





Challenges in Starting a New Mobile Anesthesia Practice for Dental Offices

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Dental Ambulatory Anesthesia
Saturday 5/20/2023

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Nothing to disclose

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Introduction

- Assistant Professor of Anesthesiology at Tufts University School of Medicine
- Fellowship in Pain Medicine – Harvard University/Beth Israel Deaconess Medical Center
- Residency - Boston University/Boston Medical Center (PGY III OMFS resident → Anesthesiology resident)
- MD-University of Athens, Greece
- DMD-University of Athens, Greece

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Categories of Challenges

- **Regulatory:**
Lack of regulatory framework
- **Equipment:**
Different type than the OR
- **Medications:**
 - a. Different concentrations and availability
 - b. Controlled substances electronic order process

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Challenge #1: Regulatory framework

Google: “dental anesthesia permit Massachusetts” →


- “Apply for an individual dentist’s anesthesia & sedation permit”
- “Apply for an anesthesia & sedation facility permit” →

234 CMR 6.00: **Administration of Anesthesia and Sedation** (22 pages document)

❖ CMR: The Code of Massachusetts Regulations (CMR) is the complete set of Administrative Law (regulations) promulgated by state agencies pursuant to the Administrative Procedures Act.

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6.01 Scope

In order to ensure the protection and safety of patients, every dental facility must be properly equipped, supplied and permitted for the administration of specific types of anesthesia and levels of sedation, and every dentist and/or dental hygienist must be properly educated, trained, and permitted for the specific type of anesthesia or sedation being administered. To guarantee a wide margin of safety for the patient, the qualifications and requirements for permits for anesthesia administration shall be based on a continuum of types of procedures, equipment, drugs, qualifications and training of personnel necessary and appropriate for each type of anesthesia or sedation to be administered at the site.

The following standards are based on the *ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists* 2007 and the *Guidelines for Office Anesthesia (OAS) Evaluation of the Massachusetts Society of Oral and Maxillofacial Surgeons*, 2006, and shall be applied in determining the adequacy of the facility and competence of the personnel administering anesthesia and/or sedation.

(1) A dentist licensed to practice dentistry in the Commonwealth pursuant to M.G.L. c. 112, § 45 and 45A, may administer local anesthesia in a facility that complies with the requirements of 234 CMR 6.15.

(2) **Facility Permits.** A dental facility where general anesthesia or deep sedation, moderate sedation, minimal sedation and/or nitrous oxide-oxygen are administered shall have a Facility Permit D issued by the Board for the type of anesthesia to be administered, unless the facility is exempt from permitting requirements pursuant to 234 CMR 6.03(1)(c).

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234 CMR 6.00 ADMINISTRATION OF ANESTHESIA AND SEDATION

Section

- 6.01: Scope
- 6.02: Definitions
- 6.03: Facility Permit: Anesthesia Permits Required for Facilities
- 6.04: Facility Permit: D-A: Facility Requirements for Administration of Moderate Sedation and Deep Sedation
- 6.05: Facility Permit D-B1: Facility Requirements for Administration of Moderate Sedation including Nitrous Oxide-oxygen in Conjunction with any Anesthetic or Enteral Sedative Agents Dispensed or Administered in the Dental Facility
- 6.06: Facility Permit D-B2: Facility Requirements for Administration of Minimal Sedation and/or Nitrous Oxide-oxygen in Conjunction with an Enteral Agent Dispensed or Administered in a Dental Facility
- 6.07: Facility Permit D-C: Administration of Nitrous Oxide-oxygen Sedation Only
- 6.08: Mobile Facility Permit D-H: Facility Requirements for Dental Offices Using Mobile and/or Portable Anesthesia Services
- 6.09: Facility Permit D-P: Requirements for the Use and Provision of Portable and/or Mobile Anesthesia Services
- 6.10: Requirements for Individual Anesthesia Permits for the Administration of General Anesthesia, Deep Sedation, Moderate Sedation, Minimal Sedation, Nitrous Oxide-oxygen, and Local Anesthesia
- 6.11: Individual Permit A: Administration of General Anesthesia and/or Deep Sedation
- 6.12: Individual Permit B-1: Administration of Moderate Sedation and Nitrous Oxide-oxygen in Conjunction with any Other Anesthetic or Enteral Sedative Agents Dispensed or Administered in a Dental Facility
- 6.13: Individual Permit B-2: Facility Requirements for Administration of Minimal Sedation and/or Nitrous Oxide-oxygen in Conjunction with an Enteral Agent Dispensed or Administered in a Dental Facility
- 6.14: Individual Permit C: Administration of Nitrous Oxide-oxygen Only or in Conjunction with Local Anesthesia
- 6.15: Administration of Local Anesthesia Only
- 6.16: Permit L: Administration of Local Anesthesia by a Dental Hygienist
- 6.17: Reporting of Adverse Occurrences
- 6.18: Penalty for Non-compliance

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6.08: Facility Permit D-H: Facility Requirements for Dental Offices Using Mobile and/or Portable Anesthesia Services

(2) Equipment and Drugs Required for Facility Permit D-H: Equipment and Drugs Required for Facility Permit D-H: A facility that hosts a mobile or portable dental anesthesia service will be required, at a minimum, to have the following equipment supplies and drugs:

(a) Equipment and Supplies

1. Alternative light source for use during power failure;
2. Automated or manual external defibrillator, except that the manual defibrillator shall only be operated by an individual certified in ACLS or PALS;
3. Disposable CPR masks (pediatric and adult);
4. Disposable syringes, assorted sizes;
5. Latex-free tourniquet;
6. Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation (including bag-valve-mask system);
7. Sphygmomanometer and sphygmocuff (pediatric and adult);
8. Suction; and
9. Any other equipment as may be required by the Board.

(b) Drugs: The following drugs and/or categories of drugs shall be provided and maintained in accordance with the ADA/ACCS Guidelines (234 CMR 6.00) or as determined by the Board for emergency use. All drugs shall be current and not expired

1. Acetylsalicylic acid (readily absorbable form);
2. Ammonia inhalants;
3. Amphetamine;
4. Antihypertensive agent;
5. Benzocaine;
6. Epinephrine preloaded syringes (pediatric and adult);
7. Two epinephrine ampules;
8. Oxygen;
9. Vasodilator; and
10. Any other drugs or categories of drugs as may be required by the Board.

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6.09: Facility Permit D-P: Requirements for the Use and Provision of Portable and/or Mobile Anesthesia Services

(1) Copies of the following:

1. Proof of current ACLS (BLS for auxiliaries) certification for the applicant and other dental professionals, as applicable for the type of anesthesia or sedation to be administered by the applicant;
2. Medical history form to be utilized by the applicant;
3. Anesthesia chart;
4. Schedule of drug and equipment checks;
5. Written protocol for management of emergencies;
6. Schedule of emergency drills; and
7. List of drugs and equipment that the applicant will provide at each site.

(2) Other information as may be requested by the Board.

(3) The holder of a Facility Permit D-P shall comply with requirements of 234 CMR 6.00 pertaining to the category of anesthesia/sedation to be administered including:

- (a) Equipment and drugs;
- (b) Auxiliary personnel;
- (c) Patient evaluation;
- (d) Pre-operative preparation;
- (e) Patient monitoring and documentation;
- (f) Management of recovery and discharge of patients;
- (g) Management of pediatric and special needs patients; and
- (h) Emergency management.

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D-A Facility Permit Equipment

(2) Equipment Required for Facility Permit D-A: The following equipment shall be required to be provided and maintained on-site:

- (a) Alternative light source for use during power failure;
- (b) Ambus-bag or portable bag-mask ventilator;
- (c) Automated or manual external defibrillator;
- (d) Current certifications in Advanced Cardiac Life Support (ACLS);
- (e) Disposable CPR masks, pediatric and adult;
- (f) Disposable syringes (assorted sizes);
- (g) Endotracheal tubes with inflatable cuffs and other equipment designed to maintain patient airway including:
 1. Pediatric endotracheal tubes, assorted sizes;
 2. Adult endotracheal tubes, assorted sizes;
 3. Connectors from tubes to gas delivery machines;
 4. Syringe for cuff inflation; and
 5. Stylet.
- (h) Endotracheal tube forceps;
- (i) Equipment for emergency cricothyrotomy and/or tracheostomy with appropriate connectors to deliver 100% oxygen and establish an emergency airway;
- (j) Equipment for the insertion and maintenance of an intravenous infusion
- (k) Equipment suitable for proper positioning of the patient for administration of cardio-pulmonary resuscitation, including a back board;

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D-A Facility Permit Equipment (cont'd)

- (l) Equipment for continuous monitoring during anesthesia;
- (m) Gas delivery system capable of positive pressure ventilation, which must include:
 1. Oxygen;
 2. Safety-keyed hose attachments;
 3. Capability to administer 100% oxygen in all rooms (operatory, recovery, examination, and reception);
 4. Gas storage in compliance with safety codes;
 5. Adequate waste gas scavenging system; and
 6. Nasal hood or cannula.
- (n) Laryngoscope (straight and/or curved blades, assorted sizes; extra batteries and bulbs);
- (o) Latex free tourniquet;
- (p) List of emergency telephone numbers clearly visible;
- (q) Magill forceps or other suitable instruments;
- (r) Means of monitoring blood pressure (pediatric and adult);

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D-A Facility Permit Equipment (cont'd)




(s) Means of monitoring heart rate and rhythm, with battery pack back-up;
 (t) Means of monitoring respirations;
 (u) Means of monitoring temperature;
 (v) Means of transporting patients;
 (w) Method to accurately record elapsed time;
 (x) Nasopharyngeal airways (pediatric and adult);
 (y) Oropharyngeal airways (pediatric and adult);
 (z) Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation including bag-valve-mask system;
 (aa) Scavenger system, if inhalation agents are used;
 (bb) Sphygmomanometer and stethoscope (pediatric and adult);
 (cc) Suction:
 1. Suction catheter for endotracheal tube;
 2. Tonsillar suction tip;
 3. Suction equipment for use during power failure; and
 4. Capability of suction in all operating and recovery rooms.
 (dd) Schedule and log for checking and recording dates when anesthesia accessories and supply of emergency drugs have been checked;
 (ee) If nitrous oxide and oxygen delivery equipment capable of delivering less than 25% oxygen is used, an inline oxygen analyzer must be used; and
 (ff) Any other equipment as may be required by the Board.

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D-A Facility Permit Drugs




(3) **Drugs Required for Facility Permit D-A.** The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired.

- (a) Acetylsalicylic acid (rapidly absorbable form);
- (b) Ammonia inhalants;
- (c) Anticonvulsant;
- (d) Antihistamine;
- (e) Antihypoglycemic agent;
- (f) Antihypertensive medications;
- (g) Antiemetic;
- (h) Atropine;
- (i) Bronchodilator;
- (j) Corticosteroid;
- (k) Dantrolene Sodium (required if a halogenated anesthesia agent e.g. halothane, enflurane, isoflurane is used or depolarizing skeletal muscle relaxants e.g. succinylcholine are administered);

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D-A Facility Permit Drugs (cont'd)




- (l) Epinephrine pre-loaded syringes and ampules (pediatric and adult);
- (m) Lidocaine;
- (n) Intravenous antihypoglycemic agent (dextrose 50% or glucagon);
- (o) Medication to treat supraventricular tachycardia (e.g. adenosine, verapamil, etc.);
- (p) Muscle relaxants;
- (q) Narcotic antagonist and reversing agents;
- (r) Oxygen;
- (s) Sodium bicarbonate;
- (t) Succinylcholine;
- (u) Vasodilator;
- (v) Vasopressor; and
- (w) And any other drugs or categories of drugs as may be required by the Board.

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6.09: Facility Permit D-P: Requirements for the Use and Provision of Portable and/or Mobile Anesthesia Services




6.09 (1) A qualified dentist anesthesiologist who travels to dental facilities or practice sites for the purpose of delivering anesthesia services or sedation services at the site must hold a Mobile Facility D-P Permit for the use of portable and/or mobile anesthesia equipment, supplies and personnel.

What about a physician anesthesiologist?

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Board of Registration in Dentistry



- The Board of Registration in Dentistry has no jurisdiction on physicians.
- There is a lack of regulatory framework for portable anesthesia services to dental offices by physician anesthesiologists.
- There is no "Medical General Anesthesia License" provided by the Dental Board (as in CA).

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Medical Societies?





MASSACHUSETTS
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Every physician matters. Every patient counts.



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Anesthesiologists

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Massachusetts Medical Society

Office-Based Surgery Guidelines

CHAPTER I: STATEMENT OF INTENT AND GOALS

"Nothing in these guidelines shall supersede the "Rules and Regulations for the Administration of General Anesthesia, Deep Sedation, Conscious Sedation, and Nitrous Oxide Sedation" of the Board of Dentistry (CMR 234-3.00) for those practitioners and facilities that qualify for regulation by the Board of Dentistry."

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American Society of Anesthesiologists

ASA Quality and Regulatory Affairs

RE: Mobile anesthesia services in Massachusetts

Good morning Dr. Sakellariou,

Thank you for your question and, as you noted, the ASA does not have specific guidance or a checklist for providing mobile anesthesia services. The ASA has several documents related to providing anesthesia in office based and ambulatory settings, as well as some materials related to dental care. Please review the website: <https://www.asahq.org/standards-and-guidelines> and these specific documents:

- Guidelines for Ambulatory Anesthesia and Surgery
- Guidelines for Office-Based Anesthesia
- Statement on Sedation and Anesthesia Administration in Dental Office Based Settings

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Current Solution?

Each dental office working with a physician anesthesiologist obtains a D-A license. A D-H (hosting license) alone would not ensure the availability of the necessary anesthetic and emergency equipment.

The necessary office equipment should be provided by the physician anesthesiologist's portable unit.

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Main issues

The D-A application is lengthier and more complex than the D-H hosting license.

While the D-P application is similar to the D-A, you have to essentially obtain multiple D-A licenses instead of one D-P license.

The dentist can be faced with anesthesia questions that are far beyond their expertise and the anesthesiologist can give only a very limited input.

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Future Options

- Continue current practice


OR

- Create a new Code of Massachusetts regulations that would allow physician anesthesiologists obtain portable anesthesia license similar to the dentist anesthesiologist colleagues.
- Ideally, this would require collaboration from both the Dental and Medical Boards.

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Challenge #2: Equipment



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Comparison

Hospital

- High-speed piston ventilator:
- Very short response time
- Decelerating flow control in cases of increased inspiratory resistance
- Synchronized volume control with adjustable flow trigger that decreases the patient's respiratory work
- Weight: 365 lbs w/o vaporizer and gas cylinders
- Price: \$15,000-\$16,000 (refurbished, no vaporizers)


Office

- No ventilator
- Single vaporizer
- Flowmeters
- Alarm module
- Weight: 26 lbs w/o the vaporizer
- Price: \$11,000-\$12,000 (new, vaporizer included)

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Office Equipment




1. Pipeline inlets (3)
2. Flowmeters
3. Single vaporizer
4. O2 flush valve
5. Common gas outlet
6. Switch
7. Visual indicator for low system pressure

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My anesthesia practice had to change

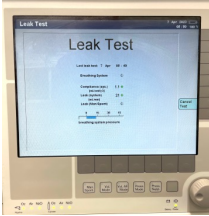


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➤ Manual leak test

Hospital Machine




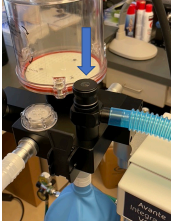
Portable machine



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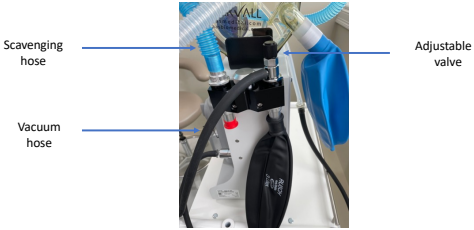
➤ APL valve w/o pressure indication

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➤ Scavenging interface vacuum adjustment



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➤ Lack of a ventilator

- Spontaneous breathing is the ventilation mode of choice.
- Apnea is occasionally unavoidable after induction or when remifentanyl is used.
 - Hand-assisted ventilation is the only option.
 - This can complicate things when the patient is unstable:

➤ I assign this task to one of the dental staff members, always reminding them not to over-deflate the reservoir bag.

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Familiarize yourself with the new equipment


Shadow a colleague.

Confirm appropriate setup with the machine's company biomedical engineer (Facetime, send pictures).

After setting up the machine, test it out before your first patient by hand-ventilating a reservoir bag (test lung) connected to the Y piece.

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Challenge #3a: drug concentrations

- Selecting the drug, dose of administration, procuring the medication and ultimately administering the medication is a multi-step process.
- Medical errors constitute the third leading cause of mortality in the United States (1).
- Medication errors are commonly implicated in adverse medical events (19.4% of all events) (2).
- Reported anesthesia-related medication errors range widely from 0.0075% to 4.17% (3).
- Pediatric dosing calculations can only complicate the medication administration process.


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Hospital medications concentrations

- One common strategy to reduce the incidence of medication errors is the standardization of drug dilutions and prefilled syringes of commonly used medications.
- It's costly.
- Available for OR pharmacies that order in bulk.
- Early expiration date




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Changes in the dental office setting

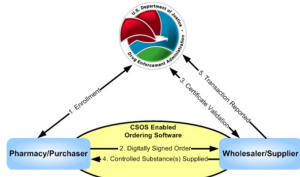


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Challenge #3b: Controlled Substances Ordering System (CSOS)



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CSOS Step 1: Form DEA-251

- DEA-251: Form for DEA registrants requesting a CSOS digital certificate
- Photocopies of:
 - 2 IDs (one government ID)
 - DEA registration certificate

The form has to be notarized and mailed.

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CSOS step 2: Signing certificates

The DEA registrant will receive:

- One **CSOS signing certificate** that can be activated after receiving:
 - an E-mail activation notice which contains a unique **access code**.
 - A postal mail activation notice that contains the **access code password**.

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Postal mail activation notice

IMPORTANT INFORMATION ON ACTIVATING YOUR CSOS CERTIFICATE
Combine this information with the access code you received via E-Mail for this DEA Registration Number. Please retain this document for future management of your certificate.

DEA Division E-Commerce Support
E-Mail: csosupport@DEAecom.gov

Name: JOHN SMITH
E-Mail address: JOHNSMITH@INTERNET.COM
CSOS Account Number: 1234
Certificate Serial Number: N123456789012
CA Thumbprint (SHA-1): F2319064 7132A900 E634BADF 2A8F35A9 5BD383D7

Step 1 - Locate your E-Mail containing this same DEA Registration Number
DEA Registration Number: **XX1234567**

Step 2 - Use this information to log in to the DEA E-Commerce Certificate Retrieval Web page
Web site Address: <Web site Address>
Web site Username: <Web site Username>
Web site Password: <Web site Password> (case sensitive)

Step 3 - Use this Access Code Password, along with the Access Code from your E-Mail to activate your certificate
Access Code Password: <Access Code Password>

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CSOS step 3: digital certificate retrieval

It requires Internet Explorer or Mozilla Firefox.

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4.1.5 Enter a File name and Password.....	36
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CSOS step 3: digital certificate retrieval (cont'd)

It is a multi-step process that includes:

- Installation of 2 certificates (Root CA and SubCA)
- Use of a certificate import wizard
- Security settings change

The certificate installation, will allow you to use the 3rd party service that the supplier uses, verifies your credentials and sends the transaction information to the DEA.

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What if you make an error?

Request new activation codes and passwords, causing a significant delay in the controlled substances ordering process.

What happens with DEA renewal?


Start from the beginning.

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Questions?



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