

1 STATE OF OKLAHOMA

2 2nd Session of the 52nd Legislature (2010)

3 SENATE BILL 2036

By: Johnson (Constance)

4
5
6 AS INTRODUCED

7 An Act relating to public health and safety; creating
8 the Donda West Office-Based Surgery Safety Act;
9 providing short title; stating purpose; providing for
10 certain exception; defining terms; requiring certain
11 practices to develop specified policies and
12 procedures; requiring certain review and update;
13 specifying certain categories of office surgery;
14 requiring certain accreditation; requiring certain
15 report; requiring certain registration; requiring
16 certain competence; prohibiting the assignment of
17 certain duties to specified personnel; requiring
18 certain training; requiring certain equipment and
19 supplies; requiring certain assistance of other
20 personnel; requiring certain transfer and emergency
21 protocols; requiring certain accreditation and
22 inspection; requiring certain patient admission and
23 discharge protocols; providing for certain non-
24 applicability of act; providing for codification; and
providing an effective date.

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19 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

20 SECTION 1. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 1-700.1 of Title 63, unless
22 there is created a duplication in numbering, reads as follows:

23 A. This act shall be known and may be cited as the "Donda West
24 Office-Based Surgery Safety Act".

1 B. The purpose of the Donda West Office-Based Surgery Safety
2 Act is to promote patient safety in the non-hospital office-based
3 setting during procedures that require the administration of local
4 anesthesia, sedation/analgesia, or general anesthesia, or minor or
5 major conduction block. Moreover, this act has been developed to
6 provide physicians performing office-based surgery, including
7 cryosurgery and laser surgery, that requires anesthesia, including
8 tumescent anesthesia, analgesia or sedation, the benefit of uniform
9 professional standards regarding qualification of practitioners and
10 staff, equipment, facilities and policies and procedures for patient
11 assessment and monitoring.

12 C. Level I procedures as defined in this act shall be excluded
13 from this regulation.

14 SECTION 2. NEW LAW A new section of law to be codified
15 in the Oklahoma Statutes as Section 1-700.2 of Title 63, unless
16 there is created a duplication in numbering, reads as follows:

17 As used in the Donda West Office-Based Surgery Safety Act:

18 1. "Advanced resuscitative technique" means current
19 certification in Advanced Trauma Life Support (ATLS), Advanced
20 Cardiac Life Support (ACLS), or Pediatrics Advanced Life Support
21 (PALS) as appropriate for the individual patient and surgical
22 situation involved;

23 2. "Anesthesiologist" means a physician who has successfully
24 completed a residency program in anesthesiology approved by the

1 Accreditation Council of Graduate Medical Education (ACGME) or the
2 American Osteopathic Association (AOA), or who is currently a
3 diplomate of either the American Board of Anesthesiology or the
4 American Osteopathic Board of Anesthesiology, or who was made a
5 Fellow of the American College of Anesthesiology before 1982;

6 3. "Board" means the State Board of Medical Licensure and
7 Supervision;

8 4. "Certified registered nurse anesthetist" means a person
9 licensed as an Advanced Practice Registered Nurse in the category of
10 certified registered nurse anesthetist;

11 5. "Complications" means untoward events occurring at any time
12 within forty eight (48) hours of any surgery, special procedure or
13 the administration of anesthesia in an office setting including, but
14 not limited to, any of the following: paralysis, malignant
15 hyperthermia, seizures, myocardial infarction, renal failure,
16 significant cardiac events, respiratory arrest, aspiration of
17 gastric contents, cerebral vascular accident, transfusion reaction,
18 pneumothorax, allergic reaction to anesthesia, unintended
19 hospitalization for more than twenty four (24) hours, or death;

20 6. "Deep sedation/analgesia" means the administration of a drug
21 or drugs that produce sustained depression of consciousness during
22 which patients cannot be easily aroused but respond purposefully
23 following repeated or painful stimulation. The ability to
24 independently maintain ventilatory function may be impaired.

1 Patients may require assistance in maintaining a patent airway, and
2 spontaneous ventilation may be inadequate. Cardiovascular function
3 is usually maintained;

4 7. "Department" means the State Department of Health;

5 8. "General anesthesia" means a drug-induced loss of
6 consciousness during which patients are not arousable, even by
7 painful stimulation. The ability to independently maintain
8 ventilatory function is often impaired. Patients often require
9 assistance in maintaining a patent airway, and positive pressure
10 ventilation may be required because of depressed spontaneous
11 ventilation or drug-induced depression of neuromuscular function.
12 Cardiovascular function may be impaired;

13 9. "Health care personnel" means any office staff member who is
14 licensed or certified by a recognized professional or health care
15 organization such as, but not limited to, a professional registered
16 nurse, licensed practical nurse, or physician assistant;

17 10. "Hospital" means a hospital licensed by the state;

18 11. "Immediately available" means being located within the
19 office and ready for immediate utilization when needed;

20 12. "Level I surgery" means minor procedures in which p.o.
21 preoperative medication and/or unsupplemented local anesthesia is
22 used in quantities equal to or less than the manufacturer's
23 recommended dose adjusted for weight and where the likelihood of
24 complications requiring hospitalization is remote. No drug-induced

1 alteration of consciousness other than preoperative minimal p.o.
2 anxiolysis of the patient shall be permitted in Level I office
3 surgery. The chances of complications requiring hospitalization
4 under Level I surgery shall be remote;

5 13. "Local anesthesia" means the administration of an agent
6 that produces a transient and reversible loss of sensation in a
7 circumscribed portion of the body;

8 14. "Major conduction block" means the injection of local
9 anesthesia to stop or prevent a painful sensation in a region of the
10 body. Major conduction blocks include, but are not limited to,
11 axillary, interscalene, and supraclavicular block of the brachial
12 plexus, spinal (subarachnoid), epidural and caudal blocks;

13 15. "Minimal sedation" (anxiolysis) means the administration of
14 a drug or drugs that produces a state of consciousness that allows
15 the patient to tolerate unpleasant medical procedures while
16 responding normally to verbal commands. Cardiovascular or
17 respiratory function should remain unaffected and defensive airway
18 reflexes should remain intact;

19 16. "Minor conduction block" means the injection of local
20 anesthesia to stop or prevent a painful sensation in a circumscribed
21 area of the body or the block of a nerve by direct pressure and
22 refrigeration. Minor conduction blocks include, but are not limited
23 to, intercostal, retrobulbar, paravertebral, peribulbar, pudental,
24 sciatic nerve, and ankle blocks;

1 17. "Moderate sedation/analgesia" means the administration of a
2 drug or drugs which produces depression of consciousness during
3 which patients respond purposefully to verbal commands, either alone
4 or accompanied by light tactile stimulation. Reflex withdrawal from
5 painful stimulation shall not be considered a purposeful response.
6 No interventions are required to maintain a patent airway, and
7 spontaneous ventilation is adequate. Cardiovascular function is
8 usually maintained. This includes dissociative anesthesia, which
9 does not meet the criteria as defined under sustained deep
10 anesthesia or general anesthesia;

11 18. "Monitoring" means continuous visual observation of a
12 patient and regular observation of the patient as deemed appropriate
13 by the level of sedation or recovery using instruments to measure,
14 display, and record physiologic values such as heart rate, blood
15 pressure, respiration and oxygen saturation;

16 19. "Office" means a location at which medical or surgical
17 services are performed and which is not subject to regulation by the
18 State Department of Health;

19 20. "Office-based practice" means procedures performed under
20 this regulation that occur in a physician's office or location other
21 than a hospital or facility licensed by the State Department of
22 Health;

23 21. "Office-based surgery" means the performance of any
24 surgical or other invasive procedure requiring anesthesia,

1 analgesia, or sedation, including cryosurgery and laser surgery,
2 which results in a necessary patient stay of less than twenty four
3 (24) consecutive hours and is performed by a physician in a location
4 other than a hospital or a diagnostic treatment center, including
5 free-standing ambulatory surgery centers;

6 22. "Operating room" means the location in the office or
7 facility dedicated to the performance of surgery or special
8 procedures;

9 23. "Physical status classification" means a description of a
10 patient used in determining if an office surgery or procedure is
11 appropriate. The American Society of Anesthesiologists (ASA)
12 enumerates classification as follows: I - Normal, healthy patient;
13 II - a patient with mild systemic disease; III- a patient with
14 severe systemic disease limiting activity but not incapacitating;
15 IV- a patient with incapacitating systemic disease that is a
16 constant threat to life; and V- Moribund, patients not expected to
17 live 24 hours with or without operation;

18 24. "Physician" means an individual holding an M.D. or D.O.
19 degree who is authorized to practice medicine in accordance with
20 state laws;

21 25. "Practitioner" means a physician, registered nurse, or
22 certified registered nurse anesthesiologist licensed and practicing
23 within the scope of practice pursuant to state law;

24

1 26. "Recovery area" means a room or limited access area of an
2 office dedicated to providing medical services to patients
3 recovering from surgery or anesthesia;

4 27. "Special procedure" means patient care which requires
5 entering the body with instruments in a potentially painful manner,
6 or which requires the patient to be immobile, for a diagnostic or
7 therapeutic procedure requiring anesthesia services. Special
8 procedures include, but are not limited to, diagnostic or
9 therapeutic endoscopy, invasive radiologic procedures, pediatric
10 magnetic resonance imaging; manipulation under anesthesia or
11 endoscopic examination with the use of general anesthetic;

12 28. "Sufficient knowledge" means a physician holds staff
13 privileges in a hospital or ambulatory surgical center which would
14 permit the physician to supervise the anesthesia, or the physician
15 is be able to document certification or eligibility by a specialty
16 board approved by the American Board of Medical Specialties or
17 American Osteopathic Association, or the physician is able to
18 demonstrate comparable background, formal training, or experience in
19 supervising the anesthesia;

20 29. "Surgery" means any operative or manual procedure performed
21 for the purpose of preserving health, diagnosing or treating
22 disease, repairing injury, correcting deformity or defects,
23 prolonging life or relieving suffering, or any elective procedure
24 for aesthetic or cosmetic purposes. This includes, but is not

1 limited to, incision or curettage of tissue or an organ, suture or
2 other repair of tissue or an organ, extraction of tissue from the
3 uterus, insertion of natural or artificial implants, closed or open
4 fracture reduction, or an endoscopic examination with use of local
5 or general anesthetic. This also includes, but is not limited to,
6 the use of lasers and any other devices or instruments in performing
7 such procedures; and

8 30. "Topical anesthesia" means the effect produced by an
9 anesthetic agent applied directly or indirectly to the skin or
10 mucous membranes, intended to produce a transient and reversible
11 loss of sensation to a circumscribed area;

12 SECTION 3. NEW LAW A new section of law to be codified
13 in the Oklahoma Statutes as Section 1-700.3 of Title 63, unless
14 there is created a duplication in numbering, reads as follows:

15 Each office-based practice shall develop and implement policies
16 and procedures. The policies and procedures shall be periodically
17 reviewed and updated. The purpose of the policies and procedures
18 are to assist in providing safe and quality surgical care, assure
19 consistent personnel performance, and promote an awareness and
20 understanding of the inherent rights of patients. Such policies and
21 procedures shall, at a minimum include the following:

22 1. A plan for the provision of emergency medical care as well
23 as the safe and timely transfer of patients to a hospital within
24 thirty (30) miles, should hospitalization be necessary;

1 2. Maintenance of age appropriate emergency supplies, equipment
2 and medication in accordance with the scope of surgical and
3 anesthesia services provided at the physician's office;

4 3. In an office where anesthesia services are provided to
5 infants and children, maintenance of emergency equipment that is
6 appropriately sized for a pediatric population, and personnel that
7 are appropriately trained to handle pediatric emergencies;

8 4. The availability and presence of a practitioner who is
9 qualified in resuscitation techniques and emergency care until all
10 patients having more than local anesthesia or minor conduction block
11 anesthesia have been discharged from the operating room or recovery
12 area;

13 5. In the event of untoward anesthetic, medical or surgical
14 complications or emergencies, the availability and presence of
15 personnel familiar with the procedures and plans to be followed who
16 are able to take the necessary actions. All office personnel shall
17 be familiar with a documented plan for the timely and safe transfer
18 of patients to a nearby hospital. This plan shall include
19 arrangements for emergency medical services, if necessary, or when
20 appropriate, the escort of the patient to the hospital or to an
21 appropriate practitioner. If advanced cardiac life support may be
22 instituted, the plan shall include immediate contact with emergency
23 medical services;

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1 6. A written procedure for initiating and maintaining a health
2 record for every patient evaluated or treated. The record shall
3 include a procedure code or suitable narrative description of the
4 procedure and shall have sufficient information to identify the
5 patient, support the diagnosis, justify the treatment and document
6 the outcome and required follow-up care. For procedures requiring
7 patient consent, there shall be a documented informed consent in the
8 patient record. If analgesia/sedation, minor or major conduction
9 block or general anesthesia are provided, the record shall include
10 documentation of the type of anesthesia used, the type and dose of
11 drugs used, fluids administered, the record of monitoring of vital
12 signs, level of consciousness during the procedure, patient weight,
13 estimated blood loss, duration of the procedure, and any
14 complications related to the procedure or anesthesia. Procedures
15 shall also be established to assure patient confidentiality and
16 security of all patient data and information;

17 7. Practices that comply with state and federal regulations
18 regarding infection control. For all surgical procedures, the level
19 of sterilization shall meet current requirements as provided by law.
20 There shall be a written procedure and schedule for cleaning,
21 disinfecting and sterilizing equipment and patient care items.
22 Personnel shall be trained in infection control practices,
23 implementation of universal precautions, and disposal of hazardous
24

1 waste products. Protective clothing and equipment shall be
2 available;

3 8. A plan for performance improvement as follows:

4 a. a performance improvement program shall be implemented
5 to provide a mechanism to periodically review the
6 current practice activities and quality of care
7 provided to patients, including peer review by members
8 not affiliated with the same practice. Performance
9 improvement may be established by:

10 (1) establishment of a performance program by the
11 practice,

12 (2) a cooperative agreement with a hospital-based
13 performance or quality improvement program,

14 (3) a cooperative agreement with another practice to
15 jointly conduct performance improvement
16 activities, or

17 (4) a cooperative agreement with a peer review
18 organization, a managed care organization,
19 specialty society, or other appropriate
20 organization dedicated to performance improvement
21 approved by the State Board of Medical Licensure
22 and Supervision, and

23 b. performance improvement activities shall include, but
24 not be limited to, review of mortalities, review of

1 the appropriateness and necessity of procedures
2 performed, emergency transfers, surgical and
3 anesthetic complications, and resultant outcomes,
4 including all postoperative infections, analysis of
5 patient satisfaction surveys and complaints, and
6 identification of undesirable trends, such as
7 diagnostic errors, unacceptable results, follow-up of
8 abnormal test results, and medication errors and
9 system problems. Findings of the performance
10 improvement program shall be incorporated into the
11 practice's educational activity;

12 9. A plan to report anesthetic or surgical events requiring
13 resuscitation or emergency transfer or resulting in death to the
14 State Board of Medical Licensure and Supervision within three (3)
15 business days using a form approved by the Board. Such reports
16 shall be considered initial complaints;

17 10. The identification of federal and state laws and
18 regulations that affect the practice and the development of
19 procedures to comply with those requirements. Office-based
20 practices shall focus on the following key requirements:

- 21 a. non-discrimination,
- 22 b. personal safety,
- 23 c. controlled substance safeguards,
- 24 d. laboratory operations and performance, and

1 e. personnel licensure scope of practice and limitations;

2 11. The recognition by office personnel of the basic rights of
3 patients and an understanding by office personnel of the importance
4 of maintaining patients' rights. A patients' rights document shall
5 be immediately available upon request.

6 SECTION 4. NEW LAW A new section of law to be codified
7 in the Oklahoma Statutes as Section 1-700.4 of Title 63, unless
8 there is created a duplication in numbering, reads as follows:

9 A. For purposes of this act, Level II office surgery includes
10 any procedure which requires the administration of minimal or
11 moderate intravenous, intramuscular, or rectal sedation/analgesia,
12 thus making post-operative monitoring necessary. Level II office
13 surgery shall be limited to procedures where there is only a
14 moderate risk of surgical and/or anesthetic complications and the
15 likelihood of hospitalization as a result of these complications is
16 unlikely. Level II office surgery includes local or peripheral
17 nerve block, minor conduction block, and Bier block.

18 B. For purposes of this act, Level III office surgery includes
19 any procedure that requires, or reasonably should require, the use
20 of deep sedation/analgesia, general anesthesia, or major conduction
21 block, and/or in which the known complications of the proposed
22 surgical procedure may be serious or life threatening.

1 SECTION 5. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 1-700.5 of Title 63, unless
3 there is created a duplication in numbering, reads as follows:

4 A. Practices performing office-based surgery or procedures that
5 require the administration of moderate or deep sedation/analgesia,
6 or general anesthesia, including Level II and III facilities as
7 specified in Section 4 of this act, shall be accredited within the
8 first year of operation by an accreditation agency, including the
9 American Association of Ambulatory Surgery Facilities (AAASF);
10 Accreditation Association for Ambulatory Health Care (AAAHC); the
11 Joint Commission on Accreditation of Healthcare Organizations
12 (JCAHO); or the Healthcare Facilities Accreditation Program (HFAP),
13 a division of the American Osteopathic Association. The accrediting
14 agency shall submit a biannual summary report for each facility to
15 the Board.

16 B. Any physician performing Level II or Level III office
17 surgery shall register with the State Board of Medical Licensure and
18 Supervision. Such registration shall include each address at which
19 Level II or Level III office surgery is performed and identification
20 of the accreditation agency that accredits each location, when
21 applicable.

22 SECTION 6. NEW LAW A new section of law to be codified
23 in the Oklahoma Statutes as Section 1-700.6 of Title 63, unless
24 there is created a duplication in numbering, reads as follows:

1 A. The specific office-based surgical procedures and anesthesia
2 services that each respective practitioner involved is qualified and
3 competent to perform shall be commensurate with each practitioner's
4 level of training and experience. Criteria to be considered to
5 demonstrate competence include:

6 1. State licensure;

7 2. Procedure-specific education, training, experience and
8 successful evaluation appropriate for the patient population being
9 treated;

10 3. a. For physicians, staff privileges in a hospital to
11 perform the same procedure or service as that being
12 performed in the office setting, or board
13 certification, board eligibility or completion of a
14 training program in a field of specialization
15 recognized by the Accreditation Council for Graduate
16 Medical Education for expertise and proficiency in
17 that field, or comparable background, formal training,
18 or experience as approved by the State Board of
19 Medical Licensure and Supervision. Board
20 certification shall include certification by the
21 American Board of Medical Specialists (ABMS) or the
22 American Osteopathic Association (AOA), and

23 b. For non-physician practitioners, certification that is
24 appropriate and applicable for the practitioner, as

1 recognized by the practitioner's licensing board or
2 the State Board of Medical Licensure and Supervision;

3 4. Professional misconduct and malpractice history;

4 5. Participation in peer and quality review proceedings;

5 6. Participation in continuing competency activities consistent
6 with the statutory requirements and requirements of the
7 practitioner's professional organization;

8 7. Malpractice insurance coverage adequate for the specialty;
9 and

10 8. Procedure-specific competence and competence in the use of
11 new procedures/technology, which encompasses education, training,
12 experience and evaluation, and which includes:

13 a. adherence to professional society standards,

14 b. hospital and/or ambulatory surgical privileges for the
15 scope of services performed in the office-based
16 setting at Levels II and III or the ability to
17 document satisfactory completion of training such as
18 board certification or board eligibility by a
19 specialty board approved by the American Board of
20 Medical Specialties, American Osteopathic Association,
21 or comparable background, formal training, or
22 experience as approved by the State Board of Medical
23 Licensure and Supervision,

- 1 c. credentials approved by a nationally recognized
2 accrediting or credentialing organization, and
3 d. for physicians, didactic course complemented by hands-
4 on, observed experience. Training shall be followed
5 by a specified number of cases supervised by a
6 practitioner already competent in the respective
7 procedure, in accordance with professional society
8 standards and guidelines.

9 B. Unlicensed or uncertified personnel shall not be assigned
10 duties or responsibilities that require professional licensure or
11 certification. Duties assigned to unlicensed or uncertified
12 personnel shall be in accordance with their training, education and
13 experience and under the direct supervision of a qualified, licensed
14 practitioner.

15 SECTION 7. NEW LAW A new section of law to be codified
16 in the Oklahoma Statutes as Section 1-700.7 of Title 63, unless
17 there is created a duplication in numbering, reads as follows:

18 A. Training required for Level II office procedures shall be as
19 follows:

20 1. The physician shall have staff privileges in a hospital to
21 perform the same procedure as that being performed in the office
22 setting or shall be able to document satisfactory completion of
23 training such as board certification or board eligibility by a
24 specialty board approved by the American Board of Medical

1 Specialties, American Osteopathic Association, or shall demonstrate
2 comparable background, formal training, or experience as approved by
3 the State Board of Medical Licensure and Supervision. The physician
4 shall maintain current certification in advanced resuscitative
5 techniques as appropriate; and

6 2. One assistant or other health care personnel who is located
7 within the office, but who is not necessarily the person assisting
8 in the procedure, shall be certified in advanced resuscitative
9 techniques as appropriate.

10 B. Equipment and supplies required for Level II office
11 procedures shall be as follows:

12 1. Emergency resuscitation equipment and a reliable source of
13 oxygen shall be current and immediately available; and

14 2. Monitoring equipment shall include a continuous suction
15 device, pulse oximeter, and noninvasive blood pressure apparatus and
16 stethoscope. Electrocardiographic monitoring shall be available for
17 patients with a history of cardiac disease. Age-and size-
18 appropriate monitors and resuscitative equipment shall be available
19 for patients.

20 C. Assistance of other personnel required for Level II office
21 procedures shall be as follows:

22 1. Supervision of the sedation/analgesia component of the
23 medical procedure shall be provided by a physician who is
24 immediately available, who possesses sufficient knowledge, and who

1 is qualified in accordance with state law to supervise the
2 administration of the sedation/analgesia or minor conduction block.

3 The physician providing supervision shall:

4 a. ensure that an appropriate pre-sedation/analgesia or
5 anesthesia examination and evaluation is performed
6 proximate to the procedure,

7 b. order the sedation/analgesia or anesthesia,

8 c. ensure that qualified health care personnel
9 participate,

10 d. remain immediately available until discharge criteria
11 are met, and

12 e. ensure the provision of indicated post-
13 sedation/analgesia or anesthesia care;

14 2. Sedation/analgesia or anesthesia shall be administered or
15 supervised only by a duly licensed, qualified and competent
16 physician. Certified registered nurse anesthetists or other
17 qualified practitioners who administer sedation/analgesia or
18 anesthesia as part of a medical procedure shall have training and
19 experience appropriate to the level of sedation/analgesia or
20 anesthesia administered and function in accordance with their scope
21 of practice. Such personnel shall have documented competence to
22 administer sedation/analgesia or anesthesia and to assist in any
23 support or resuscitation measures as required. The individual
24 administering sedation/analgesia or anesthesia and/or monitoring the

1 patient shall not play an integral role in performing the surgical
2 procedure. This paragraph shall not be construed to restrict or
3 limit the physician's ability to delegate medical tasks to other
4 qualified practitioners in Level II office procedures; and

5 3. A registered nurse or other licensed health care personnel
6 practicing within the scope of their practice who is currently
7 certified in advanced resuscitative techniques shall monitor the
8 patient postoperatively and have the capability of administering
9 medications as required for analgesia, nausea/vomiting, or other
10 indications. Monitoring in the recovery area shall include pulse
11 oximetry and non-invasive blood pressure measurement. The patient
12 shall be assessed periodically for level of consciousness, pain
13 relief, or any untoward complication. Each patient shall meet
14 discharge criteria as established by the practice prior to leaving
15 the operating room or recovery area.

16 D. Transfer and emergency protocols required for Level II
17 office procedures shall be as follows:

18 1. The physician shall have a transfer protocol in effect with
19 a hospital within reasonable proximity.

20 E. Facility accreditation required for Level II office
21 procedures shall be as follows:

22 1. The physician shall obtain and maintain accreditation of the
23 office setting by an approved accreditation agency.

24

1 SECTION 8. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 1-700.8 of Title 63, unless
3 there is created a duplication in numbering, reads as follows:

4 A. Training required for Level III office procedures shall be
5 as follows:

6 1. The physician shall have documentation of training to
7 perform the particular surgical procedure or procedures. The
8 physician shall have staff privileges in a hospital to perform the
9 same procedure as that being performed in the office setting or
10 shall be able to document satisfactory completion of training such
11 as board certification or board eligibility by a specialty board
12 approved by the American Board of Medical Specialties, American
13 Osteopathic Association, or comparable background, formal training,
14 or experience as approved by the State Board of Medical Licensure
15 and Supervision. In the event the physician is supervising the
16 administration of anesthesia by a certified registered nurse
17 anesthetist, the physician shall have sufficient knowledge of the
18 anesthesia specified for the procedure to provide effective care in
19 the case of emergency. If the physician does not possess the
20 sufficient knowledge of anesthesia, the anesthesia shall be
21 administered by or under the supervision of a qualified physician.
22 The physician shall maintain current certification in advanced
23 resuscitative techniques as appropriate; and

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1 2. One assistant or other health care personnel who is located
2 within the office, but who is not necessarily the person assisting
3 in the procedure, shall be currently certified in advanced
4 resuscitative techniques as appropriate.

5 B. Equipment and supplies required for Level III office
6 procedures shall be as follows:

7 1. Emergency resuscitation equipment, a continuous suction
8 device, and a reliable source of oxygen shall be current and
9 immediately available. At least twelve (12) ampules of dantrolene
10 sodium shall be immediately available. Age-and size-appropriate
11 monitors and resuscitative equipment shall be available for
12 patients;

13 2. Monitoring equipment shall be current and immediately
14 available, including but not limited to:

- 15 a. blood pressure apparatus and stethoscope,
- 16 b. pulse oximetry,
- 17 c. continuous electrocardiogram,
- 18 d. capnography, and
- 19 e. temperature monitoring for procedures lasting longer
20 than thirty (30) minutes; and

21 3. The facility, in terms of general preparation, equipment and
22 supplies, shall be comparable to a free standing ambulatory surgical
23 center, have provisions for proper record keeping, and have the
24 ability to recover patients after anesthesia.

1 C. Assistance of other personnel required for Level III office
2 procedures shall be as follows:

3 1. Supervision of the sedation/analgesia component of the
4 medical procedure shall be provided by a physician who is
5 immediately available, who possesses sufficient knowledge, and who
6 is qualified in accordance with state law to supervise the
7 administration of the sedation/analgesia or minor conduction block.
8 The physician providing supervision shall:

- 9 a. ensure that an appropriate pre-sedation/analgesia or
10 anesthesia examination and evaluation is performed
11 proximate to the procedure,
- 12 b. order the sedation/analgesia or anesthesia,
- 13 c. ensure that qualified health care personnel
14 participate,
- 15 d. remain immediately available until discharge criteria
16 are met, and
- 17 e. ensure the provision of indicated post-
18 sedation/analgesia or anesthesia care;

19 2. Sedation/analgesia or anesthesia shall be administered or
20 supervised only by a duly licensed, qualified and competent
21 physician. Certified registered nurse anesthetists or other
22 qualified practitioners who administer sedation/analgesia or
23 anesthesia as part of a medical procedure shall have training and
24 experience appropriate to the level of sedation/analgesia or

1 anesthesia administered and function in accordance with their scope
2 of practice. Such personnel shall have documented competence to
3 administer sedation/analgesia or anesthesia and to assist in any
4 support or resuscitation measures as required. The individual
5 administering sedation/analgesia or anesthesia and/or monitoring the
6 patient shall not play an integral role in performing the surgical
7 procedure; and

8 3. A registered nurse or other licensed health care personnel
9 practicing within the scope of their practice who is currently
10 certified in advanced resuscitative techniques shall monitor the
11 patient postoperatively and have the capability of administering
12 medications as required for analgesia, nausea/vomiting, or other
13 indications. Monitoring in the recovery area shall include pulse
14 oximetry and non-invasive blood pressure measurement. The patient
15 shall be assessed periodically for level of consciousness, pain
16 relief, or any untoward complication. Each patient shall meet
17 discharge criteria as established by the practice prior to leaving
18 the operating room or recovery area.

19 D. Transfer and Emergency Protocols required for Level III
20 office procedures shall be as follows:

21 1. The physician shall have a transfer protocol in effect with
22 a hospital within reasonable proximity.

23 E. Facility accreditation and inspection required for Level III
24 office procedures shall be as follows:

1 1. The physician shall obtain and maintain accreditation of the
2 office setting by an approved accreditation agency.

3 F. Patient admission and discharge protocols required for Level
4 III office procedures shall be as follows:

5 1. The physician shall evaluate the condition of the patient
6 and the potential risks associated with the proposed treatment plan.
7 The physician shall also provide a post-operative plan to the
8 patient and ensuring the patient is aware of the need for the
9 necessary follow-up care. Patients with pre-existing medical
10 problems or other conditions, who are at undue risk for
11 complications, shall be referred to an appropriate specialist for
12 pre-operative consultation. Patients who are considered high risk
13 or who are a physical classification status III or greater and who
14 require a general anesthetic for the surgical procedure shall have
15 the surgery performed in a hospital setting or in ambulatory surgery
16 centers. Patients with a physical status classification of III or
17 greater may be acceptable candidates for moderate
18 sedation/analgesia. Class III patients shall be specifically
19 addressed in the operating procedures of the office-based practice.
20 They may be acceptable candidates if deemed so by a physician
21 qualified to assess the specific disability and its impact on
22 anesthesia and surgical risks. Acceptable candidates for deep
23 sedation/analgesia, general anesthesia, or major conduction block in
24 office settings shall be patients with a physical status

1 classification of I or II, with no airway abnormality, and who
2 possess an unremarkable anesthetic history;

3 2. The risks, benefits, and potential complications of both the
4 surgery and anesthetic shall be discussed with the patient and/or,
5 if applicable, the patient's legal guardian prior to the surgical
6 procedure. Written documentation of informed consent shall be
7 included in the medical record;

8 3. A specialty specific medical history and physical
9 examination shall be performed, and appropriate laboratory studies
10 obtained within thirty (30) days prior to the planned surgical
11 procedure, by a practitioner qualified to assess the impact of co-
12 existing disease processes on surgery and anesthesia. The physician
13 shall assure that a preanesthetic examination and evaluation is
14 conducted immediately prior to surgery by the practitioner who will
15 be administering or supervising the anesthesia. Monitoring shall be
16 available for patients with a history of cardiac disease. Age and
17 size appropriate monitors and resuscitative equipment shall be
18 available for patients. The information and data obtained during
19 the course of these evaluations shall be documented in the patient's
20 medical record;

21 4. The physician shall evaluate the patient immediately upon
22 completion of the surgery and anesthesia. Care of the patient may
23 then be transferred to qualified health care personnel in the
24 recovery area. A qualified physician shall remain immediately

1 available until the patient meets discharge criteria. Criteria for
2 discharge for all patients who have received anesthesia shall
3 include the following:

- 4 a. confirmation of stable vital signs,
- 5 b. stable oxygen saturation levels,
- 6 c. return to pre-procedure mental status,
- 7 d. adequate pain control,
- 8 e. minimal bleeding, nausea and vomiting,
- 9 f. resolving neural block, resolution of the neuraxial
10 block, and
- 11 g. discharged in the company of a competent adult; and

12 5. The patient shall receive verbal instruction understandable
13 to the patient or guardian and confirmed by written post-operative
14 instructions and emergency contact numbers. The instructions shall
15 include:

- 16 a. the procedure performed,
- 17 b. information about potential complications,
- 18 c. telephone numbers to be used by the patient to discuss
19 complications or should questions arise,
- 20 d. instructions for medications prescribed and pain
21 management,
- 22 e. information regarding the follow-up visit date, time
23 and location, and

24

1 f. designated treatment facility in the event of
2 emergency.

3 SECTION 9. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 1-700.9 of Title 63, unless
5 there is created a duplication in numbering, reads as follows:

6 This act shall not apply to a procedure performed by an oral
7 surgeon licensed to practice dentistry who is also a physician
8 licensed to practice medicine, if the procedure is exclusively for
9 the practice of dentistry.

10 SECTION 10. This act shall become effective November 1, 2010.

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