

Economic Impact Statement

LSA Document #07-842

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

This proposed new rule adds [844 IAC 5-5](#) to establish standards for procedures performed in office-based settings that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. Beginning January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the Board under this rule.

Impact on Regulated Persons**1. Estimate of the number of regulated persons, classified by industry sector, that will be subject to the proposed rule:**

An estimate of the number of regulated persons, based upon the number of practitioners licensed in the state of Indiana, could range between 15 and 300.

The Indiana State Medical Association surveyed its approximately 9,000 physician members asking them to indicate whether or not accreditation would impact their practice, and the response was not significant enough to be statistically valid.

The applicable U.S. Census Bureau North American Standard Classification System industry sector is 621111 Offices of Physicians (except Mental Health Specialists). This U.S. industry comprises establishments of health practitioners having the degree of M.D. (Doctor of medicine) or D.O. (Doctor of osteopathy) primarily engaged in the independent practice of general or specialized medicine (except psychiatry or psychoanalysis) or surgery. These practitioners operate private or group practices in their own offices (e.g., centers, clinics) or in the facilities of others, such as hospitals or HMO medical centers.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that regulated persons will incur to comply with the proposed rule:

An estimate of the average administrative costs that regulated persons will incur to comply with the proposed rule would range between \$1,200 and \$40,000.

Offices will have the ability to choose from one of the four Board recognized accreditation organizations that are also nationally recognized and follow the standards for accreditation of facilities.

Accrediting agencies currently charge different amounts:

American Association for Accreditation of Ambulatory surgery Facilities, Inc. (AAAASF): Flat fee according to the number of surgeons and specialties (e.g., 1-2 surgeons with 1 or 2 specialties is \$675 per year).

Accreditation Association for Ambulatory Health Care, Inc. (AAAHHC): Flat fee; \$2,900 plus \$500 nonrefundable application fee for a three year accreditation.

Joint Commission on Healthcare Accreditation Organizations (JCHAO): Flat fee; \$4,400 for application and three year accreditation.

Healthcare Facilities Accreditation Program: Approximately \$1,200 per year including application fee.

Depending on how the individual practice chooses to maintain its accreditation would impact the cost on administrative costs. The practice could choose to hire additional staff to maintain daily compliance with the accreditation requirements. There will be additional hours needed to maintain the organization of records and compliance with accreditation requirements.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all regulated persons subject to the rule:

Although data is not available that would enable us to definitively determine the economic impact, it is reasonable to assume, based upon the costs associated with accreditation (annual fee, administrative costs and technological enhancements to offices), that the estimated economic impact has the potential to be greater than \$500,000 if the higher end of the estimated number of facilities seek accreditation and require upgrades to existing offices. The estimated cost per facility would range between \$1,200 - \$50,000.

Data that is currently available to provide the estimate is detailed below:

Estimated number of physicians practicing medicine in Indiana:	10,000 to 12,000
Annual estimated average cost of accreditation	\$1,200
Annual estimated average cost of administrative costs	\$1,200 – \$40,000
Estimated number of current accredited office facilities	20
Estimated number of new facilities to apply for accreditation	10 – 100

Estimated cost to facilities to comply with accreditation	\$1,200 – \$50,000
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Physicians do not need to remodel their offices to attain accreditation. However, additional cost may be associated with complying with accreditation standards with which physicians are not already in compliance. It is expected that physicians that are currently utilizing offices to perform the proposed regulated practice are doing so in a facility that has already put patient safety as the highest regard. If not, the accreditation requirements would expose these deficiencies and thus require upgrading the facility. This cost is typically found in upgrading equipment or facilities to meet accreditation facility standards, i.e., fire code. A medical office does not have to modify its physical space to meet Life Safety Code requirements in order to be accredited. As a general rule, the facility standards established by the accrediting organizations are consistent with the space requirements imposed under local building codes. Adherence to the Life Safety Code for currently regulated Ambulatory Surgical Centers (ASC) is only required if the office is seeking Medicare/Medicaid certification as an ASC.

4. Statement justifying any requirement or cost that is imposed on regulated persons by the rule; or any other state or federal law:

The proposed rule addresses a state requirement. It serves a public need by promoting public health and safety. The proposed rule does not impose an unfunded mandate on a state agency or political subdivision.

SEA 225-2005 (P.L.18-2005) amended [IC 25-22.5-2-7](#) and mandates the Board to adopt rules establishing standards for office-based procedures that require moderate sedation, deep sedation, or general anesthesia. Accreditation is needed to help ensure that office-based facilities are meeting safety standards.

Currently, 24 states and the District of Columbia have adopted legislation, regulations, or guidelines establishing standards for office-based anesthesia and sedation, including our neighboring states of Ohio, Kentucky, and Illinois. Eight additional states are in the process of adopting standards, and numerous national organizations, including the American Medical Association, the Federation of State Medical Boards, and the National Patient Safety Foundation, have called for regulation of the rapidly growing field of office-based surgery.

5. Regulatory flexibility analysis:

A. The establishment of less stringent compliance or reporting requirements for regulated persons. This is a regulation of the practice of medicine and would require accreditation for a practice of any size that does not meet the terms of the exemption as stated in the proposed rule:

[844 IAC 5-5-13](#) "Office-based setting" defined

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 16-21-2](#); [IC 25-22.5](#)

Sec. 13. As used in this rule, "office-based setting" means any:

- (1) facility;
- (2) clinic;
- (3) center;
- (4) office; or
- (5) other setting;

where procedures are performed that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. The term does not include a hospital operated by the federal government or a setting licensed under [IC 16-21-2](#) as a hospital, ambulatory surgical center, abortion clinic, or birthing center. (*Medical Licensing Board of Indiana*; [844 IAC 5-5-13](#))

B. The establishment of less stringent schedules or deadlines for compliance or reporting requirement for regulated persons.

The current deadline for a facility to receive accreditation is established in the proposed rule:

[844 IAC 5-5-20](#) Accreditation required

Authority: [IC 25-22.5-2-7](#)

Affected: [IC 25-22.5](#)

Sec. 20. After January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the board under this rule. (*Medical Licensing Board of Indiana*; [844 IAC 5-5-20](#))

This date was decided upon after discussion with all interested parties involved during the rule promulgation and was agreed upon as the date in which accreditation should be obtained.

C. The consolidation or simplification of compliance or reporting requirements for regulated persons.

The regulated person has the opportunity to evaluate the four national accreditation organizations to determine which group would best suit their structure in terms of compliance or reporting.

D. The establishment of performance standards for regulated person instead of design or operational standards imposed on other regulated entities by the rule.

The rule does not differentiate between regulated persons and other regulated entities; therefore, all facilities are treated equally and must comply by receiving accreditation by a board recognized accreditation organization.

E. The exemption of regulated persons from part or all of the requirements or costs imposed by the rule. Alternative methods to requiring accreditation considered include:

1. Requiring incident reporting with possible disciplinary action (post facto). Problems associated with this alternative include the following:

- a. under-reporting;
- b. current lack of appropriate Patient Safety Organization (PSO) reporting systems; and
- c. the need for more proactive, preventive, educational activities.

2. Dedicated funding of Board certification process and employment of office inspectors to ensure compliance with office-based procedure regulations. Problems associated with this alternative are:

- a. Funding for additional resources would result in all physician application fees increased significantly. This impact would affect the entire physician community (24,000) as opposed to the physicians that actually perform surgery in the office setting.

Accreditation is more desirable than:

1. Not doing anything;
2. Requiring reporting and using this information for disciplinary action; and
3. Dedicated funds for state certification process.

The first and second options do not acknowledge known issues of patient safety in time to prevent an adverse outcome. Finally, attempting to enforce the anesthesia requirements with state inspectors would prove to be costly and impact a larger population than requiring accreditation.

Mandatory accreditation has not caused problems in other states. There is no evidence that the cost of compliance with accreditation standards has created access problems in the states that require accreditation, including our neighboring state of Ohio. In fact, the Indiana State Medical Association's October 9 e-Report noted that "discussions with other states that have passed mandatory accreditation in some form (Conn., Ohio, PA, R.I., Tenn., Calif., Fla., La., N.C. and Texas) have not revealed major problems with compliance due to costs of achieving accreditation."

The justification for the requirements/costs is the increased patient safety associated with external review for compliance with practices known to prevent medical/adverse events (including "Safe Practices" supported by the National Quality Forum (NQF), a public-private partnership, which, via the Transfer of Technology Act, has provided these as "standards" for the Center for Medicare and Medicaid Services (CMS)). Further justification is the on-site review by experts who have the opportunity to provide practical, educational information to prevent medical errors.

Florida enacted mandatory reporting in 2000 following horrific media reports of office surgery deaths. Data reported from 2000 to 2002 showed that patients undergoing surgery in an office faced a 12 times greater risk of death or injury than a patient undergoing surgery in an ambulatory surgical center.

Accredited offices are safer offices. Accreditation increases patient safety for surgical procedures performed under moderate sedation, deep sedation, or general anesthesia. A follow-up study conducted in Florida in 2003, after most of the offices had attained accreditation, showed a steep decrease in adverse incidents without a corresponding decrease in the number of physicians performing office-based surgery. From 2000 to 2002, there were 13 procedure-related deaths and 93 injuries reported in Florida. In 2003, this number dropped to two procedure-related deaths and 18 injuries.

AAAASF, which requires reports of adverse incidents, also completed a comprehensive study of its accredited facilities and found that the overall risk of death in an AAAASF-accredited office surgery facility was comparable to that of a hospital.

Conclusion

Public health and safety is the Board's mission. The proposed rules are intended to implement a legislative mandate and strive to achieve the Board's mission of public health and safety. As documented, the estimated cost of compliance with these rules may be considered "significant" in the short term; however, the proposed rules are likely to be associated with long-term decreases in costs because of increased efficiencies and decreased human suffering and loss of life.

Supporting Data, Studies, or Analyses

- "Analysis of Outpatient Surgery Center Safety Using an Internet Based Quality Improvement and Peer Review Program": American Association for Accreditation of Ambulatory Surgery Facilities
- Evidence of patient safety problem: Institute of Medicine reports, beginning with 1999, "To Err is Human"
- Problems specifically associated with anesthesia—American Society of Anesthesiologists' Anesthesia Patient Safety Foundation
- Evidence of lack of appropriate PSO activity is evidenced by recent federal legislation to develop PSOs and appropriate common taxonomy for collecting information

- Evidence of safe practices: NQF endorsed Safe Practices
- Testimony from Ohio
- Testimony from Indiana Society of Anesthesiologists
- Collaborative Leadership for Patient Safety for Ambulatory Surgery in the Office Setting, Phase I Report of the National Patient Safety Consensus for the Community of Stakeholders for Ambulatory Surgery in the Office Setting. Prepared by Peter Schwartz, M.D., Ph.D., Shari Rudavsky, Ph.D., Alexander N. Christakis, Ph.D., Diane S. Conaway. September 2002
- Associated Press. "Study reveals 34 plastic surgery deaths in Florida since 1986," November 29, 1998
- Agency for Healthcare Research and Quality. "The Wild West: Patient Safety in Office-Based Anesthesia" www.webmm.ahrq.gov accessed August 21, 2006
- The Moffitt Monographs. "Office Surgery Can Be a Risky Operation", Hector Vila Jr., M.D.
- "2003 update: Outcomes Analysis of Procedures Performed in Florida Physician Offices and Ambulatory Surgery Centers" Hector Vila, Jr., M.D., Roy G. Soto, M.D., Rafael V. Miguel, M.D. and David C. Mackey, M.D.

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