

**Document:** Proposed Rule, **Register Page Number:** 29 IR 1270  
**Source:** January 1, 2006, Indiana Register, Volume 29, Number 4

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**TITLE 410 INDIANA STATE DEPARTMENT OF  
HEALTH**

**Proposed Rule**  
LSA Document #05-192

DIGEST

Adds 410 IAC 28 to establish reporting of any death or serious complication of a patient by physicians who perform a surgical treatment for the treatment of morbid obesity. Effective 30 days after filing with the Secretary of State.

**IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**

**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

The Indiana State Department of Health (ISDH) estimates at least 30 physicians perform surgical treatments for treatment of morbid obesity in Indiana.

**2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.**

Precise costs estimates are difficult to make because of variances in organizational structure and employee compensation schedules among the various providers. The ISDH expects that some of these functions are already performed by the centers, which will decrease the additional time or cost to comply with the rule. The following are the estimated annual costs resulting from the proposed rule:

The reporting required by the proposed rule is based on a physician's postsurgical monitoring of patients for whom the physician provided surgical treatment for morbid obesity. The rule will not impact that monitoring. The rule does require, however, that those physicians report any deaths or serious complications on those patients.

In 2003, Indiana hospitals reported over 2,500 surgical treatments for morbid obesity (bariatric procedures). There has been an increase in the number of surgeries reported over the last six years. The data do not indicate which procedures might qualify as a surgery requiring reporting of death or significant complication. For purposes of projecting costs, we assume 3,000 surgeries annually for the surgical treatment of morbid obesity in Indiana.

Nationally, surgical procedures have a death rate of between 0.8 percent and 8 percent (in 2003, Indiana hospitals reported 7 deaths and 2,540 bariatric surgeries for a death rate of less than 0.3 percent) and a complication rate of approximately 5 percent requiring immediate intervention. If those rates are applied to the projected 3,000 surgeries requiring reporting, we project the following number of reports:

<b>Period Covered</b>	<b>Surgeries (assuming 1 percent death rate)</b>	<b>Deaths (assuming 5 percent complication rate)</b>	<b>Serious Complications (assuming 5 percent complication rate)</b>	<b>Total Reports</b>
7/1/2006 to 12/31/2006	1500	15	75	90
1/1/2007 through 12/31/2007	3000	30	150	180
1/1/2008 through 12/31/2008	3000	30	150	180
1/1/2009 through 12/31/2009	3000	30	150	180
1/1/2010 through 12/31/2010	3000	30	150	180
<b>Total</b>	13,500	135	675	810

The ISDH estimates the time to prepare the required data report to be one (1) hour or less. The completion of the form may involve physician's time as well as medical records staff or nursing staff. The average estimated cost for each report is \$50. The annual reporting costs for physicians subject to reporting requirements are projected to be \$9,000 based on the above assumptions.

**3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.**

Based upon the data and estimates presented, the total annual economic impact going forward on an annual basis will \$9,000

exclusive of inflationary factors. The individual physician's cost will depend on the number of patients treated and the incidence of death or serious complications.

**4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.**

IC 16-40-3 requires physicians who perform surgical treatments for the treatment of morbid obesity to report deaths or serious complications to the ISDH. Additionally, IC 16-40-3 as added sets forth the requirements for agency rules. The ISDH believes the proposed rules are within the requirements established at IC 16-40-3.

**5. Regulatory Flexibility Analysis**

**A. Establishment of less stringent compliance or reporting requirements for small businesses.**

IC 16-40-3 makes no provisions for waiving the reporting requirements or changing the reporting requirements provided in the law.

**B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.**

IC 16-40-3 established the reporting requirements for physicians and provides no provisions for waiving or changing those requirements.

**C. Consolidation or simplification of compliance or reporting requirements for small businesses.**

The rules drafted provide for the minimum amount of data needed to fulfill the requirements of the law. There are no other reporting requirements imposed by the proposed rule.

**D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.**

IC 16-40-3 mandates reporting of data. It does not regulate the performance of surgical procedures for the treatment of morbid obesity.

**E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.**

The statute provides no waiver or exemption for the reporting of deaths or serious complications after surgical treatment for the treatment of morbid obesity.

**Conclusion:**

SEA 360 amended IC 16-40, which requires physicians who provide surgical treatment for the treatment of morbid obesity to report deaths and serious complication to the ISDH. The rules do not change medical practice for monitoring patients after the provision of surgical treatment for the treatment of morbid obesity, only the reporting of defined events after that surgical treatment. The statute provides no waiver or exemption for the reporting of deaths or serious complications after surgical treatment for the treatment of morbid obesity.

**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)*

**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)*

**410 IAC 28-1-3 "Complication" defined**

**Authority:** IC 16-40-3-5

**Affected:** IC 16-40-3

**Sec. 3. “Complication” means an additional medical problem that develops during or following a procedure, treatment, or illness. (Indiana State Department of Health; 410 IAC 28-1-3)**

**410 IAC 28-1-4 “Department” defined**

**Authority: IC 16-40-3-5**

**Affected: IC 16-40-3**

**Sec. 4. “Department” means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 28-1-4)**

**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 either of the following:**

**(1) Thirty-five (35) kilograms per meter squared, with comorbidity or coexisting medical conditions such as any of the following:**

**(A) Hypertension.**

**(B) Cardiopulmonary conditions.**

**(C) Sleep apnea.**

**(D) Diabetes.**

**(2) Forty (40) kilograms per meter squared without comorbidity.**

*(Indiana State Department of Health; 410 IAC 28-1-5)*

**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)**

**410 IAC 28-1-7 “Serious complication” defined**

**Authority: IC 16-40-3-5**

**Affected: IC 16-40-3**

**Sec. 7. “Serious complication” includes, but is not limited to, the following:**

**(1) Serious and potentially serious complications of bariatric surgery as follows:**

<b>Applicable Codes</b>	<b>Description</b>
<b>ICD-9-CM</b>	
<b>INTRAOPERATIVE COMPLICATIONS</b>	
998.2	Organ injuries
998.2	Blood vessel lacerations
998.11	Heavy bleeding requiring the use of blood or blood product transfusions
997.1	Intraoperative myocardial infarction/cardiac arrest
997.02	Intraoperative stroke
997.01	Intraoperative cerebral hypoxia
995.4	Life threatening reaction to anesthesia
995.0	Other severe medication reactions
999.4	Anaphylactic shock due to serum/transfusion
<b>PERIOPERATIVE COMPLICATIONS</b>	
997.2	Deep vein thrombosis
415.11	Pulmonary embolism
998.59	Wound infection
998.3	Wound dehiscence
998.12	Wound site hematoma

998.13	Wound site seroma
518.5	Pulmonary insufficiency/respiratory distress
518.4	Pulmonary edema
	<b>POSTOPERATIVE COMPLICATIONS</b>
536.1	Pouch dilatations
552.3, 553.3	Hiatal hernia
996.59	Slippage
560 - 560.9	Intestinal obstruction requiring hospitalization, and/or surgery, and/or leading to:
276.5	dehydration
998.0	shock
997.5	prerenal failure
997.3	aspiration pneumonia
276 - 276.9	Electrolyte imbalance
996.60	Port infections
998.59	Subphrenic abscess
997.4	Stomal stenosis or occlusion
537.89	Stomach rupture
996.79	Gastric band erosions
530.81	Gastroesophageal reflux
530.11	Esophagitis
530.0	Achalasia, aperistalsis of esophagus, megaesophagus
574 - 574.9	Cholelithiasis/Choledocholithiasis
577.0	Pancreatitis
552.21, 553.21	Incisional hernia
552.1, 553.1	Umbilical hernia
552.9, 553.9	Internal hernia
998.31	Staple line disruption
996.5 or 998.31	Leaks from staple breakdown
534 - 534.9	Marginal ulcers
998.6	Persistent postoperative fistula
567 - 567.9	Peritonitis
280 - 281.9	Iron-deficiency anemia/other deficiency anemia
733.0	Osteoporosis leading to:
733.1 - 733.19	pathologic fracture
579.3	Hypoglycemia secondary to excessive pancreatic stimulation
260, 261, 262	Protein malnutrition
579.2	Blind loop syndrome

(2) A complication that requires hospitalization.

(3) A medical procedure to treat the complication.

*(Indiana State Department of Health; 410 IAC 28-1-7)*

**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 or DRG groupings:

Reporting of Deaths or Complications from Morbid Obesity Surgeries

Applicable codes

CMS DRG

288

O.R. Procedures for Obesity

**APR-DRG****403 Procedures for Obesity****ICD-9-CM 2005, Procedure Codes**

43	Incision and excision of stomach
43.0	Gastrostomy
43.19	Other gastrostomy (excludes PEG)
43.41	Endoscopic excision or destruction of lesion or tissue of stomach
43.42	Local excision of other lesion or tissue of stomach
43.89	Other (partial gastrectomy with bypass gastrogastrostomy)
44	Other operations on stomach
44.31	High gastric bypass
44.38	Laparoscopic gastroenterostomy (Roux-en-Y)
44.39	Other gastroenterostomy (open approach Roux-en-Y)
44.5	Revision of gastric anastomosis
44.6	Other repair of stomach
44.68	Laparoscopic gastroplasty (banding, VBG)
44.69	Other (repair of stomach NOS)
44.9	Other operations on stomach
44.93	Insertion of gastric bubble/balloon obsolete
44.94	Removal of gastric bubble/balloon obsolete
44.95	Laparoscopic gastric restrictive procedure
44.96	Laparoscopic revision of gastric restrictive procedure
44.97	Laparoscopic removal of gastric restrictive devices
44.98	(Laparoscopic) adjustment of size of adjustable gastric restrictive device
45	Incision, excision, and anastomosis of intestine
45.62	Other partial resection of small intestine
46	Other operations on intestines
46.73	Suture of laceration of small intestine, except duodenum
46.79	Other repair of intestine (duodenoplasty)
46.9	Other operations on intestines
46.93	Revision of anastomosis of small intestine
86.8	Other repair and reconstruction of skin and subcutaneous tissue
86.83	Size reduction plastic operation (liposuction, other reduction of adipose tissue)

**Current Procedural Terminology (CPT) Codes**

15831	Excision, excessive skin and subcutaneous tissue (including lipectomy, paniclectomy); abdomen (abdominoplasty)
15876	Liposuction, head and neck
15877	Liposuction, trunk
15878	Liposuction, upper extremity
15879	Liposuction, lower extremity
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
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)*

**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)*

- 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.**
- (2) Report to the department any:**
  - (A) death; or**
  - (B) serious complication of the patient.**

*(Indiana State Department of Health; 410 IAC 28-2-2)*

- 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) Gender.**
- (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 at the time of the surgery.**
- (4) Body mass index at the time of surgery.**
- (5) Surgical procedures performed.**
- (6) The facility where the surgery was performed**

**(c) A physician shall report to the department the following medical information regarding the death or serious complication of the patient:**

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

**410 IAC 28-2-4 Release of reports**

**Authority: IC 16-40-3-5**

**Affected: IC 5-14-3; IC 16-40-3**

**Sec. 4. (a) The reports made under this article are public records subject to public inspection under IC 5-14-3.**

**(b) The department may not release any information contained in the reports that the department determines may reveal the patient's identity.** (*Indiana State Department of Health; 410 IAC 28-2-4*)

***Notice of Public Hearing***

*Under IC 4-22-2-24, notice is hereby given that on January 24, 2006 at 2:00 p.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed rule to establish reporting of any death or serious complication of a patient by physicians who perform a surgical treatment for the treatment of morbid obesity.*

*These rules are designed to meet the statutory mandate of IC 16-40-3-5. Requirements not expressly required by these statutes have not been imposed.*

*Copies of these rules are now on file at the Public Health Preparedness Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.*

Sue Uhl  
Deputy State Health Commissioner  
Indiana State Department of Health