TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Economic Impact Statement
LSA Document #06-561

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 Small Businesses

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

This information is unknown. The Indiana State Medical Association surveyed its approximately 9,000 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 NAICS 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 small business will incur to comply with the proposed rule.

Affected 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. (AAAHC: 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

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

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. 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 costly Life Safety Code requirements in order to be accredited. As a general rule, the facility standards established by the accrediting organizations, if any, 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.

Although the cost of the accreditation process will vary depending on the size of the office-based practice, the type of procedure performed and the accrediting agency, the average cost is about $1,200 per year per office.

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

The proposed rule addresses a state requirement and a significant market failure. It serves a public need by promoting public safety.

SEA 225-2005 amended IC 25-22.5-1-7 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.

Indiana is already lagging behind other states in the regulation of office-based surgery. 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, which has been dubbed "the wild, wild west of medicine."

5. Regulatory flexibility analysis

Alternative methods to requiring accreditation considered include:

1. Requiring incident reporting with possible disciplinary action (post facto). Problems associated with this alternative include:
   a. under-reporting;
   b. current lack of appropriate Patient Safety Organization (PSO) reporting systems;
   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. Taking no action.
2. Requiring reporting and using this information for disciplinary action.
3. Dedicated funds for state certification process.

The first does not acknowledge known issues of patient safety and the second "shuts the barn door after the cows have left." Finally, attempting to enforce the anesthesia requirements with state inspectors would prove to be costly and impact a larger population than requiring 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.

The fact that there is no data does not mean that there have been no deaths. The reason that there are no reported problems with office-based surgery in Indiana is simply because physicians are not required to report adverse incidents that occur in their offices. This does not mean adverse incidents are not occurring. Death certificates would not reveal the site of an adverse incident, and information from professional liability insurers may either be unavailable, or may not yet reflect adverse events due to the time required to bring actions to closure and the relatively recent upsurge in office-based surgery and anesthesia.

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. The proposed rules will allow Indiana to be proactive rather than reactive.

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 safety is the main Board responsibility. The proposed rules are intended to implement a legislative mandate. The cost of adoption of these rules may be considered "significant" in the short-term (because of health care organizations' lack of compliance with accreditation standards and the costs associated with becoming compliant), but 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., Alesxander 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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