding.
 - v. Leakage of stomach and/or intestinal fluids;
 - vi. Excessive narrowing of stapled stomach (stricture).
- (d) Other long-term risks:
 - i. Extreme weight loss;
 - ii. Inadequate weight loss
 - iii. Large folds of loose skin;
- iv. Depression as a result of weight loss, required diet change, or complications of surgery;
 - v. Failure of the procedure;
 - vi. Vitamin and/or mineral deficiency, possibly requiring lifelong injections;
 - vii. Hair loss;
- viii. Heartburn (acid reflux) requiring medication use and/or damage to esophagus and/or further surgery