

Final Rule

LSA Document #06-139(F)

DIGEST

Adds [410 IAC 28](#) to establish reporting of any death, serious side effect, or major complication of a patient by physicians who perform a surgical treatment for the treatment of morbid obesity. Effective 30 days after filing with the Publisher.

[410 IAC 28](#)

SECTION 1. [410 IAC 28](#) IS ADDED TO READ AS FOLLOWS:

ARTICLE 28. REPORTING OF COMPLICATIONS FROM SURGICAL TREATMENT OF MORBID OBESITY

Rule 1. Definitions

[410 IAC 28-1-1](#) Applicability

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 1. The definitions in this rule apply throughout this article.

(Indiana State Department of Health; [410 IAC 28-1-1](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-2](#) "Body mass index" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 2. "Body mass index" means weight in kilograms divided by height in meters squared.

(Indiana State Department of Health; [410 IAC 28-1-2](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-3](#) "Department" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 3. "Department" means the Indiana state department of health.

(Indiana State Department of Health; [410 IAC 28-1-3](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-4](#) "Major complication" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 4. "Major complication" means a complication from surgical treatment for morbid obesity that:

- (1) requires an extended hospitalization, additional surgical treatment, or invasive drug therapy within thirty (30) days of the original surgical treatment; or**
- (2) results in a permanent disability.**

(Indiana State Department of Health; [410 IAC 28-1-4](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-5](#) "Morbid obesity" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 5. "Morbid obesity" means a body mass index of at least:

- (1) thirty-five (35) kilograms per meter squared, with comorbidity or coexisting medical conditions such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes; or
- (2) forty (40) kilograms per meter squared without comorbidity.

(Indiana State Department of Health; [410 IAC 28-1-5](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-6](#) "Physician" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#); [IC 25-22.5](#)

Sec. 6. "Physician" means a person licensed under [IC 25-22.5](#).

(Indiana State Department of Health; [410 IAC 28-1-6](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-7](#) "Serious side effect" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 7. "Serious side effect" means a nutritional deficiency that requires extensive hospitalization or invasive therapy.

(Indiana State Department of Health; [410 IAC 28-1-7](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-1-8](#) "Surgical treatment" defined

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 8. "Surgical treatment" means any of the following procedures:

Current Procedural Terminology (CPT) Codes

- 43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en Y gastroenterostomy (roux limb 150 cm or less)
- 43645 Laparoscopic, gastric restrictive surgery, with gastric bypass and Roux-en Y gastroenterostomy (roux limb 150 cm or less) with small bowel reconstruction to limit absorption
- 43770 Laparoscopic surgical gastric restrictive procedure. Placement of adjustable gastric band
- 43842 Gastric restrictive procedure, without gastric bypass; vertical-banded gastroplasty (VBG)
- 43843 Gastric restrictive procedure, other than vertical-banded gastroplasty
- 43845 Biliopancreatic diversion with duodenal switch
- 43846 Gastric restrictive surgery, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en Y gastroenterostomy
- 43847 Gastric restrictive surgery, with gastric bypass and Roux-en Y gastroenterostomy (roux limb 150 cm or less) with small bowel reconstruction to limit absorption
- 43848 Revision of gastric restrictive procedure for morbid obesity (separate procedure)

(Indiana State Department of Health; [410 IAC 28-1-8](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

Rule 2. Reporting Requirements

[410 IAC 28-2-1](#) Application of rule

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 1. This rule applies to physicians who perform a surgical treatment for the treatment of morbid obesity.

(Indiana State Department of Health; [410 IAC 28-2-1](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-2-2](#) Reporting

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 2. A physician who performs a surgical treatment for the treatment of morbid obesity shall do the following:

- (1) Monitor the patient for five (5) years following the patient's surgery, unless the physician is unable to locate the patient after making reasonable efforts.
- (2) Report before June 30 for the cases in the last six (6) months of the preceding year and December 31 for the first half of the current year to the department any:
 - (A) death;
 - (B) serious side effect; or
 - (C) major complication;of the patient.

(Indiana State Department of Health; [410 IAC 28-2-2](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-2-3](#) Report content

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 3. (a) A physician who performs a surgical treatment for the treatment of morbid obesity shall report to the department the following information regarding the patient:

- (1) Date of birth.
- (2) Sex.
- (3) Race.
- (4) Ethnicity.
- (5) County of residence at the time of the surgical treatment for the treatment of morbid obesity.

(b) A physician shall report to the department the following medical information regarding the surgical treatment for the treatment of morbid obesity:

- (1) The date of the surgical treatment for the treatment of morbid obesity.
- (2) Diagnoses.
- (3) Existing comorbidities, body mass index, and waist circumference of patient:
 - (A) at the time of surgery; and
 - (B) thirty (30), sixty (60), ninety (90) days, and one (1) year after surgical treatment.
- (4) Whether the patient has had previous abdominal surgery.
- (5) Surgical procedures performed.
- (6) Facility where the surgery was performed.

(c) A physician shall report to the department the following medical information regarding the death,

serious side effect, or major complication of the patient:

- (1) The date of the event.
- (2) If death, the cause of death.
- (3) If a serious side effect or major complication, the type of serious side effect or major complication.
- (4) Hospitalization associated with the death, serious side effect, or major complication, including the following:
 - (A) The length of the stay.
 - (B) The discharge status.
- (5) Procedures performed to treat the serious side effect or major complication.

(d) A physician shall report to the department using forms provided by the department.

(Indiana State Department of Health; [410 IAC 28-2-3](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

[410 IAC 28-2-4](#) Release of reports

Authority: [IC 16-40-3-5](#)

Affected: [IC 16-40-3](#)

Sec. 4. (a) The reports made under this article are confidential.

(b) The department may compile statistical reports from the information contained in the reports made under section 3 of this rule. Any statistical report is subject to public inspection.

(Indiana State Department of Health; [410 IAC 28-2-4](#); filed Apr 3, 2007, 8:42 a.m.: [20070502-IR-410060139FRA](#))

LSA Document #06-139(F)

Notice of Intent: June 1, 2006; 29 IR 3043

Proposed Rule: [20070117-IR-410060139PRA](#)

Hearing Held: February 13, 2007

Approved by Attorney General: March 28, 2007

Approved by Governor: April 2, 2007

Filed with Publisher: April 3, 2007, 8:42 a.m.

Documents Incorporated by Reference: None Received by Publisher

Small Business Regulatory Coordinator: Joe Hunt, Indiana State Department of Health, 2 North Meridian Street, 5A, Indianapolis, Indiana 46204, (317) 233-7524, jhunt@isdh.state.in.us

Posted: 05/02/2007 by Legislative Services Agency

An [html](#) version of this document.