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Regulation of Office-based Surgery in South Carolina: What's Old is New Again

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In 2007, the South Carolina Board of Medical Examiners (Medical Board) promulgated S.C. Code Ann. Regs. 81-96 (2007 and Supp. 2012)[1] governing the practice of office-based surgery.[2] The regulation's promulgation reflected significant research and the development of consensus regarding the prevailing standard of care with input from various stakeholders, including anesthesiologists and certified registered nurse anesthetists (CRNAs). Concerns regarding the safety of patients under sedation outside the hospital or ambulatory surgical facility settings made the regulation necessary as more and more procedures move into the office environment. However, a recent review of the regulation's enforcement over the past 13 years revealed a disconnect between the intended impact and its actual application.

With over 22,100 licensed physicians in the State of South Carolina as of January 4, 2021, fewer than 10 had registered as office-based surgery providers since the regulation's inception. The Medical Board convened a special called meeting on January 12, 2021, to outline an administrative remedy to the situation and its staff provided an update at its regular meeting on February 2, 2021, regarding the implementation of that plan. Although the regulation's content has not changed since 2007, the Board's recent deliberations have re-emphasized its importance.

This article provides a brief overview of the regulation's most relevant provisions and its immediate impact on South Carolina physicians.

Surgery

The regulation defines "surgery" as "any operative or manual procedure performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes, but is not limited to, incision or curettage of tissue or an organ, suture or other repair of tissue or an organ, extraction of tissue from the uterus, insertion of natural or artificial implants, closed or open

fracture reduction, or an endoscopic examination with use of local or general anesthetic. This also includes, but is not limited to, the use of lasers and any other devices or instruments in performing such procedures."

Physician Registration Requirement

Any physician performing Level II or Level III office-based surgery must register with the Medical Board.[3] The physician's registration must include each address at which Level II or Level III office surgery is performed and the identification of the accreditation agency that accredits each location. It is the depth of sedation or anesthesia, rather than the specific procedure performed or the specific medications utilized to induce sedation or anesthesia, that lies at the core of differentiating Level II from Level III surgery.

Reg. 81-96 offers guidance in distinguishing between the levels of sedation. Level II office surgery includes any procedure which requires the administration of minimal or moderate intravenous, intramuscular, or rectal sedation/analgesia, thus making post-operative monitoring necessary. Level II office surgery must be limited to procedures where there is only a moderate risk of surgical and/or anesthetic complications and the likelihood of hospitalization as a result of these complications is unlikely. Level II office surgery includes local or peripheral nerve block, minor conduction block, and Bier block. Level III office surgery includes any procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction block, and/or in which the known complications of the proposed surgical procedure may be serious or life-threatening.

Physicians who perform only Level I office surgery are not required to register with the Medical Board. Level I office surgery includes minor procedures in which preoperative medication and/or unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose adjusted for weight and where the likelihood of complications requiring hospitalization is remote. No drug-induced alteration of consciousness other than preoperative minimal anxiolysis of the patient is permitted in Level I office surgery. The chances of complications requiring hospitalization must be remote.

To facilitate the registration process, the Medical Board created a registration form in January 2021, which is now available on its website. (linked here) Additionally, the licensure renewal application has been amended to prompt physicians to disclose whether they are performing office-based surgeries. Physicians may renew their licenses online here. The application for initial licensure is in the process of being amended to include information about office-based surgery.

The Medical Board has taken a comprehensive review of Regulation 81-96's enforcement history and has expressed a desire to treat physicians fairly, while also honoring the regulation's intent. The Medical Board emailed a communication to its licensees on January 25, 2021, utilizing the licensee's email on file, to remind physicians of their registration obligation, if applicable. Physicians have been given 90 days to become compliant by submitting the registration form. If physicians register before April 25, 2021, the prior non-registration will not be treated as a violation of the Medical Practice Act; however, any complaints alleging substandard care or an adverse patient event arising from office-based sedation will be fully investigated and prosecuted. Presumably, the Medical Board's determination that the absence of registration alone is not a violation of the South Carolina Medical Practice Act will resolve any potential questions by payors regarding regulatory compliance in connection with this specific issue.

Facility Accreditation

Practices performing office-based surgery or procedures that meet the criteria of Level II or Level III must be accredited within the first year of operation by an approved accrediting agency. The accrediting agencies identified in the regulation include: the American Association of Ambulatory Surgery Facilities (AAASF); Accreditation Association for Ambulatory Health Care (AAAHC); the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); or the Healthcare Facilities Accreditation Program (HFAP), a division of the American Osteopathic Association; or any other agency approved by the Medical Board. The accrediting agency must submit a biannual summary report for each facility to the Medical Board. Physicians may wish to inquire of their accrediting agency whether it submits a biannual report to the Medical Board, as required, to ensure the accrediting agency is aware of its obligation to do so.

Staffing Requirements

Reg. 81-96 sets forth specific requirements for the physician and non-physician practitioners involved in office-based surgery procedures.

(1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge,[4] and who is qualified in accordance with law supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:

1. ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;
2. order the sedation/analgesia or anesthesia;
3. ensure that qualified health care personnel participate;
4. remain immediately available until discharge criteria are met; and
5. ensure the provision of indicated post-sedation/analgesia or anesthesia care.

(2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs, AAs, or other qualified practitioners who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure. This is not intended to restrict or limit the physician's ability to delegate medical tasks to other qualified practitioners in Level II office procedures.

(3) A registered nurse or other licensed health care personnel practicing within the scope of their practice who is currently certified in advanced resuscitative techniques must monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area must include pulse oximetry and non-invasive blood pressure measurement. The patient must be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient must meet

discharge criteria as established by the practice, prior to leaving the operating room or recovery area.

A practitioner who is qualified in resuscitation techniques and emergency care must be present and available until all patients having more than local anesthesia or minor conduction block anesthesia have been discharged from the operating room or recovery area.

Adverse Event Reporting

Anesthetic or surgical events requiring resuscitation, emergency transfer, or resulting in death must be reported to the Medical Board within three business days using a form approved by the Board. Such reports shall be considered initial complaints under the S.C. Medical Practice Act. The reporting form is available on the Medical Board's website. The failure to submit the report may be a violation of the S.C. Medical Practice Act as non-compliant with a regulation promulgated by the Board.

Potential Consequences of Non-Compliance

The failure to comply with all regulatory requirements attached to one's license to practice medicine, whether intentional or unintentional, has potential consequences in multiple forums.

As a professional licensee, a physician who fails to comply with a regulation promulgated by the Board may be found to be in violation of the South Carolina Medical Practice Act and subjected to disciplinary action. S.C. Code Ann. § 40-47-110 (B) (14) specifically provides, " 'Misconduct' that constitutes grounds for disciplinary action is a showing to the board by the preponderance of evidence that a licensee has . . . violated a provision of this chapter or a regulation or order of the board." The Board took no enforcement action between 2007 and January 2021 for a physician's failure to register as required by Reg. 81-96. However, the Board's recent efforts to educate its licensees about the regulation's requirements and extension of a 90-day grace period for enforcement suggest an intent to engage in a more robust enforcement endeavor upon the expiration of that grace period.

Additionally, if a physician submits claims to an insurance provider for compensation for office-based surgery procedures, he or she must maintain compliance with the payor's specific requirements for reimbursement. Such requirements typically include certification of adherence to applicable laws and regulations applicable to the procedure for which reimbursement is sought. The failure to comply with the registration and/or accreditation requirements imposed by Reg. 81-96 may trigger a payor's audit of claims previously paid or form the basis of a denial for future payment. The appeals process that may ultimately result from such an action is time-consuming and expensive.

Conclusion

Reg. 81-96 was promulgated almost 14 years ago, but the recent review of its potential impact upon physicians makes its compliance a priority for physicians who practice outside a hospital or other facility regulated by DHEC.

[1] The full text of the regulation is available here: Reg. 81-96. Specific requirements regarding monitoring, equipment, and written policies are set forth in the regulation in addition to the provisions discussed in this article.

[2] The regulation defines "office" as a location at which medical or surgical services are performed and which is not subject to regulation by the South Carolina Department of Health and Environmental Control.

[3] The regulation does not apply to an oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine, if the procedure is exclusively for the practice of dentistry.

[4] "Sufficient knowledge" means a physician holds staff privileges in a South Carolina hospital or ambulatory surgical center which would permit the physician to supervise the anesthesia, or the physician must be able to document certification or eligibility by a specialty board approved by the American Board of Medical Specialties or American Osteopathic Association, or the physician must be able to demonstrate comparable background, formal training, or experience in supervising the anesthesia, as approved by the Board.