NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2317.)

[R12-168]

PREAMBLE

R4-11-101	Amend
R4-11-1301	Amend
R4-11-1302	Amend
R4-11-1303	Amend
R4-11-1304	Repeal
R4-11-1304	New Section
R4-11-1305	Repeal

Article, Part, or Section Affected (as applicable) Rulemaking Action

R4-11-1305 New Section R4-11-1306 Amend R4-11-1307 New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1207(A)(1) and (14) Implementing statute: A.R.S. § 32-1207(B)(3)(b) and (E)

3. <u>Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:</u>

Notice of Rulemaking Docket Opening: 18 A.A.R. 1146, May 18, 2012

4. The agency's contact person who can answer questions about the rulemaking:

Name: Elaine Hugunin, Executive Director

Address: State Board of Dental Examiners

4205 N. 7th Ave., Suite 300

Phoenix, AZ 85013

Telephone: (602) 242-1492 Fax: (602) 242-1445

E-mail: elaine.hugunin@azdentalboard.us

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

In October 2008 the Board reviewed the Draft Proposed Rules for Article 13 presented by the Anesthesia Committee. The Board voted to proceed with the rulemaking process through the Governor's Regulatory Review Council (G.R.R.C.). Before the docket could be opened with the Secretary of State, the Governor issued an Executive Order mandating a rulemaking moratorium. In 2011 a new Executive Order was issued and was interpreted to exempt 90/10 Agencies from the Order. Since the draft proposed rules were three years old, the Anesthesia Committee met to

Notices of Proposed Rulemaking

review the draft. The Board approved the staff to move forward with a docket opening on the draft proposed rules presented by the Anesthesia Committee.

The rulemaking will include the following changes to Article 1 and Article 13:

- Update definitions to be consistent with the American Dental Association, American Academy of Pediatric Dentistry and American Association of Oral and Maxillofacial Surgeons.
- Add oral examination over medical emergencies language, which was inadvertently left out of the original 2003 language.
- Add language to address on-site onsite evaluation failures.
- Add language to define a mobile permit for Section 1301, 1302 and 1303.
- Add language to require a new infusion line and new fluid bag for each patient.
- Add language to require the utilization of supplemental oxygen and monitoring of the patient from the initiation
 of anesthesia until stabilization at all permit levels.
- Remove language from Section 1301 which allowed a general dentist to obtain a Section 1301 permit to work with a physician anesthesiologist and created a new permit level, Section 1304 specifically for those who want to employ a physician anesthesiologist or certified registered nurse anesthetist (CRNA). This new permit acts more like a facility permit.
- Amend language to allow current Section 1301, 1302, or 1303 permit holders to employ a certified registered nurse anesthetist (CRNA).
- Add language creating more education pathways for Section 1301, 1302 and 1303 applicants.
- Amend language to change the permit renewal period from three to five years.
- Amend language to change the number of evaluators to two evaluators for initial evaluations, one evaluator for renewal evaluations, two evaluators for subsequent evaluations and evaluation failures.

The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing the Board's complaint investigation process.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, licensees, business entities, and the public.

The rules' impact on established Board of Dental Examiner's procedures and office-related costs is a decrease in costs. The current rules require a Section 1302 and Section 1303 permit holders who employ a physician anesthesiologist to obtain a Section 1301 permit. The proposed rules allow a Section 1302 and Section 1303 permit holders to employ a physician anesthesiologist without obtaining a second permit. Currently there are 34 Section 1302 and Section 1303 permit holders who also hold a Section 1301 permit to employ a physician anesthesiologist. The rules will eliminate the requirement for a second permit, thus decreasing office related costs to the Board and decreasing revenue by \$3,060 (\$340 to the General Fund) annually. The rules increase the renewal period from three to five years without a fee increase. This decreases the cost to permit holders from \$100 per year to \$60 per year. The impact to the Board is a \$17,460 (\$1,940 to the General Fund) decrease in revenue each year. The rules net economic impact for the Board is moderate.

The rule's impact the licensee will eliminate the requirement for a second permit, resulting in the elimination of the \$300 fee for the 34 licensees currently holding two permits. Further, the administrative cost and loss of productivity during the onsite evaluation will decrease for the licensee. The rules increase the renewal period from three to five years without a fee increase. This decreases the cost to permit holders from \$100 per year to \$60 per year. Over the years, the number of Anesthesia/Sedation permit holders has increased, which means onsite evaluations have increased. Manpower to complete onsite evaluations has become a problem. Most onsite evaluators volunteer their services; they take time away from their practices to perform the evaluations. The rules reduce the number of required evaluators to one evaluator for renewal onsite evaluations. This doubles the pool of evaluators, and reduces the number of evaluations completed by each evaluator thereby decreasing their loss of productivity. The rules place a new requirement for using a new infusion line and new fluid bag for each patient, which increases costs to those licensees who reuse infusion lines and fluid bags. Standard of care dictates these items are one-time use, disposable items. The licensee must absorb the cost. The rules net economic impact for the licensee is minimal.

The rules' impact on Business Entities will be the same as a licensee, if the business entity pays the fees on behalf of a licensee.

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There will be no impact on physician anesthesiologists or certified registered nurse anesthetists (CRNA) employed by

The rules' impact on the public could be decreased cost for anesthesia/sedation services, because of the decreased permit costs to the licensee, if licensees pass the cost savings on to patients.

The Board, licensees, business entities, and the public benefit from rules that are clear, concise, and understandable. The rules' benefit the public health and safety by clarifying the anesthesia/sedation rules while continuing to ensure the education, training, and monitoring of dental practitioners.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name: Elaine Hugunin, Executive Director

> State Board of Dental Examiners 4205 N. 7th Ave., Suite 300

Phoenix, AZ 85013

Telephone: (602) 242-1492 Fax: (602) 242-1445

E-mail: elaine.hugunin@azdentalboard.us

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, October 22, 2012. An oral proceeding is scheduled for:

Date: October 22, 2012

Time: 10:00 a.m.

4205 N. 7th Ave., Suite 300 Location:

Phoenix, AZ 85013

A person may request information about the oral proceeding by contacting the person listed above.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

Not applicable

Address:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

A general permit is not used. The rule requires a specific permit as established in A.R.S. § 32-1207(E).

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness

of business in this state to the impact on business in other states:

- 12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules: None
- 13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

ARTICLE 1. DEFINITIONS

Section

R4-11-101. Definitions

ARTICLE 13. GENERAL ANESTHESIA AND SEDATION

Section	
R4-11-1301.	General Anesthesia and Semi-conscious Deep Sedation
R4-11-1302.	Conscious Parenteral Sedation
R4-11-1303.	Oral Conscious Sedation
R4-11-1304.	Reports of Adverse Occurrences Permit to Employ or Work with a Physician Anesthesiologist or Certified
	Registered Nurse Anesthetist (CRNA)
R4-11-1305.	Education Reports of Adverse Occurrences
R4-11-1306.	Renewal of Permit Education; Continued Competency
R4-11-1307.	Renewal of Permit

ARTICLE 1. DEFINITIONS

R4-11-101. Definitions

The following definitions, and definitions in A.R.S. § 32-1201, apply to this Chapter:

"Analgesia" means a state of decreased sensibility to pain produced by using nitrous oxide (N_2O) and oxygen (O_2) with or without local anesthesia.

"Anxiolysis" means the reduction or elimination of anxiety.

"Application" means, for purposes of Article 3 only, forms designated as applications and all documents and additional information the Board requires to be submitted with an application.

"Business Entity" means a business organization that offers to the public professional services regulated by the Board and is established under the laws of any state or foreign country, including a sole practitioner, partnership, limited liability partnership, corporation, and limited liability company, unless specifically exempted by A.R.S. § 32-1213(H).

"Calculus" means a hard mineralized deposit attached to the teeth.

"Certificate holder" means a denturist who practices denture technology under A.R.S. Title 32, Chapter 11, Article 5.

"Charitable Dental Clinic or Organization" means a non-profit organization meeting the requirements of 26 U.S.C. 501(c)(3) and providing dental or dental hygiene services.

"Clinical evaluation" means a dental examination of a patient named in a complaint regarding the patient's dental condition as it exists at the time the examination is performed.

"Closed subgingival curettage" means the removal of the inner surface of the soft tissue wall of a periodontal pocket in a situation where a flap of tissue has not been intentionally or surgically opened.

"Combination inhalation and enteral conscious sedation" is conscious sedation induced by the administration of nitrous oxide and oxygen in combination with one or more enteral drugs or non-drug substances.

"Controlled substance" has the meaning prescribed in A.R.S. § 36-2501(A)(3).

"Credit hour" means one clock hour of participation in a recognized continuing dental education program.

"Deep sedation" has the same meaning as "semi-conscious sedation" is a drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

"Dental laboratory technician" or "dental technician" has the meaning prescribed in A.R.S. § 32-1201(6).

"Dentist of record" means a dentist who examines, diagnoses, and formulates treatment plans for a patient and may provide treatment to the patient.

"Designee" means a person to whom the Board delegates authority to act on the Board's behalf regarding a particular task specified by this Chapter.

"Direct supervision" means, for purposes of Article 7 only, that a licensed dentist is present in the office and available to provide immediate treatment or care to a patient and observe a dental assistant's work.

"Direct supervision" means, for purposes of Article 13 only, that a licensed dentist is physically present in the operatory and actually performing dental procedures.

"Disabled" means a dentist, dental hygienist, or denturist has totally withdrawn from the active practice of dentistry, dental hygiene, or denturism due to a permanent medical disability and based on a physician's order.

"Dispense for profit" means selling a drug or device for any amount above the administrative overhead costs to inventory.

"Documentation of attendance" means documents that contain the following information:

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Name of sponsoring entity;

Course title;

Number of credit hours;

Name of speaker; and

Date, time, and location of the course.

"Drug" means:

Articles recognized, or for which standards or specifications are prescribed, in the official compendium;

Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the human body;

Articles other than food intended to affect the structure or any function of the human body; or

Articles intended for use as a component of any articles specified in this definition but does not include devices or components, parts, or accessories of devices.

"Emerging scientific technology" means any technology used in the treatment of oral disease that is not currently generally accepted or taught in a recognized dental or dental hygiene school and use of the technology poses material risks.

"Enteral" means an administration technique in which a drug or non-drug substance is absorbed through the oral, rectal, sublingual, or nasal mucosa.

"Epithelial attachment" means the layer of cells that extends apically from the depth of the gingival (gum) sulcus (crevice) along the tooth, forming an organic attachment.

"Ex-parte communication" means a written or oral communication between a decision maker, fact finder, or Board member and one party to the proceeding, in the absence of other parties.

"General anesthesia" is a state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway and to respond appropriately to physical stimulation or verbal command, that is induced by a drug or non-drug method or a combination of both methods drug-induced loss of consciousness during which the patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. The patient often requires assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

"General supervision" means, for purposes of Article 7 only, a licensed dentist is available for consultation, whether or not the dentist is in the office, regarding procedures or treatment that the dentist authorizes and for which the dentist remains responsible.

"Homebound patient" means a person who is unable to receive dental care in a dental office as a result of a medically diagnosed disabling physical or mental condition.

"Informal interview" means a proceeding conducted under A.R.S. § 32-1263.02, during which a Board member, acting as an informal interviewing officer, and other investigators, hear testimony from a complainant, licensee, or certificate holder, and any witnesses, and receive and review evidence relating to a complaint to form findings of fact, conclusions of law, and a recommended disposition for presentation to the full Board.

"Intravenous or intramuseular sedation" is the parenteral use of a drug or non-drug substance to induce general anesthesia, semi-conscious sedation, or conscious sedation.

"Investigative interview" means a proceeding conducted under A.R.S. § 32-1263.02, during which an investigator or investigative panel hears testimony from a complainant, licensee, or certificate holder, and any witnesses, and receives and reviews evidence relating to a complaint to form findings of fact, conclusions of law, and a recommended disposition for presentation to the full Board.

"Irreversible procedure" means a single treatment, or a step in a series of treatments, that causes change in the affected hard or soft tissues and is permanent or may require reconstructive or corrective procedures to correct the changes.

"Jurisdiction" means the Board's power to investigate and rule on complaints that allege grounds for disciplinary action under A.R.S. Title 32, Chapter 11 or this Chapter.

"Licensee" means a dentist, dental hygienist, dental consultant, retired licensee, or person who holds a restricted permit under A.R.S. §\frac{\xi}{x} 32-1237 or 32-1292.

"Local anesthesia" is the elimination of sensations, such as pain, in one part of the body by the injection of an anesthetic drug.

"Minimal sedation" is a minimally depressed level of consciousness that retains a patient's ability to independently and continuously maintain an airway and respond appropriately to light tactile stimulation, not limited to reflex with-drawal from a painful stimulus, or verbal command and that is produced by a pharmacological or non-pharmacological method or a combination thereof. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. In accord with this particular definition, the drugs or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

"Moderate sedation" is a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands either alone or accompanied by light tactile stimulation, not limited to reflex withdrawal from a painful stimulus. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The drugs or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of a drug before the effects of previous dosing can be fully recognized may result in a greater alteration of the state of consciousness than intended by the permit holder.

"Nitrous oxide analgesia" means nitrous oxide (N2O/O2) used as an inhalation analgesic.

"Nonsurgical periodontal treatment" means plaque removal, plaque control, supragingival and subgingival scaling, root planing, and the adjunctive use of chemical agents.

"Nurse anesthetist" means a licensed nurse with special training in all phases of anesthesia.

"Official compendium" means the latest revision of the United States Pharmacopeia and the National Formulary and any current supplement.

"Oral eonseious sedation" is eonseious sedation induced by an enterally administered the enteral administration of a drug or non-drug substance or combination inhalation and enterally administered drug or non-drug substance on an outpatient basis in a dental office or dental clinic to achieve minimal or moderate sedation.

"Outpatient" means an individual who receives treatment in a dental office or clinic.

"Conscious <u>Parenteral</u> sedation" is a <u>minimally depressed level of consciousness that allows the patient to retain the ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and is induced by a drug or non-drug method or a combination of both methods technique of administration in which the drug bypasses the gastrointestinal track.</u>

"Patient of record" means a patient who has undergone a complete dental evaluation performed by a licensed dentist.

"Periodontal examination and assessment" means to collect and correlate clinical signs and patient symptoms that point to either the presence of or the potential for periodontal disease.

"Periodontal pocket" means a pathologic fissure bordered on one side by the tooth and on the opposite side by crevicular epithelium and limited in its depth by the epithelial attachment.

"Plaque" means a film-like sticky substance composed of mucoidal secretions containing bacteria and toxic products, dead tissue cells, and debris.

"Polish" means, for the purposes of A.R.S. § 32-1291(B) only, a procedure limited to the removal of plaque and extrinsic stain from exposed natural and restored tooth surfaces that utilizes an appropriate rotary instrument with rubber cup or brush and polishing agent. A licensee or dental assistant shall not represent that this procedure alone constitutes an oral prophylaxis.

"Prescription-only device" means:

Any device that is restricted by the federal act, as defined in A.R.S. § 32-1901, to use only under the supervision of a medical practitioner; or

Any device required by the federal act, as defined in A.R.S. § 32-1901, to bear on its label the legend "Rx Only."

"Prescription-only drug" does not include a controlled substance but does include:

Any drug that, because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts, qualified by scientific training and experience to evaluate its safety and efficacy, as safe for use except by or under the supervision of a medical practitioner;

Any drug that is limited by an approved new drug application under the federal act or A.R.S. § 32-1962 to use under the supervision of a medical practitioner;

Every potentially harmful drug, the labeling of which does not bear or contain full and adequate directions for use by the consumer; or

Any drug, other than a controlled substance, required by the federal act to bear on its label the legend "Rx Only." "President's designee" means the Board's executive director, an investigator, or a Board member acting on behalf of

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the Board president.

"Preventative and therapeutic agents" means substances used in relation to dental hygiene procedures that affect the hard or soft oral tissues to aid in preventing or treating oral disease.

"Prophylaxis" means a scaling and polishing procedure performed on patients with healthy tissues to remove coronal plaque, calculus, and stains.

"Public member" means a person who is not a dentist, dental hygienist, dental assistant, denturist, or dental technician

"Recognized continuing dental education" means a program whose content directly relates to the art and science of oral health and treatment, provided by a recognized dental school as defined in A.R.S. § 32-1201(17), recognized dental hygiene school as defined in A.R.S. § 32-1201(16), or recognized denturist school as defined in A.R.S. § 32-1201(18), or sponsored by a national or state dental, dental hygiene, or denturist association, dental, dental hygiene, or denturist study club, governmental agency, or commercial dental supplier.

"Representative" means, for purposes of Article 15 only, a person recognized by the Board as authorized to act on behalf of a complainant or a party in proceedings governed by this Chapter.

"Restricted permit holder" means a dentist who meets the requirements of A.R.S. § 32-1237 or a dental hygienist who meets the requirements of A.R.S. § 32-1292 and is issued a restricted permit by the Board.

"Retired" means a dentist, dental hygienist, or denturist is at least 65 years old and has totally withdrawn from the active practice of dentistry, dental hygiene, or denturism.

"Root planing" means a definitive treatment procedure designed to remove cementum or surface dentin that is rough, impregnated with calculus, or contaminated with toxins or microorganisms.

"Scaling" means use of instruments on the crown and root surfaces of the teeth to remove plaque, calculus, and stains from these surfaces.

"Section 1301 permit" means a permit to administer general anesthesia and semi-conscious deep sedation, employ or work with a physician anesthesiologist, or employ or work with a Certified Registered Nurse Anesthetist (CRNA) under Article 13.

"Section 1302 permit" means a permit to administer conscious parenteral sedation, employ or work with a physician anesthesiologist, or employ or work with a Certified Registered Nurse Anesthetist (CRNA) under Article 13.

"Section 1303 permit" means a permit to administer oral eonscious sedation, employ or work with a physician anesthesiologist, or employ or work with a Certified Registered Nurse Anesthetist (CRNA) under Article 13.

"Section 1304 permit" means a permit to employ or work with a physician anesthesiologist, or employ or work with a Certified Registered Nurse Anesthetist (CRNA) under Article 13.

"Semi-conscious sedation" means use of drug or non-drug methods, or a combination of the two methods, to induce a state of depressed consciousness accompanied by partial loss of protective reflexes, and the inability to continually maintain an airway independently or respond appropriately to physical stimulation or verbal command.

"Study club" means a group of at least five Arizona licensed dentists, dental hygienists, or denturists who provide written course materials or a written outline for a continuing education presentation that meets the requirements of Article 12.

"Treatment records" means all documentation related directly or indirectly to the dental treatment of a patient.

"Triage" means a review during which investigators examine a complaint, the licensee's response, and dental records to form a recommended disposition for presentation to the full Board.

ARTICLE 13. GENERAL ANESTHESIA AND SEDATION

R4-11-1301. General Anesthesia and Semi-conscious Deep Sedation

- A. Before inducing administering general anesthesia by any means, or semi-conscious deep sedation by intravenous or intra-museular any means, on an outpatient basis in a dental office or dental clinic, a dentist shall possess a Section 1301 permit issued by the Board. A The dentist may renew a Section 1301 permit every three five years by complying with R4-11-1306 R4-11-1307.
- **B.** To obtain or renew a Section 1301 permit, a dentist shall:
 - 1. Submit a completed application on a form supplied provided by the Board office that, in addition to the requirements of subsections (B)(2) and (B)(3), and R4-11-1306 R4-11-1307, includes:
 - a. General information about the applicant such as:
 - i. Name:
 - ii. Home and office addresses and telephone numbers;
 - iii. Limitations of practice;

- iv. Hospital affiliations;
- v. Denial, curtailment, revocation, or suspension of hospital privileges;
- vi. Denial of membership in, denial of renewal of membership in, or disciplinary action by a dental organization; and
- vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body; and
- b. The dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules;
- 2. On forms provided by the Board, provide a dated and signed affidavit attesting that a facility any office or dental clinic where the dentist will administer general anesthesia or semi-conscious deep sedation:
 - a. Contains the following properly operating equipment and supplies <u>during the provision of general anesthesia and deep sedation:</u>
 - i. Anesthesia or analgesia machine,
 - ii.i. Emergency drugs;
 - iii.ii. Electrocardiograph monitor;
 - iv.iii. Pulse oximeter;
 - v.iv. Cardiac defibrillator or automated external defibrillator (AED);
 - vi.v. Positive pressure oxygen and supplemental oxygen;
 - vii.vi. Suction equipment, including endotracheal, tonsillar, or pharyngeal and emergency backup medical suction device;
 - viii.vii. Laryngoscope and multiple blades, backup batteries and backup bulbs;
 - ix.viii. Endotracheal tubes and appropriate connectors;
 - x.ix. Magill forceps;
 - xi.x. Oral Oropharyngeal and nasopharyngeal airways;
 - xi. Auxiliary lighting;
 - xii. Stethoscope; and
 - xiii. Blood pressure monitoring device; and
 - b. Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents. All personnel involved in administering and monitoring general anesthesia or semi-conscious deep sedation shall hold a current eertificate course completion confirmation in basic cardiopulmonary resuscitation (CPR) Healthcare Provider Level;
- 3. Hold a valid license to practice dentistry in this state;
- 4. Maintain a current permit to prescribe and administer controlled substances in this state issued by the United States Drug Enforcement Administration; and
- 5. Hold a current certificate from the American Heart Association or the American Red Cross in advanced cardiac life support (ACLS); and Provide confirmation of completing coursework within the two years prior to submitting the permit application in one or more of the following:
 - a. Advanced cardiac life support (ACLS) from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - b. Pediatric advanced life support (PALS) in a practice treating pediatric patients; or
 - c. A recognized continuing education course in advanced airway management.
- 6.C. Meet one or more of <u>Initial applicants shall meet</u> the following conditions:
 - a-1. Complete, within the three years before submitting the permit application, a full credit load, as defined by the training program, during one calendar year of training, in anesthesiology or related academic subjects, beyond the undergraduate dental school level in a training program described in R4-11-1305(A) R4-11-1306(A), offered by a hospital accredited by the Joint Commission on Accreditation of Hospitals Organization, or sponsored by a university accredited by the American Dental Association Commission on Dental Accreditation; and
 - b.2. Be, within the three years before submitting the permit application, a Diplomate of the American Board of Oral and Maxillofacial Surgeons or eligible for examination by the American Board of Oral and Maxillofacial surgeons, a Fellow of the American Association of Oral and Maxillofacial surgeons, or a Fellow of the American Dental Society of Anesthesiology, or eligible for examination by the American Dental Society of Anesthesiology a Diplomate of the National Dental Board of Anesthesiology, or
 - e.3. Employ or work with a licensed allopathic or osteopathic physician who is a member of the anesthesiology staff of an accredited hospital in this state and ensure that the anesthesiologist remains on the dental facility premises until any patient given general anesthetic or semi-conscious sedation regains consciousness and is discharged. For an applicant who completed the requirements of subsections (C)(1) or (2) more than three years before submitting the permit application, provide the following documentation:
 - a. On a form provided by the Board, a written affidavit affirming that the applicant has administered general anesthesia or deep sedation to a minimum of 25 patients within the year before submitting the permit application or

- 75 patients within the last five years before submitting the permit application; or
- b. A copy of the general anesthesia or deep sedation permit in effect in another state or certification of military training in general anesthesia or deep sedation from the applicant's commanding officer; and
- c. On a form provided by the Board, a written affidavit affirming the completion of 30 clock hours of continuing education taken within the last five years as outlined in R4-11-1306(B)(1)(a) through (f).
- C.D. After submitting the application and written evidence of compliance with requirements in subsection (B) and, if applicable, subsection (C) to the Board, the dentist applicant shall schedule an onsite evaluation by the Board during which the dentist applicant shall administer general anesthesia and or semi-conscious deep sedation. After a dentist the applicant completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a Section 1301 permit shall be issued to the applicant.
 - 1. The onsite evaluation team shall consist of:
 - a. Two dentists who are Board members, or Board designees for initial applications; or
 - b. One dentist who is a Board member or Board designee for renewal applications.
 - 2. The onsite evaluation team shall look for evaluate the following:
 - a. The availability of equipment and personnel as specified in subsection (B)(2);
 - b. Proper administration of general anesthesia or parenteral semi-conscious deep sedation to a patient by the dentist applicant in the presence of the evaluation team;
 - c. Successful responses by the dentist applicant to oral examination questions from the evaluation team, about patient management, medical emergencies, and emergency medications;
 - d. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving receipt, administration, dispensing, and destroying destruction of controlled substances; and
 - e. Proper recordkeeping as specified in subsection (D) (E) by reviewing the records generated for the patient specified in subsection (C)(1)(b): (D)(2)(b); and
 - f. For renewal applicants, records supporting continued competency as specified in R4-11-1306.
 - 2.3. The evaluation of a subsequent facility in which general anesthesia or semi-conscious sedation is administered by a dentist who possesses a Section 1301 permit may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a) team shall recommend one of the following:
 - a. Pass. Successful completion of the onsite evaluation;
 - b. Conditional approval for failing to have appropriate equipment, proper documentation of controlled substances, or proper recordkeeping. The applicant must submit proof of correcting the deficiencies before a permit is issued:
 - c. Category 1 Evaluation Failure. The applicant must review the appropriate subject matter and schedule a subsequent evaluation by two Board Members or Board designees not less than 30 days from the failed evaluation. An example is failure to recognize and manage one emergency;
 - d. Category 2 Evaluation Failure. The applicant must complete Board approved continuing education in subject matter within the scope of the onsite evaluation as identified by the evaluators and schedule a subsequent evaluation by two Board Members or Board designees not less than 60 days from the failed evaluation. An example is failure to recognize and manage more than one emergency; or
 - e. Category 3 Evaluation Failure. The applicant must complete Board approved remedial continuing education with the subject matter outlined in R4-11-1306 as identified by the evaluators and reapply not less than 90 days from the failed evaluation. An example is failure to recognize and manage an anesthetic urgency.
 - 4. The onsite evaluation of an additional dental office or dental clinic in which general anesthesia or deep sedation is administered by an existing Section 1301 permit holder may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (D)(2)(a).
 - 5. A Section 1301 mobile permit may be issued if a Section 1301 permit holder travels to dental offices or dental clinics to provide anesthesia or deep sedation. The applicant must submit a completed affidavit verifying:
 - a. That the equipment and supplies for the provision of anesthesia or deep sedation as required in subsection (B)(2)(a) either travel with the Section 1301 permit holder or are in place and in appropriate condition at the dental office or dental clinic where anesthesia or deep sedation is provided, and
 - b. Compliance with subsection (B)(2)(b).
- **D.E.** A dentist Section 1301 permit holder shall keep an anesthesia or deep sedation record for each general anesthesia and semi-conscious deep sedation administered procedure that:
 - 1. Includes includes the following entries:
 - a.1. Pre-operative and post-operative electrocardiograph reports documentation;
 - b.2. Pre-operative, post-operative, and intra-operative, and post-operative pulse oximeter readings documentation;
 - e.3. Pre-operative, and post-operative intra-operative, and post-operative blood pressure and vital signs sign documentation;
 - d. Intra operative blood pressures; and
 - e.4. A list of all medications given, with dosage and time intervals and route and site of administration; and
 - 2. May include the following entries:

- a. Route and site of administration;
- b.5. Type of catheter or portal with gauge;
- e.6. Indicate nothing by mouth or time of last intake of food or water;
- d.7. Consent form; and
- e.8. Time of discharge and status, including name of escort.
- **E.F.** A dentist The Section 1301 permit holder, for intravenous access, who obtains a Section 1301 permit may employ a nurse anesthetist to administer general anesthesia or semi-conscious sedation under the dentist's direct supervision shall use a new infusion set, including a new infusion line and new bag of fluid, for each patient.
- **F.G.** The Section 1301 permit holder who obtains a Section 1301 permit may also induce conscious sedation without obtaining a Section 1302 permit shall utilize supplemental oxygen for all patients receiving general anesthesia or deep sedation for the duration of the procedure.
- H. The Section 1301 permit holder shall continuously supervise the patient from the initiation of anesthesia or deep sedation until termination of the anesthesia or deep sedation procedure and oxygenation, ventilation, and circulation are stable. The Section 1301 permit holder shall not commence with the administration of a subsequent anesthetic case until the patient is in monitored recovery or meets the guidelines for discharge.
- I. A Section 1301 permit holder may employ the following health care professionals to administer general anesthesia or deep sedation and shall ensure that the health care professional continuously supervises the patient from the administration of anesthesia or deep sedation until termination of the anesthesia or deep sedation procedure and oxygenation, ventilation, and circulation are stable:
 - 1. An allopathic or osteopathic physician currently licensed in Arizona by the Arizona Medical Board or the Arizona Board of Osteopathic Examiners who has successfully completed a residency program in anesthesiology approved by the American Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or who is certified by either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology and is credentialed with anesthesia privileges through an Arizona licensed medical facility, or
 - 2. A Certified Registered Nurse Anesthetist (CRNA) currently licensed in Arizona who provides services under the Nurse Practice Act.
- J. A Section 1301 permit holder may also administer parenteral sedation without obtaining a Section 1302 permit.

R4-11-1302. Conscious Parenteral Sedation

- A. A dentist who possesses a Section 1301 permit may also induce conscious sedation. Before inducing administering conscious parenteral sedation by intravenous or intramuscular means on an outpatient basis in a dental office or dental clinic, a dentist who does not possess a Section 1301 permit shall possess a Section 1302 permit issued by the Board. A The dentist may renew a Section 1302 permit every three five years by complying with R4-11-1306 R4-11-1307.
 - 1. A Section 1301 permit holder may also administer parenteral sedation.
 - 2. A Section 1302 permit holder shall not administer or employ any agents which have a narrow margin for maintaining consciousness including, but not limited to, ultra-short acting barbiturates, propofol, parenteral ketamine, or similarly acting drugs, agents, or techniques, or any combination thereof that would likely render a patient deeply sedated, generally anesthetized or otherwise not meet the conditions of moderate sedation.
- **B.** To obtain or renew a Section 1302 permit, the dentist shall:
 - 1. Submit a completed application on a form supplied provided by the Board office that, in addition to the requirements of subsections (B)(2) and (B)(3) (3) and R4-11-1306 R4-11-1307, includes:
 - a. General information about the applicant such as:
 - i. Name;
 - ii. Home and office addresses and telephone numbers;
 - iii. Limitations of practice;
 - iv. Hospital affiliations;
 - v. Denial, curtailment, revocation, or suspension of hospital privileges;
 - vi. Denial of membership in, denial of renewal of membership in, or disciplinary action by a dental organiza-
 - vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body;
 - b. The dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules;
 - 2. On forms provided by the Board, provide a dated and signed affidavit attesting that a facility any dental office or dental clinic where the dentist will administer conscious parenteral sedation by intravenous or intramuscular route:
 - a. Contains the following properly operating equipment and supplies <u>during the provision of parenteral sedation by</u> the permit holder or general anesthesia or deep sedation by a physician anesthesiologist or Certified Registered Nurse Anesthetist (CRNA):
 - i. Emergency drugs;

- ii. Positive pressure oxygen and supplemental oxygen;
- iii. Stethoscope.;
- iv. Suction equipment, including tonsillar or pharyngeal and emergency backup medical suction device;
- v. Nasopharyngeal tubes Oropharyngeal and nasopharyngeal airways; vi. Pulse oximeter;
- vii. Oropharyngeal tubes Auxiliary lighting; and
- viii. Blood pressure monitoring device; and
- ix. Cardiac defibrillator or automated external defibrillator (AED); and
- b. Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents, including at least one staff member who:
 - Holds a current eertificate course completion confirmation in basic cardiopulmonary resuscitation (CPR) healthcare provider level:
 - ii. Is present during the eonseious parenteral sedation procedure; and
 - iii. After the procedure, monitors the patient until discharge;
- 3. Hold a valid license to practice dentistry in this state;
- 4. Maintain a current permit to prescribe and administer controlled substances in this state issued by the United States Drug Enforcement Administration;
- 5. Hold a current certificate from the American Heart Association or the American Red Cross in advanced cardiac life support (ACLS); Provide confirmation of completing coursework within the two years prior to submitting the permit application in one or more of the following:
 - Advanced cardiac life support (ACLS) from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - b. Pediatric advanced life support (PALS) in a practice treating pediatric patients; or
 - c. A recognized continuing education course in advanced airway management; and
- 6.C. Participate in 60 clock hours of Board-approved undergraduate, graduate, or post graduate education within the three years before submitting the permit application, that covers training in basic conscious sedation, including Initial applicants shall meet one of the following conditions:
 - Successfully complete Board-recognized undergraduate, graduate, or postgraduate education within the three years before submitting the permit application, that includes the following:
 - a. Administration of parenteral sedative medications to at least 10 patients;
 - a. Sixty didactic hours of basic parenteral sedation to include:
 - b.i. Physical evaluation;
 - e.ii. Management of medical emergencies;
 - diii. The importance of and techniques for maintaining proper documentation; and
 - e.iv. Monitoring and the use of monitoring equipment.; and
 - b. Hands-on administration of parenteral sedative medications to at least 20 patients in a manner consistent with this Section; or
 - 2. An applicant who completed training in parenteral sedation more than three years before submitting the permit application shall provide the following documentation:
 - On a form provided by the Board, a written affidavit affirming that the applicant has administered parenteral sedation to a minimum of 25 patients within the year or 75 patients within the last five years before submitting the permit application;
 - b. A copy of the parenteral sedation permit in effect in another state or certification of military training in parenteral sedation from the applicant's commanding officer; and
 - c. On a form provided by the Board, a written affidavit affirming the completion of 30 clock hours of continuing education taken within the last five years as outlined in R4-11-1306(B)(1)(b) through (f).
- E.D. After submitting the application and written evidence of compliance with requirements outlined in subsection (B) and, if applicable, subsection (C) to the Board, the dentist applicant shall schedule an onsite evaluation by the Board during which the dentist applicant shall administer eonseious parenteral sedation. After a dentist the applicant completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a Section 1302 permit to the applicant.
 - 1. The onsite evaluation team shall consist of:
 - <u>a.</u> two <u>Two</u> dentists who are Board members, or Board designees <u>for initial applications</u>,
 - b. One dentist who is a Board member or Board designee for renewal applications.
 - 2. The onsite evaluation team shall look for evaluate the following:
 - a. The availability of equipment and personnel as specified in subsection (B)(2);
 - Proper administration of conscious parenteral sedation to a patient by the dentist applicant in the presence of the evaluation team:
 - c. Successful responses by the dentist applicant to oral examination questions from the evaluation team about

- patient management, medical emergencies, and emergency medications;
- d. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving receipt, administration, dispensing, and destroying destruction of all controlled substances; and
- e. Proper recordkeeping as specified in subsection (D) (E) by reviewing the records generated for the patient receiving eonseious parenteral sedation as specified in subsection (C)(1)(b) (D)(2)(b); and
- f. For renewal applicants, records supporting continued competency as specified in R4-11-1306.
- 2.3. The onsite evaluation of a subsequent facility in which conscious sedation is administered by a dentist who possesses a Section 1302 permit may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a) team shall recommend one of the following:
 - a. Pass. Successful completion of the onsite evaluation:
 - b. Conditional approval for failing to have appropriate equipment, proper documentation of controlled substances, or proper recordkeeping. The applicant must submit proof of correcting the deficiencies before a permit is issued;
 - c. Category 1 Evaluation Failure. The applicant must review the appropriate subject matter and schedule a subsequent evaluation by two Board Members or Board designees not less than 30 days from the failed evaluation. An example is failure to recognize and manage one emergency;
 - d. Category 2 Evaluation Failure. The applicant must complete Board approved continuing education in subject matter within the scope of the onsite evaluation as identified by the evaluators and schedule a subsequent evaluation by two Board Members or Board designees not less than 60 days from the failed evaluation. An example is failure to recognize and manage more than one emergency; or
 - e. Category 3 Evaluation Failure. The applicant must complete Board approved remedial continuing education with the subject matter outlined in R4-11-1306 as identified by the evaluators and reapply not less than 90 days from the failed evaluation. An example is failure to recognize and manage an anesthetic urgency.
- 4. The onsite evaluation of an additional dental office or dental clinic in which parenteral sedation is administered by an existing Section 1302 permit holder may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (D)(2)(a).
- 5. A Section 1302 mobile permit may be issued if a Section 1302 permit holder travels to dental offices or dental clinics to provide parenteral sedation. The applicant must submit a completed affidavit verifying:
 - a. That the equipment and supplies for the provision of parenteral sedation as required in R4-11-1302(B)(2)(a) either travel with the Section 1302 permit holder or are in place and in appropriate condition at the dental office or dental clinic where parenteral sedation is provided, and
 - b. Compliance with R4-11-1302(B)(2)(b).
- **D.E.** A dentist Section 1302 permit holder shall keep an anesthesia a parenteral sedation record for each conscious parenteral sedation administered procedure that:
 - 1. Includes the following entries:
 - a. Pre-operative, post-operative, and intra-operative, and post-operative pulse oximeter readings documentation;
 - b. Pre-operative, and post-operative intra-operative, and post-operative blood pressure and vital signs sign documentation;
 - e. Intra-operative blood pressures; and
 - d.c. A list of all medications given, with dosage and time intervals and route and site of administration; and
 - 2. May include the following entries:
 - a. Pre-operative and post-operative electrocardiograph report;
 - b. Route and site of administration;
 - e.d. Type of catheter or portal with gauge;
 - e.e. Indicate nothing by mouth or time of last intake of food or water;
 - d.f. Consent form; and
 - e.g. Time of discharge and status, including name of escort; and
 - 2. May include pre-operative and post-operative electrocardiograph report.
- **E.F.** A dentist The Section 1302 permit holder who obtains a Section 1302 permit may employ a nurse anesthetist to administer conscious sedation under the dentist's direct supervision shall establish intravenous access on each patient receiving parenteral sedation utilizing a new infusion set, including a new infusion line and new bag of fluid.
- **G.** The Section 1302 permit holder shall utilize supplemental oxygen for all patients receiving parenteral sedation for the duration of the procedure.
- **H.** The Section 1302 permit holder shall continuously supervise the patient from the initiation of parenteral sedation until termination of the parenteral sedation procedure and oxygenation, ventilation and circulation are stable. The Section 1302 permit holder shall not commence with the administration of a subsequent anesthetic case until the patient is in monitored recovery or meets the guidelines for discharge.
- A Section 1302 permit holder may employ the following healthcare professionals to provide anesthesia services and shall ensure that the employed healthcare professional continuously supervises the patient from the administration of parenteral sedation until termination of the pareneral sedation procedure and oxygenation, ventilation, and circulation are stable:

- 1. An allopathic or osteopathic physician, currently licensed in Arizona by the Arizona Medical Board or the Arizona Board of Osteopathic Examiners who has successfully completed a residency program in anesthesiology approved by the American Council on Graduate, Medical Education (ACGME) or the American Osteopathic Association (AOA) or who is certified by either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology and is credentialed with anesthesia privileges through an Arizona licensed medical facility, or
- A Certified Registered Nurse Anesthetist (CRNA) licensed in Arizona who provides services under the Nurse Practice Act.

R4-11-1303. Oral Conscious Sedation

- A. Before <u>inducing administering</u> oral <u>conscious</u> sedation on an <u>outpatient basis</u> in a <u>dental office</u> or <u>dental clinic</u>, a dentist shall possess a Section 1303 permit issued by the Board, <u>unless the dentist qualifies for a permit under subsection</u> (E). A <u>The</u> dentist may renew a Section 1303 permit every <u>three five</u> years by complying with <u>R4-11-1306</u> <u>R4-11-1307</u>.
 - 1. A dentist Section 1301 permit holder or Section 1302 permit holder who possesses a Section 1301 or Section 1302 permit may also induce administer oral conscious sedation without obtaining a Section 1303 permit.
 - 2. The administration of an anti-anxiety a single drug is not combination inhalation and enteral conscious sedation for minimal sedation does not require a Section 1303 permit if:
 - a. Only one dose of one anti-anxiety drug is administered; The administered dose is within the Food and Drug Administration's (FDA) maximum recommended dose as printed in FDA approved labeling for unmonitored home use;
 - i. Incremental multiple doses of the drug may be administered until the desired effect is reached, but does not exceed the maximum recommended dose; and
 - ii. During minimal sedation, a single supplemental dose may be administered. The supplemental dose may not exceed one-half of the initial dose and the total aggregate dose may not exceed one and one-half times the FDA maximum recommended dose on the date of treatment; and
 - b. The intent of administering the anti-anxiety drug is anxiolysis only; and Nitrous oxide/oxygen may be administered in addition to the oral drug as long as the combination does not exceed minimal sedation.
 - c. The administered dose of anti-anxiety drug is within the current guidelines for anxiolysis dosage on the manufacturer's package insert or other recognized drug reference;
- **B.** To obtain or renew a Section 1303 permit, a dentist shall:
 - 1. Submit a completed application on a form supplied provided by the Board office that, in addition to the requirements of subsections (B)(2) and (B)(3) (3) and R4-11-1306 R4-11-1307, includes:
 - a. General information about the applicant such as:
 - i. Name:
 - ii. Home and office addresses and telephone numbers;
 - iii. Limitations of practice;
 - iv. Hospital affiliations;
 - v. Denial, curtailment, revocation, or suspension of hospital privileges;
 - vi. Denial of membership in, denial of renewal of membership in, or disciplinary action by a dental organization; and
 - vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body; and
 - b. The dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules;
 - 2. On forms provided by the Board, provide a dated and signed affidavit attesting that a facility any dental office or dental clinic where the dentist will administer oral conscious sedation:
 - a. Contains the following properly operating equipment and supplies during the provision of sedation:
 - i. Emergency drugs;
 - ii. Cardiac defibrillator or automated external defibrillator (AED);
 - ii. iii. Positive pressure oxygen and supplemental oxygen;
 - iii.iv.Precordial stethoscope Stethoscope;
 - iv.y. Suction equipment, including tonsillar or pharyngeal and emergency backup medical suction device;
 - v.vi. Pulse oximeter;
 - vi.vii.Blood pressure monitoring device; and
 - vii.viii.Auxiliary lighting; and
 - b. Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents, including at least one staff member who:
 - i. Holds a current certificate in basic cardiopulmonary resuscitation (CPR) Healthcare Provider Level;
 - ii. Is present during the oral conscious sedation procedure; and
 - iii. After the procedure, monitors the patient until discharge;

- 3. Hold a valid license to practice dentistry in this state;
- 4. Maintain a current permit to prescribe and administer controlled substances in this state issued by the United States Drug Enforcement Administration;
- 5. Provide confirmation of completing coursework within the two years prior to submitting the permit application from the American Heart Association or the American Red Cross in basic cardiopulmonary resuscitation (CPR) in one or more of the following:
 - a. Cardiopulmonary resuscitation (CPR) Healthcare Provider Level from the American Heart Association, American Red Cross, or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association or American Red Cross;
 - b. Pediatric advanced life support (PALS) in a practice treating pediatric patients; or
 - c. A recognized continuing education course in advanced airway management.; and
- 6.C. Meet Initial applicants shall meet one or both of the following:
 - a.1. Complete a Board-approved Board-recognized post-doctoral residency program that includes documented training in oral eonscious sedation within the last three years before submitting the permit application; or
 - 2. An applicant who completed a Board recognized post-doctoral residency program that includes documented training in oral sedation more than three years before submitting the permit application shall provide the following documentation:
 - a. On a form provided by the Board, a written affidavit affirming that the applicant has administered oral sedation to a minimum of 25 patients within the year or 75 patients within the last five years before submitting the permit application;
 - b. A copy of the oral sedation permit in effect in another state or certification of military training in oral sedation from the applicant's commanding officer; and
 - c. On a form provided by the Board, a written affidavit affirming the completion of 30 hours of continuing education taken within the last five years as outlined in R4-11-1306(C)(1)(a) through (f); or
 - b.3. Participate Proof of participation in 30 clock hours of Board-approved Board-recognized undergraduate, graduate, or post-graduate education in oral eonscious sedation within the five three years before submitting the permit application, that include includes:
 - i.a. Training in basic oral eonscious sedation,
 - ii. Administration or observation of the oral conscious sedation of at least five patients,
 - iii.b.Pharmacology,
 - iv.c. Physical evaluation,
 - v.d. Management of medical emergencies,
 - vi.e. The importance of and techniques for maintaining proper documentation, and
 - vii.f.Monitoring and the use of monitoring equipment.
- C.D. After submitting the application and written evidence of compliance with requirements in subsection (B) and, if applicable, subsection (C) to the Board, the dentist applicant shall schedule an onsite evaluation by the Board. After a dentist the applicant completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a Section 1303 permit to the applicant.
 - 1. The onsite evaluation team shall consist of:
 - <u>a.</u> For initial applications, two dentists who are Board members, or Board designees.
 - b. For renewal applications, one dentist who is a Board member, or Board designee.
 - 2. The onsite evaluation team shall look for evaluate the following:
 - a. The availability of equipment and personnel as specified in subsection (B)(2);
 - b. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving, administering, dispensing, and destroying of controlled substances; and Successful responses by the applicant to oral examination questions from the evaluation team about patient management, medical emergencies, and emergency medications;
 - c. Proper recordkeeping as specified in subsection (D) by reviewing the forms that document the anesthesia record documentation of controlled substances, that includes a perpetual inventory log showing the receipt, administration, dispensing, and destruction of controlled substances;
 - d. Proper recordkeeping as specified in subsection (E) by reviewing the forms that document the oral sedation record; and
 - e. For renewal applicants, records supporting continued competency as specified in R4-11-1306.
 - 2.3. The evaluation of a subsequent facility in which oral conscious sedation is administered by a dentist who possesses a Section 1303 permit may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a) team shall recommend one of the following:
 - a. Pass. Successful completion of the onsite evaluation;
 - b. Conditional approval for failing to have appropriate equipment, proper documentation of controlled substance, or proper recordkeeping. The applicant must submit proof of correcting the deficiencies before permit will be

- issued;
- c. Category 1 Evaluation Failure. The applicant must review the appropriate subject matter and schedule a subsequent evaluation by two Board Members or Board designees not less than 30 days from the failed evaluation. An example is failure to recognize and manage one emergency. or
- d. Category 2 Evaluation Failure. The applicant must complete Board approved continuing education in subject matter within the scope of the onsite evaluation as identified by the evaluators and schedule a subsequent evaluation by two Board Members or Board designees not less than 60 days from the failed evaluation. An example is failure to recognize and manage more than one emergency.
- 4. The onsite evaluation of an additional dental office or dental clinic in which oral sedation is administered by a Section 1303 permit holder may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (D)(2)(a).
- 5. A Section 1303 mobile permit may be issued if the Section 1303 permit holder travels to dental offices or dental clinics to provide oral sedation. The applicant must submit a completed affidavit verifying:
 - a. That the equipment and supplies for the provision of oral sedation as required in R4-11-1303(B)(2)(a) either travel with the Section 1303 permit holder or are in place and in appropriate condition at the dental office or dental clinic where oral sedation is provided, and
 - b. Compliance with R4-11-1303(B)(2)(b).
- **D.E.** A dentist Section 1303 permit holder who induces oral conscious sedation shall keep an anesthesia oral sedation record for each oral conscious sedation procedure that:
 - 1. Includes the following entries:
 - a. Pre-operative, <u>intra-operative</u>, <u>and</u> post-operative, and intra operative pulse oximeter oxygen saturation and pulse rate readings documentation;
 - b. Pre-operative and post-respiratory rate;
 - e.b. Pre-operative and post-operative blood pressure;
 - d.c. Documented reasons for not taking vital signs if a patient's behavior or emotional state prevents monitoring personnel from taking vital signs;
 - e.d. List of all medications given, including dosage and time intervals;
 - f.e. Patient's weight;
 - g.f. Consent form;
 - h.g. Special notes, such as, nothing by mouth or last intake of food or water; and
 - i:h. Time of discharge and status, including name of escort; and
 - 2. May include the following entries:
 - a. Pre-operative and post-operative electrocardiograph report; and
 - b. Intra-operative blood pressures.
- E. To continue inducing oral conscious sedation after May 1, 2004, a dentist licensed in this state who has been inducing oral conscious sedation for at least three years before May 1, 2003 may obtain a Section 1303 permit without meeting the educational requirements of subsection (B)(6) by:
 - 1. Applying for a Section 1303 permit on or before May 1, 2004;
 - 2. Complying with subsections (B)(1) through (B)(5); and
 - 3. Providing the Board with the following:
 - a. Documentation of 12 oral conscious sedation cases per year for the previous three years;
 - b. Documentation of 12 continuing education hours in oral conscious sedation in the previous three years; and
 - e. Records from the last 10 consecutive oral conscious sedation cases with an affidavit attesting that the records are the licensee's last 10 consecutive cases.
- <u>F.</u> The Section 1303 permit holder shall utilize supplemental oxygen for all patients receiving oral sedation for the duration of the procedure.
- <u>G.</u> The Section 1303 permit holder shall ensure the continuous supervision of the patient from the administration of oral sedation until oxygenation, ventilation and circulation are stable and the patient is appropriately responsive for discharge from the dental office or dental clinic.
- **H.** A Section 1303 permit holder may employ a healthcare professional to provide anesthesia services if all of the following conditions are met:
 - 1. The healthcare professional is an allopathic or osteopathic physician currently licensed in Arizona by the Arizona Medical Board or the Arizona Board of Osteopathic Examiners who has successfully completed a residency program in anesthesiology approved by the American Council on Graduate, Medical Education (ACGME) or the American Osteopathic Association (AOA) or who is certified by either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology and is credentialed with anesthesia privileges through an Arizona licensed medical facility or a certified registered nurse anesthestist (CRNA) licensed in Arizona who provides services under the Nurse Practice Act;
 - 2. The Section 1303 permit holder shall provide all dental treatment and ensure that the physician anesthesiologist or

- CRNA remains on the dental office or dental clinic premises until any patient receiving anesthesia or sedation services is discharged;
- 3. The Section 1303 permit holder has completed coursework within the two years prior to submitting the permit application in one or more of the following:
 - a. ACLS from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - b. PALS in a practice treating pediatric patients;
 - c. A recognized continuing education course in advanced airway management;
- 4. The Section 1303 Permit Holder ensures that:
 - a. The dental office or clinic contains the equipment and supplies listed in R4-11-1304(B)(2)(a) during the provision of anesthesia or sedation by the physician anesthesiologist or CRNA;
 - b. The anesthesia or sedation record contains all the entries listed in R4-11-1304(D);
 - c. For intravenous access, the physician anesthesiologist or CRNA uses a new infusion set, including a new infusion line and new bag of fluid for each patient; and
 - d. The patient is continuously supervised from the administration of anesthesia or sedation until the termination of the anesthesia or sedation procedure and oxygenation, ventilation and circulation are stable. The Section 1303 permit holder shall not commence with a subsequent procedure or treatment until the patient is in monitored recovery or meets the guidelines for discharge.

R4-11-1304. Reports of Adverse Occurrences Permit to Employ or Work with a Physician Anesthesiologist or Certified Registered Nurse Anesthetist (CRNA)

If a death, or incident causing a patient temporary or permanent physical or mental injury or requiring medical intervention, occurs in an outpatient facility as a direct result of the administration of general anesthesia, semi-conscious sedation, conscious sedation, or oral conscious sedation, the permit holder and the treating dentist involved shall submit a complete report of the incident to the Board within 10 days after the occurrence.

- A. This Section does not apply to a Section 1301 permit holder or a Section 1302 permit holder practicing under the provisions of R4-11-1302(I) or a Section 1303 permit holder practicing under the provisions of R4-11-1303(H). A dentist may utilize a physician anesthesiologist or certified registered nurse anesthesist (CRNA) for anesthesia or sedation services while the dentist provides treatment in the dentist's office or dental clinic after obtaining a Section 1304 permit issued by the Board.
 - 1. The physician anesthesiologist shall be an allopathic or osteopathic physician, currently licensed in Arizona by the Arizona Medical Board or the Arizona Board of Osteopathic Examiners who has successfully completed a residency program in anesthesiology approved by the American Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or who is certified by either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology and is credentialed with anesthesia privileges through an Arizona licensed medical facility.
 - 2. The CRNA shall be licensed in Arizona under the Nurse Practice Act.
 - 3. The dentist permit holder shall provide all dental treatment and ensure that the physician anesthesiologist or CRNA remains on the dental office or dental clinic premises until any patient receiving anesthesia or sedation services is discharged.
 - 4. A dentist may renew a Section 1304 permit every five years by complying with R4-11-1307.
- **B.** To obtain or renew a Section 1304 permit, a dentist shall:
 - 1. Submit a completed application on a form provided by the Board office that, in addition to the requirements of subsections (B)(2) and (3) and R4-11-1307 includes:
 - <u>a.</u> General information about the applicant such as:
 - i. Name;
 - ii. Home and office addresses and telephone numbers;
 - iii. Limitations of practice;
 - iv. Hospital affiliations;
 - v. Denial, curtailment, revocation, or suspension of hospital privileges;
 - vi. Denial of membership in, denial of renewal of membership in, or disciplinary action by a dental organization; and
 - vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body; and
 - b. The dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules;
 - 2. On forms provided by the Board, provide a dated and signed affidavit attesting that any dental office or dental clinic where the dentist provides treatment during administration of general anesthesia or sedation by a physician anesthesiologist or CRNA:

- a. Contains the following properly operating equipment and supplies during the provision of general anesthesia and sedation:
 - i. Emergency drugs;
 - ii. Electrocardiograph monitor;
 - iii. Pulse oximeter;
 - iv. Cardiac defibrillator or automated external defibrillator (AED);
 - v. Positive pressure oxygen and supplemental continuous flow oxygen:
 - vi. Suction equipment, including endotrachael, tonsillar or pharyngeal and emergency backup medical suction device;
 - vii. Larvngoscope, multiple blades, backup batteries and backup bulbs:
 - viii. Endotracheal tubes and appropriate connectors;
 - ix. Magill forceps;
 - x. Oropharyngeal and nasopharyngeal airways:
 - xi. Auxillary lighting;
 - xii. Stethoscope; and
 - xiii. Blood pressure monitoring device; and
- b. Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents. All personnel involved in administering and monitoring general anesthesia or sedation shall hold a current course completion confirmation in cardiopulmonary resuscitation (CPR) Healthcare Provider level;
- 3. Hold a valid license to practice dentistry in this state; and
- 4. Provide confirmation of completing coursework within the last two years prior to submitting the permit application in one or more of the following:
 - a. Advanced cardiac life support (ACLS) from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - b. Pediatric advanced life support (PALS) in a practice treating pediatric patients; or
 - c. A recognized continuing education course in advanced airway management.
- C. After submitting the application and written evidence of compliance with requirements in subsection (B) to the Board, the applicant shall schedule an onsite evaluation by the Board. After the applicant completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the applicant a Section 1304 permit.
 - 1. The onsite evaluation team shall consist of one dentist who is a Board member, or Board designee.
 - 2. The onsite team shall evaluate the following:
 - a. The availability of equipment and personnel as specified in subsection (B)(2);
 - b. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receipt, administration, dispensing, and destruction of controlled substances; and
 - c. Proper recordkeeping as specified in subsection (E) by reviewing previous anesthesia or sedation records.
 - 3. The evaluation team shall recommend one of the following:
 - a. Pass. Successful completion of the onsite evaluation; or
 - <u>Conditional approval for failing to have appropriate equipment, proper documentation of controlled substances, or proper recordkeeping.</u> The applicant must submit proof of correcting the deficiencies before a permit is issued.
 - 4. The evaluation of an additional dental office or dental clinic in which a Section 1304 permit holder provides treatment during the administration general anesthesia or sedation by a physician anesthesiologist or CRNA may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (B)(2).
- **D.** A Section 1304 permit holder shall keep an anesthesia or sedation record for each general anesthesia and sedation procedure that includes the following entries:
 - 1. Pre-operative and post-operative electrocardiograph documentation;
 - 2. <u>Pre-operative</u>, intra-operative, and post-operative, pulse oximeter documentation;
 - 3. Pre-operative, intra-operative, and post-operative blood pressure and vital sign documentation; and
 - 4. A list of all medications given, with dosage and time intervals and route and site of administration;
 - 5. Type of catheter or portal with gauge;
 - 6. Indicate nothing by mouth or time of last intake of food or water;
 - 7. Consent form; and
 - 8. Time of discharge and status, including name of escort.
- E. For intravenous access, a Section 1304 permit holder shall ensure that the physician anesthesiologist or CRNA uses a new infusion set, including a new infusion line and new bag of fluid for each patient.
- F. A Section 1304 permit holder shall ensure that the physician anesthesiologist or CRNA utilizes supplemental continuous flow oxygen for all patients receiving general anesthesia or sedation for the duration of the procedure.
- G. The Section 1304 permit holder shall continuously supervise the patient from the administration of anesthesia or sedation until termination of the anesthesia or sedation procedure and oxygenation, ventilation and circulation are stable. The Sec-

tion 1304 permit holder shall not commence with a subsequent procedure or treatment until the patient is in monitored recovery or meets the guidelines for discharge.

R4-11-1305. Education Reports of Adverse Occurrences

- A. To obtain a Section 1301 permit by satisfying the education requirement of R4-11-1301(B)(6), a dentist shall successfully complete an advanced graduate or post-graduate education program in pain control.
 - 1. The program shall include instruction in the following subject areas:
 - a. Anatomy and physiology of the human body and its response to the various pharmacologic agents used in pain control:
 - b. Physiological and psychological risks for the use of various modalities of pain control;
 - e. Psychological and physiological need for various forms of pain control and the potential response to pain control procedures;
 - d. Techniques of local anesthesia, sedation, and general anesthesia, and psychological management and behavior modification, as they relate to pain control in dentistry; and
 - e. Handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.
 - 2. The program shall consist of didactic and clinical training. The didactic component of the program shall:
 - a. Be the same for all dentists, whether general practitioners or specialists; and
 - b. Include each subject area listed in subsection (A)(1).
 - 3. The program shall provide at least one calendar year of training as prescribed in R4-11-1301 (B)(6)(a).
- B. To maintain a Section 1301 or 1302 permit under R4-11-1301 or R4-11-1302, a dentist shall:
 - 1. Participate in 12 clock hours of continuing education every three years in one or more of the following areas:
 - a. General anesthesia:
 - b. Conscious sedation:
 - e. Physical evaluation;
 - d. Medical emergencies;
 - e. Monitoring and use of monitoring equipment; or
 - f. Pharmacology of drugs and non-drug substances used in general anesthesia or conscious sedation; and
 - 2. Hold a current certificate from the American Heart Association or American Red Cross in advanced cardiac life support (ACLS).
- C. To maintain a Section 1303 permit issued under R4 11 1303, a dentist shall:
 - 1. Participate in six clock hours of continuing education every three years in one or more of the following areas:
 - a. Oral conscious sedation,
 - b. Physical evaluation,
 - e. Medical emergencies,
 - d. Monitoring and use of monitoring equipment, or
 - e. Pharmacology of oral conscious sedation drugs and non-drug substances, and
 - 2. Hold a current certificate in basic cardiopulmonary resuscitation (CPR).

If a death, or incident requiring emergency medical response, occurs in a dental office or dental clinic during the administration of or recovery from general anesthesia, deep sedation, moderate sedation, or minimal sedation, the permit holder and the treating dentist involved shall submit a complete report of the incident to the Board within 10 days after the occurrence.

R4-11-1306. Renewal of Permit Education; Continued Competency

- A. To renew obtain a Section 1301, 1302, or 1303 permit by satisfying the education requirement of R4-11-1301(B)(6), a dentist shall; successfully complete an advanced graduate or post-graduate education program in pain control.
 - 1. Provide written documentation of compliance with the applicable continuing education requirements in R4-11-1305; The program shall include instruction in the following subject areas:
 - a. Anatomy and physiology of the human body and its response to the various pharmacologic agents used in pain control;
 - b. Physiological and psychological risks for the use of various modalities of pain control;
 - c. Psychological and physiological need for various forms of pain control and the potential response to pain control procedures;
 - d. Techniques of local anesthesia, sedation, and general anesthesia, and psychological management and behavior modification, as they relate to pain control in dentistry; and
 - e. <u>Handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.</u>
 - 2. Before December 31 of the year the permit expires, submit a completed application on a form supplied by the Board office as described in R4-11-1301, R4-11-1302, or R4-11-1303; and The program shall consist of didactic and clinical training. The didactic component of the program shall:

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- a. Be the same for all dentists, whether general practitioners or specialists; and
- b. Include each subject area listed in subsection (A)(1).
- 3. Not less than 90 days before the expiration of a dentist's current permit, arrange for a new onsite evaluation as described in R4-11-1301, R4-11-1302, or R4-11-1303. The program shall provide at least one calendar year of training as prescribed in R4-11-1301(B)(6)(a).
- **B.** After a dentist successfully completes the evaluation and submits the required affidavits, the Board shall issue a renewal To maintain a Section 1301, or 1302, or 1303 permit- under R4-11-1301 or R4-11-1302 a permit holder shall:
 - 1. Participate in 30 clock hours of continuing education every five years in one or more of the following areas:
 - a. General anesthesia,
 - b. Parenteral sedation,
 - c. Physical evaluation,
 - d. Medical emergencies,
 - e. Monitoring and use of monitoring equipment, or
 - f. Pharmacology of drugs and non-drug substances used in general anesthesia or parenteral sedation; and
 - 2. Provide confirmation of completing coursework within the two years prior to submitting the renewal application from one or more of the following:
 - a. Advanced cardiac life support (ACLS) from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - b. Pediatric advanced life support (PALS) in a practice treating pediatric patients; or
 - c. A recognized continuing education course in advanced airway management;
 - 3. Complete at least 10 general anesthesia, deep sedation or parenteral sedation cases a calendar year; and
 - 4. Apply a maximum of six hours from subsection (B)(2) toward the continuing education requirements for subsection (B)(1).
- C. The Board may stagger due dates for renewal applications. To maintain a Section 1303 permit issued under R4-11-1303, a permit holder shall:
 - 1. Participate in 30 clock hours of continuing education every five years in one or more of the following areas:
 - a. Oral sedation,
 - b. Physical evaluation,
 - c. Medical emergencies,
 - d. Monitoring and use of monitoring equipment, or
 - e. Pharmacology of oral sedation drugs and non-drug substances; and
 - 2. Provide confirmation of completing coursework within the two years prior to submitting the renewal application from one or more of the following:
 - a. Cardiopulmonary resuscitation (CPR) Healthcare Provider level from the American Heart Association, American Red Cross or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association or American Red Cross;
 - b. Advanced cardiac life support (ACLS) from the American Heart Association or another agency that follows the same procedures, standards, and techniques for training as the American Heart Association;
 - c. Pediatric advanced life support (PALS);
 - d. A recognized continuing education course in advanced airway management; and
 - 3. Complete at least 10 oral sedation cases a calendar year.

R4-11-1307. Renewal of Permit

- A. To renew a Section 1301, 1302, or 1303 permit, the permit holder shall:
 - 1. Provide written documentation of compliance with the applicable continuing education requirements in R4-11-1306;
 - 2. Provide written documentation of compliance with the continued competency requirements in R4-11-1306;
 - 3. Before December 31 of the year the permit expires, submit a completed application on a form provided by the Board office as described in R4-11-1301, R4-11-1302, or R4-11-1303; and
 - 4. Not less than 90 days before the expiration of a permit holder's current permit, arrange for an onsite evaluation as described in R4-11-1301, R4-11-1302, or R4-11-1303.
- **B.** To renew a Section 1304 permit, the permit holder shall:
 - 1. Before December 31 of the year the permit expires, submit a completed application on a form provided by the Board office as described in R4-11-1304; and
 - 2. Not less than 90 days before the expiration of a permit holder's current permit, arrange for an onsite evaluation as described in R4-11-1304.
- C. After the permit holder successfully completes the evaluation and submits the required affidavits, the Board shall issue a renewal Section 1301, 1302, 1303, 1304 permit.
- **<u>D.</u>** The Board may stagger due dates for renewal applications.