

# OFFICE BASED SURGERY



# New York State Department of Health Office-Based Surgery Update on:

- Implementation
- Reporting Requirements
- Adverse Event Reporting

Presentation to the State Hospital Review  
and Planning Council

October 2, 2008

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Office Of Health Systems Management

# CHAPTER 365 OF THE LAWS OF 2007

- **OBS Law signed July 18, 2007**
- **Provides oversight of office-based surgery**
- **Two components:**
  - **Adverse event reporting (effective January 2008)**
  - **Accreditation requirement (effective July 2009)**

# **BACKGROUND**

- **Ten year history of analysis on this issue**
- **Committee on Quality Assurance in OBS established in December 1997**
- **Committee membership - physicians, consumers, Bernard Rosof, MD - Chairman**
- **Product was clinical guidelines for OBS**
- **Distributed to medical community in winter 2001**
- **Educational sessions held around state with MSSNY**
- **Legal challenge by NYS Associates of Nurse Anesthetists (NYSNA) caused distribution to be suspended in 2001**

# **BACKGROUND** (CONTINUED)

- **March '04 - NYS Court of appeals rules in favor of DOH**
- **Guidelines redistributed**
- **Committee reconvened in Fall 2005 due to concerns regarding several egregious OPMC misconduct cases**
- **Original committee reestablished with additional representation by consumers, nursing and medical specialties**
- **Committee's goal is to improve quality of care in OBS**
- **Committee held four full day meetings**

# **BACKGROUND** (CONTINUED)

- **Four subcommittees formed:**
  - **Statutory/Regulation William Rosenblatt, MD**
  - **Adverse Events - James Tift, MD**
  - **Guidelines - Russell Bessette, MD**
  - **Accreditation - Rebecca Twersky, MD**

# **BACKGROUND** (CONTINUED)

- **Committee heard testimony from:**
  - **States of FL & CA**
  - **Organizations that accredit OBS (AAAASF, AAAHC, JC)**
  - **Hospital Associations**
  - **Provider organizations, e.g., MSSNY, NYSANA, ACS, NYS - Academy of Family Physicians**

# COMMITTEE RECOMMENDATIONS

- **DOH should seek legislative authority to provide oversight over the quality of care in OBS**
- **Report includes a model legislative proposal which provides that offices be accredited by a national accrediting body and that adverse events be reported to DOH - OPMC**
- **DOH through Governors office submits proposal to Legislature for introduction in January 2007**
- **Bill is negotiated and passed in June 2007**
- **Bill signed by Governor on July 18, 2007**

# KEY COMPONENTS OF BILL

## OBS Includes

- any surgical or other invasive procedure requiring general anesthesia, moderate sedation or deep sedation and liposuction
- Liposuction of > 500 cc's adipose tissue

# KEY COMPONENTS OF BILL

## OBS Excludes

- **“minor procedures”** defined as:
  - procedures done using only local anesthesia
  - liposuction of < 500 cc’s adipose tissue
- **“minimal sedation”**
  - a drug induced state in which patients respond normally to verbal commands and although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected

# INCLUDED

- **Medical practices only - not dentistry, podiatry or any other licensed professional**
- **Depends on level of sedation you provide - not procedure specific (exception – Liposuction)**
- **Moderate/deep sedation/general anesthesia - requires accreditation of the practice**

# HOW IS ADVERSE EVENT REPORTING DEFINED ?

- **Adverse events must be reported within one business day and are defined as:**
  - 1. Patient death within 30 days of the OBS**
  - 2. Unplanned transfer to a hospital (ED)**
  - 3. Unscheduled hospital admission within 72 hours of the office-based surgery**
  - 4. Any other serious or life-threatening event**
- **Confidentiality protections are provided for the adverse event reporting**

# **CHAPTER 477 of the LAWS of 2008**



**Patient Safety Bill 2008 - Legislation to improve patient safety and to educate, support and advance more rigorous infection control practices**

# OFFICE-BASED SURGERY



- **Additional Reporting Requirements:**
- **Revised Section 230-d(4) of the Public Health Law**

# INFECTION CONTROL REPORTING



- **Added by section 15 of chapter 477**
- **Effective September 2, 2008**
- **Use adverse events report form**
- **Certified mail to Patient Safety Center (PSC)**
- **Hedley Building, 433 River Street, Troy, New York 12180**

# REPORTING OF ANY SUSPECTED HEALTH CARE DISEASE TRANSMISSION



- **Originates in OBS practice**
- **Bloodborne pathogens (BBP)**
- **Health care professional to patient**
- **Patient to patient transmission**



# BLOODBORNE PATHOGENS

- **Microorganisms in human blood causing disease**
- **Examples include:**
  - **Hepatitis B virus (HBV)**
  - **Hepatitis C virus (HCV)**
  - **Human immunodeficiency virus (HIV)**



# REPORTING OF BBPs

- Licensees – part of OBS practice
- Within one business day of becoming aware of possible transmission of a BBP
- [www.nyhealth.gov/professionals/office-based\\_surgery/](http://www.nyhealth.gov/professionals/office-based_surgery/)
- Same confidentiality provisions as for adverse events

# Office-Based Surgery New Adverse Event Reporting Requirements Effective September 2, 2008

## 1. Where can I find the Statutory Provision Related to this New Reporting Requirement?

- Public Health Law § 230-d(4)

## 2. What must be reported?

- Any suspected health care disease transmission originating in an office-based surgery (OBS) practice must be reported to the Department's Patient Safety Center (PSC). A health care disease transmission means the transmission of a reportable communicable disease that is bloodborne from a health care professional to a patient or between patients. Bloodborne pathogens are microorganisms that when present in human blood can cause disease. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

3. How are reports of suspected bloodborne pathogen transmission made?
  - Reports of any suspected bloodborne pathogen transmissions originating in an OBS practice must be sent to the PSC. Forms, which are the same as those used to report adverse events, are located on the Department's website at [http://www.nyhealth.gov/professionals/office-based\\_surgery/](http://www.nyhealth.gov/professionals/office-based_surgery/) and must be sent, via certified mail, as follows: New York State Department of Health, Patient Safety Center, Hedley Building, 433 River Street, Troy, New York 12180.
4. Who Must File Reports of Suspected Bloodborne Pathogen Transmission?
  - Persons required to file such reports are licensed physicians, PAs and SAs who are part of an OBS practice and suspect that there has been a transmission of a bloodborne pathogen from a health care professional to a patient or between patients originating within the practice. It is important to note that all licensed physicians, PAs and SAs who are part of the OBS practice are subject to the reporting requirement, if they have a suspicion, even if they were not directly involved with a patient's care.

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

#### 5. When Must Reports of Suspected Bloodborne Pathogen Transmission Be Made?

- The report must be made to the PSC within one business day of the day that a licensed physician, PA, or SA, who is part of the OBS practice, has reason to suspect that there has been a transmission of a bloodborne pathogen from a healthcare professional to a patient or between patients originating in the OBS practice.

#### 6. Are hospitals required to report?

- No. The reporting requirements for suspected bloodborne pathogen transmission are limited to licensed physicians, PAs and SAs who are part of the OBS practice.

#### 7. Is a licensed physician, PA or SA, who is part of an OBS practice required to report a suspected transmission of a bloodborne pathogen from a patient to a health care professional?

- No, there are no reporting requirements under those circumstances.

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

NEW YORK STATE DEPARTMENT OF HEALTH  
Patient Safety Center

## Office-Based Surgery - Adverse Event Report

**1. Who Must Report  
Adverse Events**

LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_  
Title  MD/DO  PA  SA  Other, specify: \_\_\_\_\_

**2. License Number**

**3. Legal Name of Practice**

**4. Phone #** (       ) \_\_\_\_\_

**5. Address Where  
Procedure  
Performed**

ADDRESS 1 \_\_\_\_\_  
ADDRESS 2 \_\_\_\_\_  
CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_

**6. Name/  
License #(s)  
(if applicable)  
of All Person(s)  
Present in OBS  
Practice on Date  
of Procedure**

**a. Individual who determined drug and dosage**

LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_  
LICENSE # \_\_\_\_\_

**b. Individual who administered medication**

LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_  
LICENSE # \_\_\_\_\_

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

<b>7. Type of Anesthesia and Specific Drugs Administered</b>	<b>a. Level of Anesthesia Achieved</b> <input type="checkbox"/> Local/Regional _____ <input type="checkbox"/> Minor _____ <input type="checkbox"/> Moderate _____ <input type="checkbox"/> Deep _____ <input type="checkbox"/> General _____	<b>b. Specify Drugs Administered Including Route</b> <table border="0" style="width: 100%;"> <tr> <td>_____</td> <td><input type="checkbox"/> PO</td> <td><input type="checkbox"/> Inhaled</td> <td><input type="checkbox"/> IV</td> <td><input type="checkbox"/> IM</td> <td><input type="checkbox"/> Other</td> </tr> <tr> <td>_____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>_____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>_____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	_____	<input type="checkbox"/> PO	<input type="checkbox"/> Inhaled	<input type="checkbox"/> IV	<input type="checkbox"/> IM	<input type="checkbox"/> Other	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<b>8. Name/License #(s) of Principal Surgeon or Proceduralist</b>	LAST _____ FIRST _____ MI _____ LICENSE # _____																									
<b>9. Name/License #(s) of Other Person(s) Participating in Procedure</b>	<b>a.</b> LAST _____ FIRST _____ MI _____ LICENSE # _____  <b>b.</b> LAST _____ FIRST _____ MI _____ LICENSE # _____  <b>c.</b> LAST _____ FIRST _____ MI _____ LICENSE # _____																									
<b>10. Patient Name</b>	LAST _____ FIRST _____ MI _____																									
<b>11. Patient DOB</b>	MM ____ DD ____ YY ____																									
<b>12. Patient Gender</b>	<input checked="" type="checkbox"/> M <input type="checkbox"/> F																									
<b>13. Patient Address</b>	ADDRESS 1 _____ ADDRESS 2 _____ CITY _____ STATE _____ ZIP _____																									

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

14. Procedure Date MM \_\_\_\_\_ DD \_\_\_\_\_ YY \_\_\_\_\_

15. Full Description of Suspected Transmission\* of a Bloodborne Pathogen

*\*Reporting is required when there is a suspected transmission of a bloodborne pathogen from a health professional to a patient or between patients as a result of improper infection control practices. This report is in addition to any other communicable disease reporting requirements in state law.*

16. Reportable Adverse Event

- a.  Patient death within 30 days
- b.  Unplanned Transfer to a Hospital
- c.  Unscheduled Hospital Admission for longer than 24 hours within 72 hours of undergoing OBS
- d.  Any Serious or Life-Threatening Event
- e.  Any suspected transmission of a bloodborne pathogen from a health care professional to a patient or between patients

Hospital Name and Address

NAME \_\_\_\_\_  
ADDRESS 1 \_\_\_\_\_  
ADDRESS 2 \_\_\_\_\_  
CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_

17. Bloodborne Pathogen \_\_\_\_\_

18. Type of Transmission  Health care professional to Patient  Between or Among Patients

19. Other Possible Affected Patients

LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_  
LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_  
LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_

# Office-Based Surgery

## New Adverse Event Reporting Requirements

### Effective September 2, 2008

**20. Description of Possible Causes and/or Contributing Factors Leading to and Including the Reportable Event** *Be as specific as possible and attach additional pages if needed.*

**21. Effective July 14, 2009, all practices in which office-based surgery is performed must be accredited by an agency designated by the Commissioner of Health.**

a. If your practice is accredited, what designated accrediting agency has provided that accreditation?  
 NAME \_\_\_\_\_ DATE \_\_\_\_\_

b. If your practice is not yet accredited, to what designated accrediting agency have you applied?  
 NAME \_\_\_\_\_ DATE \_\_\_\_\_

**22. Procedure Code(s) and Name(s)**

Procedure HCPCS/CPT Code	Procedure Name
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____
___ ___ ___ ___	_____

**23. Adverse Event Date or Date of Suspicion of Bloodborne Pathogen Transmission**

MM \_\_\_\_\_ DD \_\_\_\_\_ YY \_\_\_\_\_


# Office-Based Surgery New Adverse Event Reporting Requirements Effective September 2, 2008

## 24. Date of Report


MM \_\_\_\_\_ DD \_\_\_\_\_ YY \_\_\_\_\_

## 25. Signature of Reporter(s)


By my signature below, I am hereby attesting to the accuracy of this report.

 SIGNATURE \_\_\_\_\_


(PRINTNAME) LAST \_\_\_\_\_ SIGNATURE (click to sign) \_\_\_\_\_ MI \_\_\_\_\_

 SIGNATURE \_\_\_\_\_

(PRINTNAME) LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_

 SIGNATURE \_\_\_\_\_

(PRINTNAME) LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_

 SIGNATURE \_\_\_\_\_

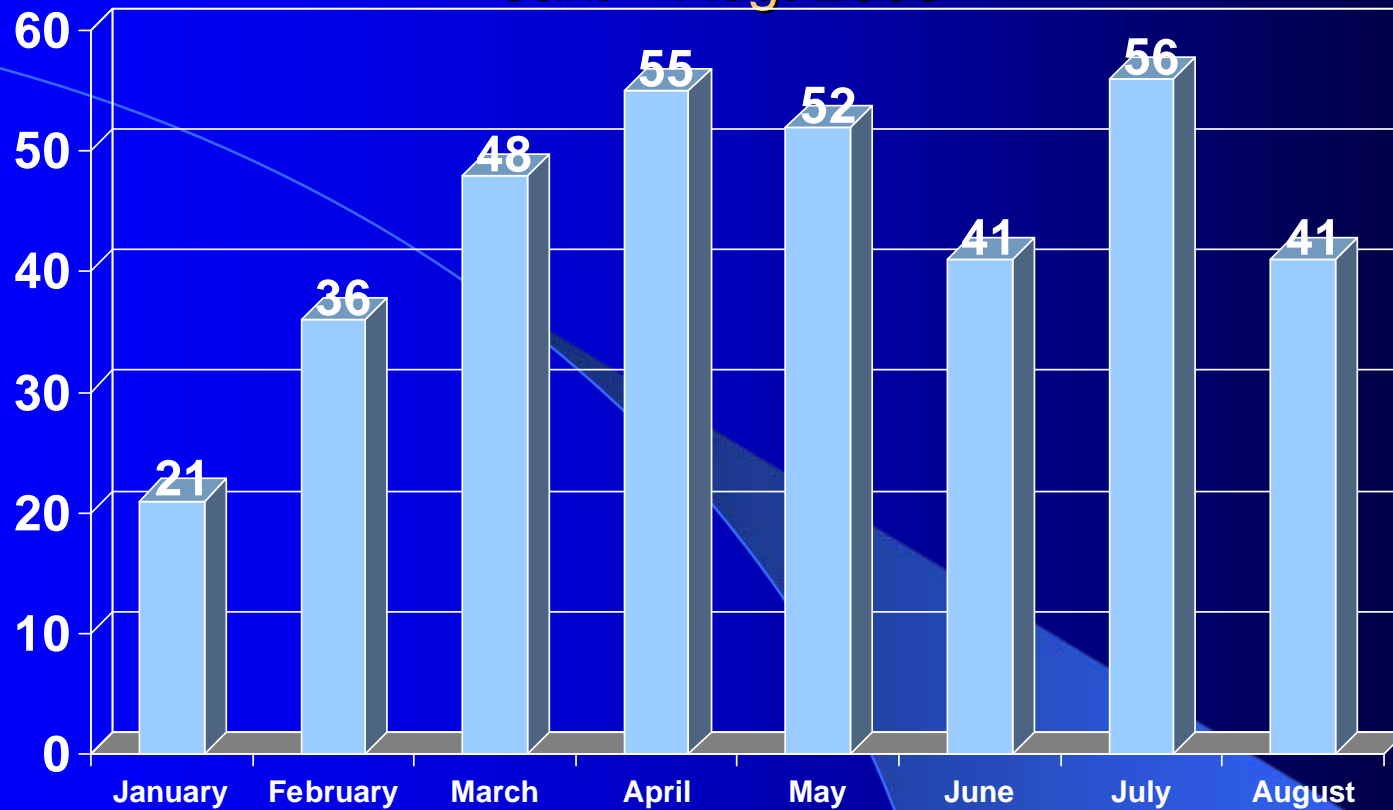
(PRINTNAME) LAST \_\_\_\_\_ FIRST \_\_\_\_\_ MI \_\_\_\_\_

If the adverse event reported is a suspected transmission of a bloodborne pathogen, this transmission report must be submitted to the PSC within one business day of the licensee becoming aware of the suspected transmission. Describe the circumstances, including the date, pursuant to which you became aware of such transmission. If this report is filed more than one business day after you became aware of such transmission, provide a description of the factors that prevented you from filing the report within the acceptable time frame.

Please submit Adverse Event Form via certified mail to:

**New York State Department of Health  
Patient Safety Center  
Hedley Building  
433 River Street  
Troy, New York 12180**

# Office-Based Surgery Adverse Event Reporting System Reports Received Jan. – Aug. 2008

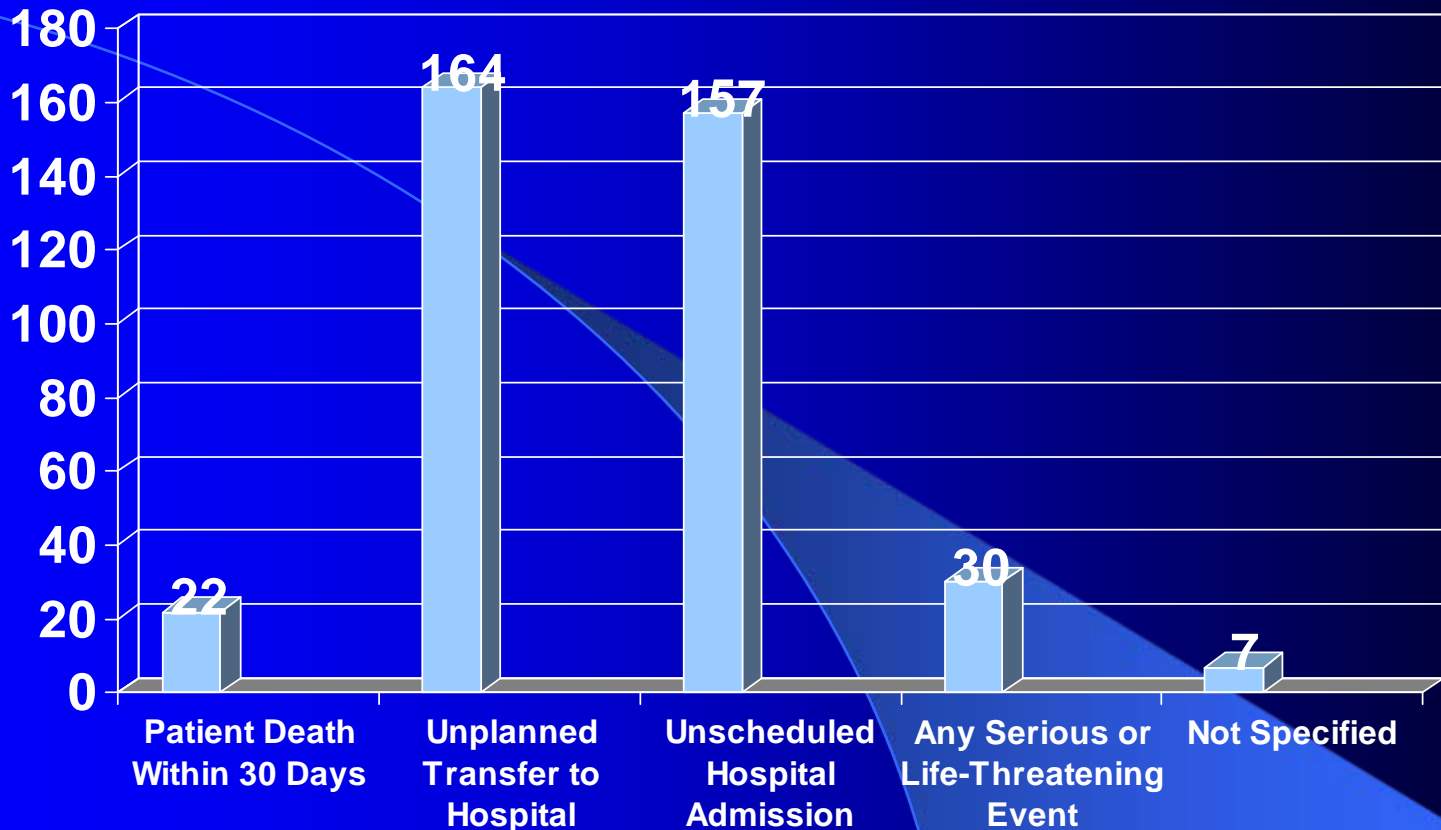


Total: 350

Average Per Month (Feb. – Aug.): 47

- Notes:**
1. Reporting requirements became effective January 14, 2008.
  2. Counts include 24 patients for whom 2 or more reports received.

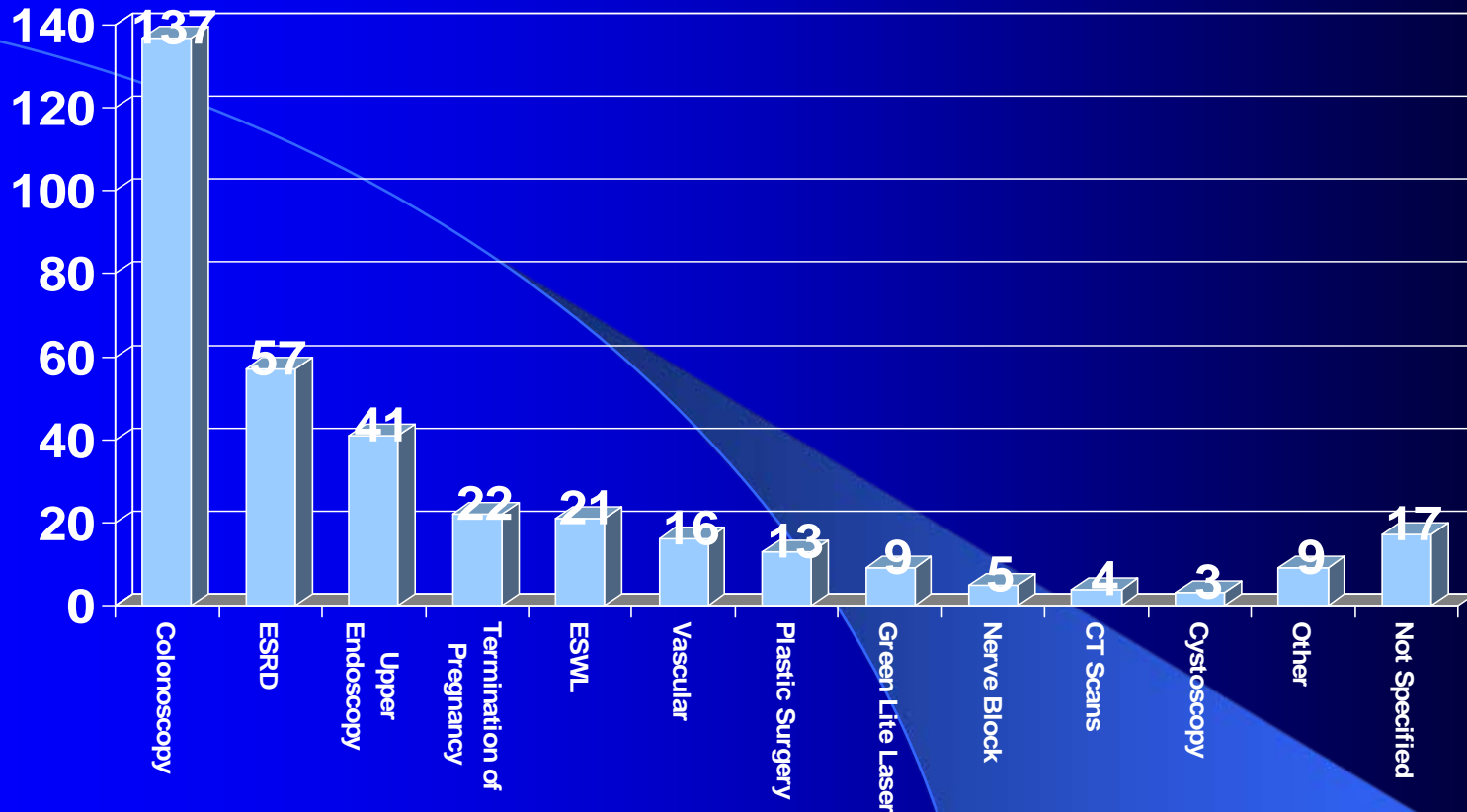
# Office-Based Surgery Adverse Event Reporting System Type of Adverse Events Jan. – Sept. 2008



**Notes:**

1. Counts do not include events reported in multiple reports on same patient.
2. Some reports reported more than one event.
3. Counts reflect reports received as of September 23, 2008.

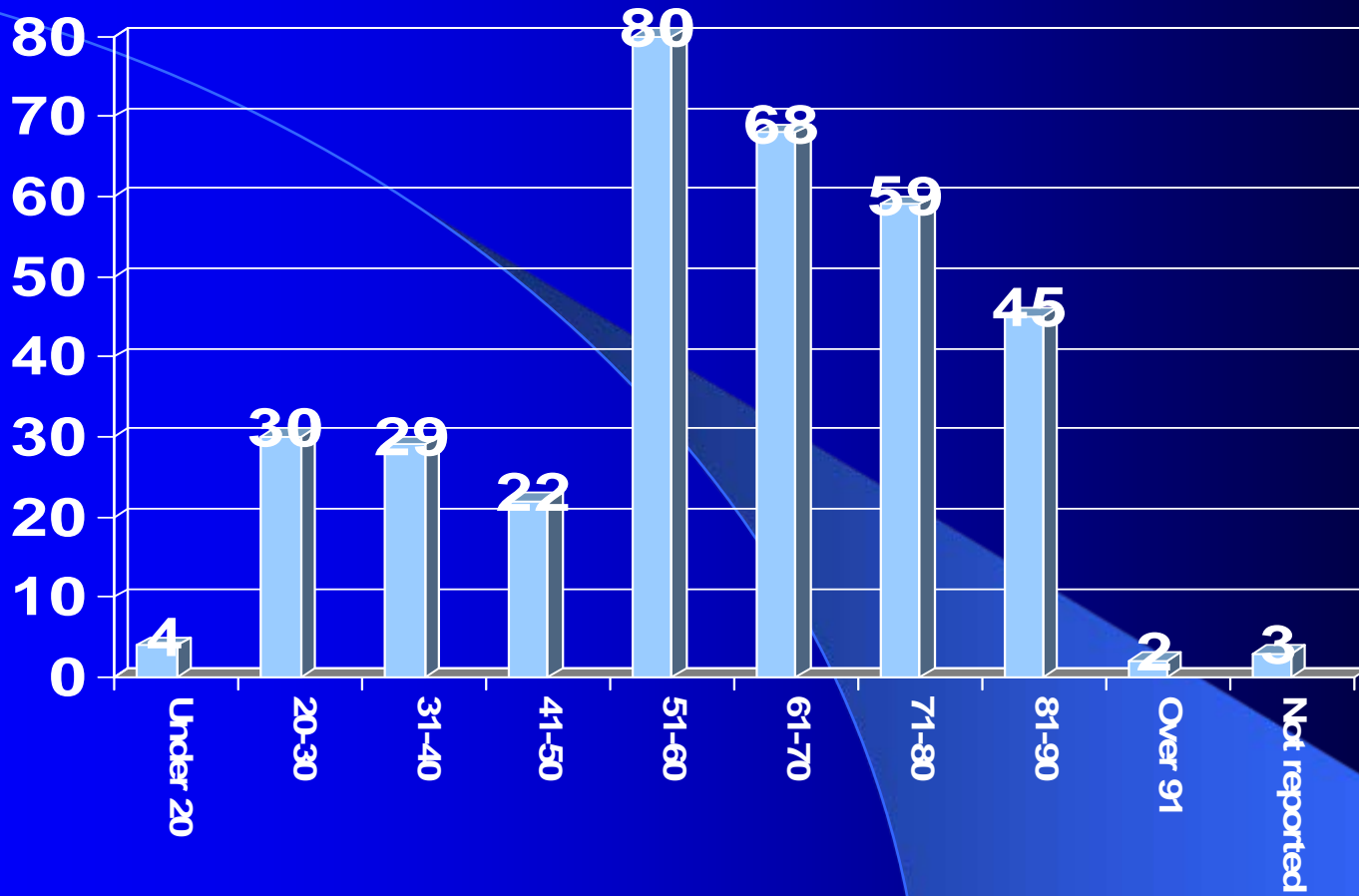
# Office-Based Surgery Adverse Event Reporting System Medical Condition or Type of Procedure Jan. – Sept. 2008



**Notes:**

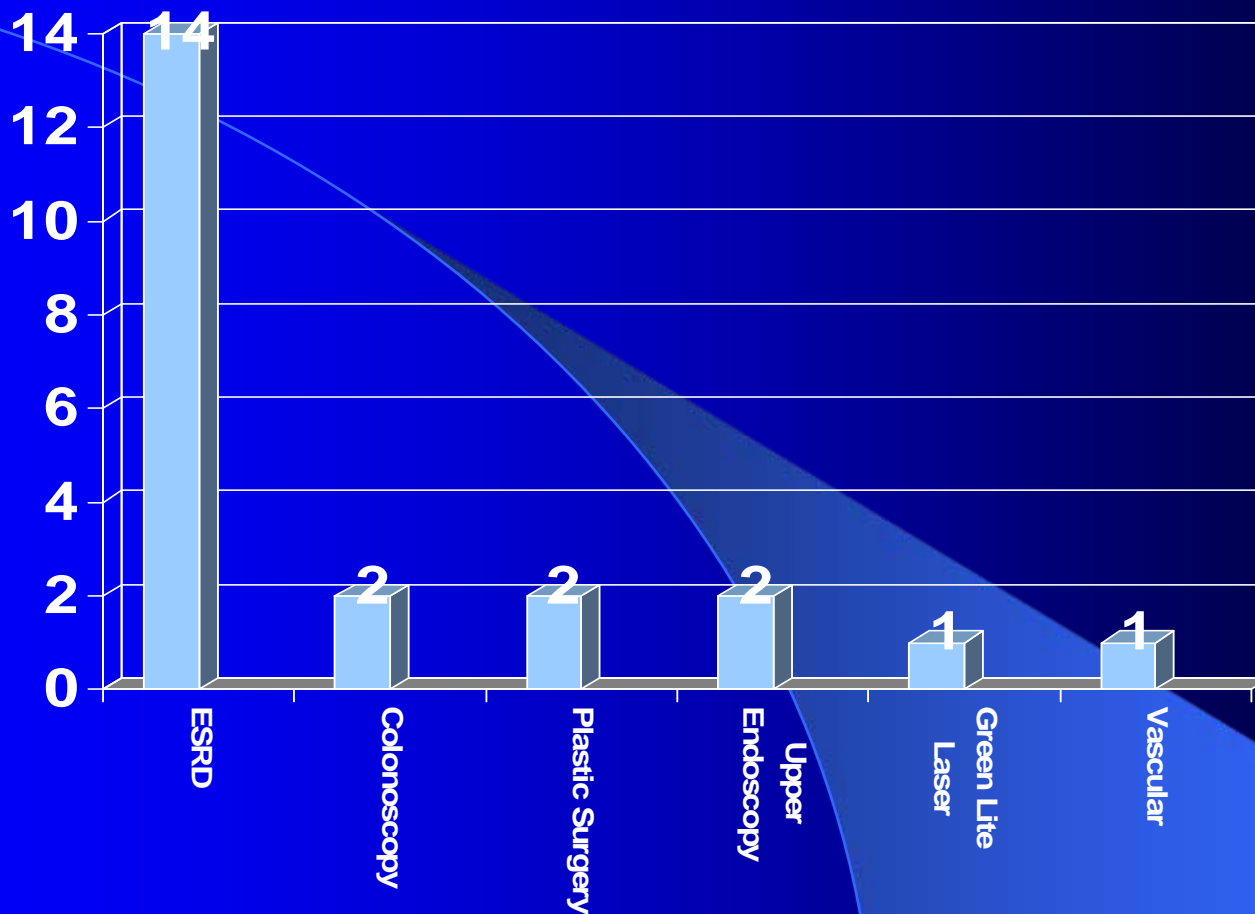
1. Colonoscopy include Sigmoidoscopies
2. ESRD includes such procedures as Thrombectomy, Venous PTA, Fistulagram, Catheter Exchange or Insertion
3. Upper Endoscopy includes procedures such as: Upper Endoscopy, EGD, Gastroscopy
4. Vascular procedures include such procedures as Angiogram, Aortagram, Venogram, Angioplasty, Stent
5. Plastic Surgery includes such procedures as: Breast Augmentation, Abdominoplasty, Liposuction, Rhinoplasty
6. Some reports indicated more than one procedure (e.g. Colonoscopy, Upper Endoscopy)
7. Counts reflect reports received as of September 23, 2008

# Office-Based Surgery Adverse Event Reporting System Ages of Patients Jan. – Sept. 2008



**Notes:** 1. Counts reflect reports received as of September 23, 2008.

# Office-Based Surgery - Adverse Event Reporting System Patient Deaths Within 30 Days by Medical Condition or Procedure Jan. – Sept. 2008



**Notes:** 1. Counts reflect reports received as of September 23, 2008.

# Office-Based Surgery Future Activities

- Conduct OBS Conference Fall 2008
- Complete Implementation of New Reporting Requirements
- Continue Collecting and Analyzing OBS Adverse Event Reports
- Continue Efforts to Achieve OBS Practice Accreditation by July 14, 2009
- Follow-Up on Referrals Resulting from Adverse Event Reporting

# That's All Folks!



# THANK YOU