

**REGULATION #27  
INFORMED CONSENT FOR GASTRIC BYPASS SURGERY**

Pursuant to Act 1356 of the 84<sup>th</sup> General Assembly of 2003, all physicians in this state, prior to performing gastric bypass surgery, also known as open or laparoscopic Roux En Y, will have the patient sign an informed consent form acknowledging that they have been told information about various complications that can result from the surgery. The complications and information the patient must be informed of are as follows:

- A. The potential risks, complications and benefits of the weight loss surgery.
- B. The alternatives to surgery including non-surgical options.
- C. The need for dietary changes, a development of an exercise plan and the possible need for counseling.
- D. The importance of proper nutrition, eating a balanced diet and taking vitamin and mineral supplements for the remainder of their life.
- E. There is no guarantee of weight loss or long-term weight management as a result of getting the surgery.
- F. A lifetime of follow up medical care is required.
- G. Lab work will be required annually or more often than that as directed by the physician.
- H. Potentially serious complications from the surgery could result in death, further surgery or prolonged hospital stays for the patient.
- I. The following surgical complications may arise:
  - 1. Bleeding, this may require a transfusion of blood or blood products.
  - 2. Surgical site infections, either superficial or deep to include port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.
  - 3. Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas.
  - 4. Sepsis
  - 5. Systemic Inflammatory Response Syndrome (SIRS)
  - 6. Adult Respiratory Distress Syndrome (ARDS)
  - 7. Myocardial infarction (heart attack)
  - 8. Cardiac rhythm disturbances
  - 9. Congestive heart failure
  - 10. Atelectasis
  - 11. Pneumonia
  - 12. Pulmonary edema (fluid in the lungs)
  - 13. Pleural effusions (fluid around the lungs)
  - 14. Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon.
  - 15. Possible removal of the spleen
  - 16. Stroke
  - 17. Kidney failure
  - 18. Pressure sores
  - 19. Deep vein thrombosis (blood clots in the legs or arms)
  - 20. Pulmonary embolism (blood clots migrating to the heart and lungs)
  - 21. Staple line disruption
  - 22. Ulcer formation (marginal ulcer or in the distal stomach)
  - 23. Small bowel obstructions
  - 24. Internal hernias
  - 25. Incisional hernias, this includes port sites for laparoscopic access

26. Dehiscence or evisceration
  27. Inadequate or excessive weight loss
  28. Kidney stones
  29. Gout
  30. Encephalopathy
  31. Stoma stenosis
  32. Urinary tract infections
  33. Esophageal, pouch or small bowel motility disorders
- J. Nutritional complications to include:**
1. Protein malnutrition
  2. Vitamin deficiencies, including B12, B1, B6, Folate and fat soluble vitamins A, D, E and K
  3. Mineral deficiencies, including calcium, magnesium, iron, zinc, copper and other trace minerals
  4. Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage, that is neuropathy
- K. Psychiatric complications include:**
1. Depression
  2. Bulimia
  3. Anorexia
  4. Dysfunctional social problem
- L. Other complications to include:**
1. Adverse outcomes may be precipitated by smoking
  2. Constipation
  3. Diarrhea
  4. Bloating
  5. Cramping
  6. Development of gallstones
  7. Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness
  8. Low blood sugar, especially with improper eating habits
  9. Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition
  10. Loose skin
  11. Intertriginous dermatitis due to loose skin
  12. Malodorous gas, especially with improper food habits
  13. Hair loss (alopecia)
  14. Anemia
  15. Bone disease
  16. Stretching of the pouch or the stoma
  17. Low blood pressure
  18. Cold intolerance
  19. Fatty liver disease or non-alcoholic liver disease (NALF)
  20. Progression of preexisting NALF or cirrhosis
  21. Vitamin deficiencies some of which may already exist before surgery
  22. Diminished alcohol tolerance
- M. Pregnancy complications should be explained as follows:**
1. Pregnancy should be deferred for 12-18 months after surgery or until after the weight loss is stabilized
  2. Vitamin supplementation during the pregnancy should be continued
  3. Extra folic acid should be taken if the pregnancy is planned

- 4. Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects**
- 5. Pregnancy should be discussed with the obstetrician**
- 6. Special nutritional needs may be indicated or necessary**
- 7. Secure forms of birth control should be used in the first year after surgery**
- 8. Fertility may improve with weight loss**

**Some or all of the complications listed in this regulation may exist in a patient whether the surgical procedure of gastric bypass is performed on the patient or not. This regulation is not meant to imply that in all cases gastric bypass surgery is the only cause of these complications.**

**The failure of a physician to inform a patient, prior to gastric bypass surgery, of the above complications and obtaining the patient's signature on a form acknowledging the same will be a violation of the Arkansas Medical Practices Act and may result in disciplinary proceedings before the Board pursuant to law.**

**History: Adopted December 4, 2003; Amended February 5, 2004**