






TO: The Professional Practice Committee

FROM: Douglas E. Lentivech


SUBJECT: Proposed Amendment to Section 61.10 of the Regulations of the Commissioner of Education Relating to the Dental Anesthesia Certification Requirements for Licensed Dentists

DATE: September 1, 2016


AUTHORIZATION(S):


SUMMARY

Issue for Discussion

Should the Board of Regents amend section 61.10 of the Regulations of the Commissioner of Education relating to the dental anesthesia certification requirements for licensed dentists?

Reason for Consideration

Review of policy.

Proposed Handling

The proposed rule will be presented to the Professional Practice Committee for discussion at the September 2016 meeting of the Board of Regents.

Procedural History

The proposed rule was discussed by the Professional Practice Committee at the February 2016 Regents meeting. A Notice of Proposed Rule Making was published in the State Register on March 9, 2016, for a 45-day public comment period. A copy of the proposed rule is attached.

In response to public comment, as well as to clarify certain requirements and correct certain grammatical and/or typographical errors, substantial revisions have been

made to the proposed rule. Additionally, the effective dates of the various provisions of the proposed rule have been revised to provide the field with more time to comply with them. All of these revisions are further discussed in the Revisions to Proposed Rule section below. It is anticipated that a Notice of Revised Rule Making will be published in the State Register no later than October 5, 2016 for an additional 30-day public comment period.

A copy of the revised proposed rule and an Assessment of Public Comment are attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Chapter 615 of the Laws of 1999 amended section 6605-a of the Education Law to require licensed dentists to obtain a dental anesthesia certificate in order to employ conscious sedation or deep sedation in the course of their professional practices at locations other than general hospitals, such as dental offices, regardless of the route of administration. Prior to Chapter 615 of the Laws of 1999, the law required such certification only when conscious sedation or deep sedation was obtained parenterally (e.g., intravenously), despite the fact that these levels of sedation could be achieved through other routes of administration (e.g., gastrointestinally). Although, at that time, dental anesthesia administered in a dental office was considered to be a safe and cost effective procedure, the intent of Chapter 615 of the Laws of 1999 was to ensure that licensed dentists using conscious or deep sedation, regardless of the delivery route, be fully trained and certified in the use and administration of dental anesthesia in order to enhance the protection of the public. In 2001, the Board of Regents amended section 61.10 of the Regulations of the Commissioner of Education to implement Chapter 615 of the Laws of 1999 by establishing educational and training requirements for licensed dentists to be certified to employ conscious sedation, deep sedation, or general anesthesia in the practice of dentistry at any location other than a general hospital, and to establish practice requirements for the use of conscious sedation, deep sedation, or general anesthesia by such licensed dentists.

Subsequently, there were changes in the practice of dental anesthesia administration. In 2007, the American Dental Association (ADA) revised several dental anesthesia related definitions. One of these revisions was the replacement of the term “conscious sedation” with the term “moderate sedation.”

The proposed amendment to section 61.10 of the Regulations of the Commissioner of Education conforms the regulation to the current practice of dental anesthesia administration and improves the protection of the public. The proposed amendments to this section also update New York’s definitions to reflect those currently used in the profession. It further re-defines the levels of sedation and the routes of administration, as well as defines the terms “continual/continually”, “continuous/continuously”, “patent,” and “time-oriented anesthesia record” and adds the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications.

The proposed amendments to subdivision (a) of section 61.10 of the Regulations of the Commissioner of Education re-define the types of anesthesia used by dentists that are subject to certification.

Proposed amendments to subdivision (b) of section 61.10 of the Regulations of the Commissioner of Education reflect the definitional changes made to certain methods of sedation and add new certifications for administering parenteral conscious (moderate) sedation and for administering enteral conscious (moderate) sedation to pediatric patients aged 12 years old and younger.

The certificates created under this section are: (1) general anesthesia; (2) dental parenteral conscious (moderate) sedation for patients 13 years old and older; (3) dental parenteral conscious (moderate) sedation for patients 12 years old and younger; (4) dental enteral conscious (moderate) sedation for patients 13 years old and older; and (5) dental enteral conscious (moderate) sedation for patients 12 years old and younger.

Additional amendments to subdivision (b) of section of 61.10 delete outdated references to certificates issued prior to January 2001 as being valid until the end of their term and provide a transition pathway for current holders of parenteral conscious sedation certificates and enteral conscious sedation certificates, who wish to continue to provide sedation to pediatric patients, until the end of their certificate term.

The proposed amendments to subdivision (c) of section 61.10 of the Regulations of the Commissioner of Education would eliminate redundant anesthesia certificate descriptions already set forth in subdivision (b) of section 61.10; incorporate the definitional changes set forth in subdivision (a) of section 61.10(a); amend the education requirements to at least 60 hours of coursework provided through didactic instruction and/or an anesthesia rotation for all certificates, with the exception of a general anesthesia certificate; amend the experience requirements for the parenteral conscious (moderate) sedation certificate and the enteral conscious (moderate) sedation certificate to include live clinical experiences with dental patients; include a requirement that post-doctoral education necessary for acquiring a certificate in dental parenteral conscious (moderate) sedation or dental enteral conscious (moderate) sedation be previously approved by the Department; include the requirements required to obtain a certificate to administer general anesthesia or conscious (moderate) sedation through endorsement from another jurisdiction; include the education and training requirements as well as the renewal requirements for the new certificates for parenteral conscious (moderate) sedation pediatric and for enteral conscious (moderate) sedation pediatric; add Advanced Cardiac Life Support (ACLS) to the parenteral and enteral conscious (moderate) sedation certificates for patients ages 13 years and older; add Pediatric Advanced Life Support (PALS) to the parenteral and enteral conscious (moderate) sedation certificates for patients ages 12 years old and younger and for those Oral Surgeons and Dental Anesthesiologists administering general anesthesia to children 12 years old and younger; and delete the provisions for licensed dentists who applied for certificates prior to January 1, 2002.

Additionally, the proposed amendments to subdivision (d) of section 61.10 reflect the definitional changes referenced in section 61.10(a); provide that a licensed dentist can administer conscious (moderate) sedation, deep sedation and general anesthesia

to more than one patient at a time when supervising dental students or residents; provide that licensed dentists administering conscious (moderate) sedation, deep sedation and general anesthesia are responsible for pre-operative preparation for the patient; set forth specific pre-operative requirements for administering deep sedation and general anesthesia and separate pre-operative requirements for administering conscious (moderate) sedation; eliminate the existing requirements for monitoring during the administration of general anesthesia, deep sedation and moderate sedation, and set forth new monitoring requirements for the administration of those types of sedation; delete existing reference to dietary instructions and oral or written instructions since they would now be included in the pre-operative instructions; include an exception for a requirement for the recording of blood pressure records on patients who are being administered conscious (moderate) sedation using an enteral route; include a provision that dentists maintain proof of completing the twelve hours of education in sedation/anesthesia as required for the new provision for renewal of their certificate to administer conscious (moderate) parenteral sedation or deep sedation or general anesthesia; include a provision setting forth the overall responsibility of the dentist administering general anesthesia, deep sedation and conscious (moderate) sedation; and include guidelines for reporting mortality or irreversible morbidity to the Department.

Revisions to Proposed Rule

Since the publication of the Notice of Proposed Rule Making in the State Register on March 9, 2016, the proposed rule was revised in response to public comment and to clarify certain requirements and correct certain grammatical and/or typographical errors, as follows:

- Section 61.10(b)(5) has been revised to remove the following language: “Patient names are not required to be redacted from the copied material. If the licensed dentist decides to redact patient names, no other information should be redacted from the copied material submitted to the department.” This revision is being made because the Department has no need to collect such patient information in order to fulfill its obligations under this regulation.
- Section 61.10(c)(1)(iii)(c) has been revised to require applicants for the certificate in dental parenteral conscious (moderate) sedation for patients 12 years old or younger to complete a clinical experience, acceptable to and previously approved by the Department, demonstrating the successful use of dental parenteral conscious (moderate) sedation by the intravenous route on no fewer than 15 live dental patients who shall be 12 years old or younger and five live dental patients who shall be 13 years old or older in a 1 doctor/student to 1 patient ratio, instead of 20 live dental patients who shall be 12 years old or younger in a 1 doctor/student to 1 patient ratio. This revision is being made because some licensed dentists with this certificate may regularly treat patients who are 13 years old or older, who may typically have some kind of developmental disability, which makes it more appropriate for them to be treated by licensed dentists that specialize in pediatric dentistry. Thus, in order to ensure such patients’ safety, the rule has been revised, based on public comment, to require licensed dentists seeking this particular dental anesthesia certificate, to

have clinical experience in treating, at least, five live dental patients who are 13 years old or older with dental parenteral conscious (moderate) sedation.

- Section 61.10(c)(1)(v)(c) has been revised to require applicants for the certificate in dental enteral conscious (moderate) sedation for patients 12 years old or younger to complete a clinical experience demonstrating the successful use of dental enteral conscious (moderate) sedation on no fewer than 15 live clinical dental patients 12 years old or younger and five live clinical dental patients 13 years old or older in a 2:1 doctor/student to patient ratio, instead of 20 live clinical dental patients 12 years old or younger in a 2:1 doctor/student to patient ratio. This revision is being made because some licensed dentists with this certificate may regularly treat patients who are 13 years old or older, who may typically have some kind of developmental disability, which makes it more appropriate for them to be treated by licensed dentists that specialize in pediatric dentistry. Thus, in order to ensure such patients' safety, the rule has been revised, based on public comment, to require licensed dentists seeking this particular dental anesthesia certificate, to have clinical experience in treating, at least, five live dental patients who are 13 years old or older with dental enteral conscious (moderate) sedation.
- Section 61.10(c)(2)(iii)(c) has been revised to require applicants for certification through endorsement for the certificate in dental parenteral conscious (moderate) sedation for patients 12 years old and younger to provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered parenteral conscious (moderate) sedation (via the intravenous route) in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the Department for review with no patients having had irreversible morbidity or mortality due to the sedation provided by the applicant, instead of 20 anesthesia records of patients 12 years old and younger. This revision is being made because some applicants for certification through endorsement for this certificate may regularly treat patients who are 13 years old and older, who may typically have some kind of developmental disability, which makes it more appropriate for them to be treated by licensed dentists that specialize in pediatric dentistry. Thus, in order to ensure such patients' safety, the rule has been revised, based on public comment, to require applicants for certification through endorsement for this particular dental anesthesia certificate, to have experience in administering dental parenteral conscious (moderate) sedation to, at least, five live dental patients who are 13 years old and older with no such patients having had irreversible morbidity or mortality due to the sedation provided by the applicant.
- Section 61.10(c)(2)(v)(c) has been revised to require applications for certification through endorsement for the certificate in dental enteral conscious (moderate) sedation for patients 12 years old and younger to provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered enteral conscious (moderate) sedation in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the

Department for review. This revision is being made because some applicants for certification through endorsement for this certificate may regularly treat patients who are 13 years old and older, who may typically have some kind of developmental disability, which makes it more appropriate for them to be treated by licensed dentists that specialize in pediatric dentistry. Thus, in order to ensure such patients' safety, the rule has been revised, based on public comment, to require applicants for certification through endorsement for this particular dental anesthesia certificate, to have experience in administering dental enteral conscious (moderate) sedation to, at least, five live dental patients who are 13 years old and older.

- Section 61.10(c)(3)(i)(c) has been revised to clarify that for the renewal of certificates in dental general anesthesia, a licensed dentist must complete an additional 12 clock hours of education (exclusive of the ACLS and PALS requirements contained in clauses (a) and (b), respectively, of 61.10(c)(3)(i)) in anesthesia/sedation techniques approved by an acceptable accrediting body and the Department, including, but not limited to, coursework in medications and recognition and management of complications and emergencies including rescue from deeper levels of sedation as may occur in both pediatric and adult patient populations.
- Section 61.10(c)(3)(ii)(c) has been revised to clarify that for the renewal of certificates in dental parenteral conscious (moderate) sedation for patients 12 years old and younger, and dental enteral conscious (moderate) sedations for patients 12 years old and younger, the licensed dentists must successfully complete an additional 12 clock hours of education (exclusive of the ACLS and PALS requirements contained in clauses (a) and (b), respectively, of 61.10(c)(3)(ii)) in anesthesia/sedation techniques, approved by an acceptable accrediting body and the Department, including, but not limited to, coursework in medications and recognition and management of complications and emergencies including rescue from deeper levels of sedation as may occur in both the pediatric and adult patient populations.
- Section 61.10(c)(3)(iii)(b) has been revised to clarify that for the renewal of certificates in dental parenteral and enteral conscious (moderate) sedation for patients 13 years old and older the licensed dentist must successfully complete an additional 12 clock hours of education (exclusive of the ACLS requirement contained in clause (a) of 61.10(c)(3)(iii)) in anesthesia/sedation techniques, approved by an acceptable accrediting body and acceptable to and previously approved by the Department, including, but not limited to, coursework in medications and recognition and management of complications and emergencies, including rescue from deeper levels of sedation as may occur in both the pediatric and adult patient populations.
- Section 61.10(d)(4)(i)(a)(2) has been revised to clarify that one of the practice requirements for deep sedation or general anesthesia pre-operative preparation is consultation with the patient's physician, as appropriate, for patients ASA III (a patient with severe systemic disease, according to the American Association of

Anesthesiologists patient physical status classification system) or greater, instead of requiring such consultation in all instances.

- Section 61.10(d)(4)(i)(a)(7) has been revised to add the requirement that, in deep sedation or general anesthesia pre-operative preparation, when a patient's baseline vital signs cannot be obtained because the patient's behavior prohibits it, this fact must be noted in the time-oriented anesthesia record.
- Section 61.10(d)(4)(ii)(a)(2) has been revised to clarify that one of the practice requirements for conscious (moderate) sedation pre-operative preparation is consultation with the patient's physician, as appropriate, instead of requiring such consultation in all instances, for patients ASA III (a patient with severe systemic disease, according to the American Association of Anesthesiologists patient physical status classification system) or greater.
- Section 61.10(d)(4)(ii)(a)(7) has been revised to add the requirement that, in conscious (moderate) sedation pre-operative preparation, when a patient's baseline vital signs cannot be obtained because the patient's behavior prohibits it, this fact must be noted in the time-oriented anesthesia record.
- Section 61.10(d)(8)(ii) has been revised to correct inadvertent typographical errors. The words "or" and "agents" were removed so that the revised language of the second sentence states: "In addition, a licensed dentist who completes twelve clock hours of education in anesthesia/sedation techniques for the renewal of a certification to administer conscious (moderate) enteral sedation, conscious (moderate) parenteral sedation, deep sedation or general anesthesia shall be required to maintain records documenting completion of such course work for six years from the completion of the coursework."
- The effective dates of subdivisions (b) and (c) of section 61.10 have been revised from January 1, 2017 to January 1, 2018 in order to provide residency programs and post-graduate programs sufficient time to update their curriculum to comply with the regulation's requirements.
- The effective date of subdivisions (a) and (d) of section 61.10 have been revised from January 1, 2017 to July 1, 2017 in order to provide licensed dentists with dental anesthesia certification(s) sufficient time to comply with the regulation's practice requirements.

Timetable for Implementation

It is anticipated that the revised proposed rule will be presented for adoption at the December 2016 Regents meeting, after publication of a Notice of Revised Rule Making and expiration of the 30-day public comment period. If adopted at the December meeting, the proposed amendments to subdivisions (b) and (c) of section 61.10 will become effective January 1, 2018 and the proposed amendment to subdivisions (a) and (d) of section 61.10 will become effective July 1, 2017.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 6601, and 6605-a of the Education Law

1. Subdivision (a) of section 61.10 of the Regulations of the Commissioner of Education is amended, effective July 1, 2017, as follows:

(a) Definitions. For purposes of this section, the following definitions shall apply:

(1) . . .

(2) Conscious (moderate) sedation means a [minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command and that is produced by a pharmacologic or non-pharmacologic method or a combination thereof. Patients whose only response is reflex withdrawal from repeated painful stimuli shall not be considered to be in a state of conscious sedation] drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(3) Deep sedation means [an induced state of depressed consciousness accompanied by partial loss of protective reflexes, including the inability to continually maintain an airway independently and/or to respond purposefully to physical stimulation or verbal command, and is produced by a pharmacologic or non-pharmacologic method or a combination thereof.] a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful

stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(4) [Enteral means a technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa, including but not limited to oral, rectal, and sublingual administration.

(5) General anesthesia means [an induced state of unconsciousness, accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and is produced by a pharmacologic or non-pharmacologic method or a combination thereof.] a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require 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.

(5) Enteral means a technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa, including but not limited to oral, rectal, and sublingual administration.

(6) [Inhalation means a technique of administration in which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to the absorption through the pulmonary bed.

(7) Parenteral means a technique of administration in which the drug bypasses the gastrointestinal tract, including but not limited to intramuscular, intravenous, intranasal, submucosal, subcutaneous, and intraocular administration.

(7) Inhalation means a technique of administration in which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to the absorption through the pulmonary bed.

(8) Continual or continually means repeated regularly and frequently in a steady succession.

(9) Continuous or continuously means prolonged without any interruption in time.

(10) Patent means open, unobstructed, or not closed.

(11) Time-oriented anesthesia record means an organized document which shows at appropriate time intervals, drugs and doses administered, and physiologic data obtained through patient monitoring, during the course of conscious (moderate) sedation, deep sedation, or general anesthesia, to include the preoperative, intraoperative and recovery stages of treatment.

(12) American Society of Anesthesiologists (ASA) Patient Physical Status Classification

ASA I – A normal healthy patient

ASA II – A patient with mild systemic disease

ASA III – A patient with severe systemic disease

ASA IV – A patient with severe systemic disease that is a constant threat to life

ASA V – A moribund patient who is not expected to survive without the operation

ASA VI- A declared brain-dead patient whose organs are being removed for donor purposes

E – Emergency operation of any variety (used to modify one of the above classifications, i.e., ASA III-E)

2. Subdivision (b) of section 61.10 of the Regulations of the Commissioner of Education is amended, effective January 1, 2018, as follows:

(b) Certification requirements.

(1) A licensed dentist shall not employ conscious (moderate) sedation, deep sedation, or general anesthesia in the practice of dentistry, at any location other than a general hospital, unless such dentist possesses a dental anesthesia certificate issued by the department pursuant to this section, except that such certification shall not be required for use of anesthesia as prescribed in section 6605-a(3) of the Education Law. For such certification the licensed dentist shall meet the requirements of this section, including the educational and training requirements prescribed in subdivision (c) of this section and the practice requirements prescribed in subdivision (d) of this section. Such certificates shall be issued for a three-year term.

(2) Effective January 1, [2001] 2018, certificates shall be issued in the titles:

(i) dental general anesthesia, which authorizes a licensed dentist to employ conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents), deep sedation, and general anesthesia;

(ii) dental parenteral conscious (moderate) sedation for patients 13 years old and older, which authorizes a licensed dentist to employ conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents) on all patients 13 years old and older; [and]

(iii) dental parenteral conscious (moderate) sedation for patients 12 years old and younger, which authorizes a licensed dentist to employ conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents) on all patients;

(iv) dental, enteral conscious (moderate) sedation for patients 13 years old and older, which authorizes a licensed dentist to employ conscious (moderate) sedation (enteral route only with or without inhalation agents) [.] on all patients 13 years old and older; and

(v) dental enteral conscious (moderate) sedation for patients 12 years old and younger, which authorizes a licensed dentist to employ conscious (moderate) sedation (enteral route only with or without inhalation agents) on all patients.

(3) Certificates to administer dental general anesthesia; [and] dental parenteral conscious sedation and [to administer] dental [parenteral] enteral conscious sedation [for parenteral conscious sedation] only which were issued prior to January 1, [2001] 2018 shall continue to be valid until the expiration of their term, at which time the licensed dentist shall be required to [apply for a new initial certificate.] submit an application to the department for renewal of his or her certificate pursuant to the applicable requirements set forth in this section:

[(4) A licensed dentist who holds a certificate to administer general anesthesia and parenteral sedation may also administer conscious sedation using the enteral or parenteral route with or without inhalation agents, and a licensed dentist who holds a certificate to administer conscious sedation using a parenteral route may also administer conscious sedation using an enteral route with or without inhalation agents.]

(i) For renewal of a certificate in dental general anesthesia, a licensed dentist shall satisfy the requirements contained in paragraph (3) of subdivision (c) of this section.

(ii) For the first renewal period for a licensed dentist with an existing dental enteral or parenteral conscious sedation certificate issued prior to January 1, 2018 who seeks to administer dental enteral or dental parenteral conscious (moderate) sedation to patients 12 years old and younger, the licensee shall satisfy the requirements contained in paragraph (3) of subdivision (c) of this section and submit to the department for review nine time-oriented anesthesia records of such patients who either were:

(a) treated by the licensed dentist utilizing conscious (moderate) sedation (enteral/parenteral) during his or her last triennial registration period; or

(b) patients where the licensed dentist was the supervising attending dentist or a faculty member supervising the student who was administering the conscious (moderate) sedation technique (enteral/parenteral) being administered during his or her last triennial registration period.

(iii) If a licensed dentist who seeks to administer dental enteral or dental parenteral conscious (moderate) sedation to patients 12 years old and younger does not meet the aforementioned requirements, the department may issue him or her the corresponding certificate for patients 13 years old and older, if the licensed dentist meets the renewal requirements for said certificate as set forth in paragraph (3) of subdivision (c) of this section.

(4) Upon the request of the department, the licensed dentist shall submit to the department copies of time-oriented anesthesia records that satisfy the recordkeeping requirements contained in paragraph (8) of subdivision (d) of this section, with or without the patient charts, to verify that the licensed dentist is in compliance with the above-referenced record-keeping requirements and ensure that the licensed dentist is practicing within the scope of the dental anesthesia certificate held by him or her.

(5) Upon renewal of a dental anesthesia certification, the department may request copies of patient charts or time-oriented anesthesia records.

3. Subdivision (c) of section 61.10 of the Regulations of the Commissioner of Education is amended, effective January 1, 2018, as follows:

(c) Educational and training requirements.

(1) Initial certification.

(i) Certificate in dental general anesthesia. A licensed dentist shall meet the educational and training requirements in this subparagraph for the initial certificate in dental general anesthesia.], which authorizes the licensed dentist to employ conscious sedation (enteral or parenteral route with or without inhalation agents), deep sedation, and general anesthesia.] The licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact; and

(b) if the licensed dentist is administering general anesthesia to patients 12 years old and younger, a course in pediatric advanced life support (PALS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact; and

(c) either:

(1) for post-doctoral education completed prior to January 1, 2002, at least one year of such education in anesthesia acceptable to the department, which shall include but not be limited to, coursework in anesthesia, anxiety and pain control, establishing and maintaining emergency airway, and use and interpretation of appropriate monitoring; or at least two years of such education in an approved specialty program or residency, which includes acceptable training and experience, including but not limited to, instruction in general anesthesia and parenteral sedation; provided that the candidate has applied to the department for the initial certificate to employ conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents), deep sedation, and general anesthesia prior to January 1, 2004; or

(2) at least two years of post-doctoral education acceptable to the department and accredited by an acceptable accrediting body, which shall include but not be limited

to coursework in anesthesia and anxiety and pain control; and one year devoted exclusively to clinical training in general anesthesia and related subjects such as establishing and maintaining an emergency airway and use and interpretation of appropriate monitoring prior to January 1, 2019; or

(3) at least three years of post-doctoral education acceptable to the department and accredited by an acceptable accrediting body, which shall include but not be limited to coursework in anesthesia and anxiety and pain control; and one year devoted exclusively to clinical training in general anesthesia and related subjects such as establishing and maintaining an emergency airway and use and interpretation of appropriate monitoring as of January 1, 2019; or

(4) a graduate level program in oral and maxillofacial surgery acceptable to the department and accredited by an acceptable accrediting body, which shall include but not be limited to instruction in general anesthesia, parenteral sedation, and anxiety and pain control.

(ii) Certificate in dental parenteral conscious (moderate) sedation for patients 13 years old and older. A licensed dentist shall meet the educational and training requirements [in] of this subparagraph for the initial certificate in dental parenteral conscious (moderate) sedation for patients 13 years older and older.[, which authorizes the licensed dentist to employ conscious sedation using an enteral or parenteral route, with or without inhalation agents, which certificate shall not authorize the licensed dentist to employ general anesthesia or deep sedation.] The licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact; and

(b) [either:

(1) for post-doctoral education completed prior to January 1, 2002, a minimum of 60 clock hours of post-doctoral education acceptable to the department, no fewer than 20 clock hours of which shall consist of the successful use of parenteral conscious sedation on no fewer than 20 patients, the remainder consisting of but not limited to patient evaluation and monitoring, management of emergencies, pharmacology and the control of pain and anxiety; provided that the candidate has applied to the department for the initial certificate to employ conscious sedation using a parenteral or enteral route, with or without inhalation agents, prior to January 1, 2004; or

(2) pre-doctoral or post-doctoral education acceptable to the department and accredited by an acceptable accrediting body, which shall include a formal course consisting of at least 60 clock hours of coursework[,] that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the department. Simulation experiences may be part of the required coursework, which shall include [including] but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, rescue of patients from deep sedation, management of the pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and the control of pain and anxiety; and in addition to the 60 clock hours of coursework, a clinical experience demonstrating the successful use of dental parenteral conscious (moderate) sedation on no fewer than 20 live dental patients via the intravenous route[.] who shall be 13 years old or older in a 1 doctor/student to 1 patient ratio. The student/licensed dentist enrolled in the course shall have his or her name listed on the anesthesia record and shall be the individual administering the medications and documenting said administration, as well as the physiologic findings required on the anesthesia record.

The patients shall be monitored, at a minimum, pursuant to the practice requirements as set forth in subdivision (d) of this section. If the clinical portion of the course is given outside a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

(iii) Certificate in dental parenteral conscious (moderate) sedation for patients 12 years old and younger. A licensed dentist shall meet the educational and training requirements of this subparagraph for the initial certificate in dental parenteral conscious (moderate) sedation for patients 12 years old and younger. The licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact;

(b) a course in pediatric advanced life support (PALS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact; and

(c) pre-doctoral or post-doctoral education accredited by an acceptable accrediting body, which shall include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the department. Simulation experiences can be part of the coursework which shall include but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, rescue of patients from deep sedation, management of the pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult

pharmacology, and the control of pain and anxiety; and in addition to the 60 clock hours of coursework, a clinical experience, acceptable to and previously approved by the department, demonstrating the successful use of dental parenteral conscious (moderate) sedation by the intravenous route on no fewer than 15 live dental patients who shall be 12 years old or younger and five live dental patients who shall be 13 years old or older in a 1 doctor/student to 1 patient ratio. The student/licensed dentist enrolled in the course shall have his or her name listed on the anesthesia record and shall be the individual administering the medications and documenting said administration, as well as the physiologic findings required on the anesthesia record. The patients shall be monitored, at a minimum, pursuant to the practice requirements as set forth in subdivision (d) of this section. If the clinical portion of the course is given outside a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

(iv) Certificate in dental enteral conscious (moderate) sedation for patients 13 years old and older. A licensed dentist shall meet the educational and training requirements of [clause (a) of] this subparagraph[, unless such requirements are waived pursuant to clause (b) of this subparagraph,] for the initial certificate in dental enteral conscious (moderate) sedation for patients 13 years old and older. [, which authorizes the licensed dentist to employ conscious sedation using only an enteral route of administration, with or without inhalation agents, which certificate shall not authorize the licensed dentist to employ conscious sedation using a parenteral route or deep sedation or general anesthesia.

(a)] The licensed dentist shall successfully complete:

(1)a a course in [basic life support (BLS)] advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact; and

[(2) either:]

(i)b pre-doctoral education or post-doctoral education [consisting of a specialty program or residency, which education is accredited by an acceptable accrediting body and which includes coursework in basic life support (BLS) and additional coursework consisting of at least 18 clock hours, which includes but is not limited to, instruction in nitrous oxide use and emergency management. In addition to the coursework in BLS and the 18 clock hours of coursework, the program shall require 20 clinically-oriented experiences in the use of enteral conscious sedation techniques. Clinically-oriented experiences may include group observations of patients undergoing enteral conscious sedation techniques; or

(ii) post-doctoral coursework approved by the department, which has equivalent rigor as coursework approved by an acceptable accrediting body as prescribed in item (i) of this subclause, and which includes coursework in basic life support (BLS) and additional coursework consisting of at least 18 clock hours, which includes but is not limited to, instruction in nitrous oxide use and emergency management. In addition to the coursework in ELS and the 18 clock hours of coursework, the program shall require 20 clinically-oriented experiences in the use of enteral conscious sedation techniques. Clinically-oriented experiences may include group observations of patients undergoing enteral conscious sedation techniques.

(b) For licensed dentists who apply to the department prior to January 1, 2002 for the certificate to employ conscious sedation using only an enteral route with or without inhalation agents, the department shall waive the educational and training requirement

prescribed in clause (a) of this subparagraph, provided that such licensed dentist has lawfully employed enteral conscious sedation with or without inhalation agents successfully on at least 30 patients during the period beginning January 1, 1997 and ending December 31, 2000, and that the candidate has never had a mortality or morbidity related to the employment of such sedation, which facts the licensed dentist shall be required to adequately document to the department upon request, except that the licensed dentist shall be required to successfully complete a course in Basic Life Support (BLS), or its equivalent as determined by the department, within one year of the effective date of the certificate to employ conscious sedation using only an enteral route with or without inhalation agents, and have current documentation of BLS course completion attesting to this fact.] accredited by an acceptable accrediting body, and which shall include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the department. Simulation experiences may be part of the required coursework which shall include but not be limited to, coursework in patient evaluation and monitoring, management of emergencies including IV access, rescue of patients from deep sedation, management of the pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and the control of pain and anxiety; and in addition to the 60 clock hours of coursework, a clinical experience, acceptable to and previously approved by the department, demonstrating the successful use of dental enteral conscious (moderate) sedation on no fewer than ten (10) live clinical dental patients who shall be 13 years old or older and who are physically present in the same location as the students. The students may be in groups no larger than five. The patients shall be monitored, at a minimum, pursuant to the practice requirements as set forth in subdivision (d) of this

section. If the clinical portion of the course is given outside a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

(v) Certificate in dental enteral conscious (moderate) sedation for patients 12 years old and younger. A licensed dentist shall meet the educational and training requirements in this subparagraph for the initial certificate in dental enteral conscious (moderate) sedation for patients 12 years old and younger. The licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation of course completion attesting to this fact;

(b) a course in pediatric advanced life support (PALS), or its equivalent as determined by the department and have current documentation of course completion attesting to the fact; and

(c) pre-doctoral or post-doctoral education acceptable to the department and accredited by an acceptable accrediting body, which shall include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the department. Simulation experiences can be part of the coursework which shall include but not be limited to coursework in patient evaluation and monitoring, management of emergencies, including IV access, rescue of patients from deep sedation, management of the pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and the control of pain and anxiety; and in addition to the 60 clock hours of coursework, a clinical experience demonstrating

the successful use of dental enteral conscious (moderate) sedation on no fewer than 15 live clinical dental patients 12 years old or younger and five live clinical dental patients 13 years old or older in a 2:1 doctor/student to patient ratio. For the purpose of this section, a 2:1 doctor/student to patient ratio means the doctor/student providing dental care to the patient and a second doctor/student monitoring and documenting the sedation care can receive credit for the procedure as it relates to the minimum number of sedations required for certification. Both of these doctors/students shall be with the patient during the entire time of treatment and cannot be involved with any other activities or responsibilities. Only the two doctors/students involved in direct patient care/monitoring can receive credit for treating the patient undergoing the procedure and sedation. The student/licensed dentist enrolled in the course shall have his or her name listed on the anesthesia record and shall be the individual administering the medications and documenting said administration, as well as the physiologic findings required on the anesthesia record. The patients shall be monitored, at a minimum, pursuant to the practice requirements set forth in subdivision (d) of this section. If the clinical portion of the course is given outside a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

(2) Certification through endorsement.

For endorsement of a dental anesthesia certificate from another jurisdiction of the United States or Canada, the applicant shall submit to the department a certificate of good standing from said jurisdiction and currently be registered to practice dentistry in the State of New York, and shall submit satisfactory evidence of having met the following requirements for the requested certificate:

(i) General anesthesia:

Certificate of completion of a Commission on Dental Accreditation (CODA) accredited oral and maxillofacial surgery program or a CODA accredited dental anesthesia program.

(ii) Dental parenteral conscious (moderate) sedation for patients 13 years old and older:

(a) if the applicant has ever had any patients with irreversible morbidity or mortality due to the sedation provided by him or her, the applicant must provide an explanation of the incident(s) to the department for review, in a form prescribed by the department. Depending on the circumstances, the department may require remediation before a dental parenteral conscious (moderate) sedation for patients 13 years old and older certificate will be issued;

(b) provide 20 anesthesia records of patients that the applicant has administered parenteral conscious (moderate) sedation (by the intravenous route) in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the department for review with no patients having had irreversible morbidity or mortality due to the sedation provided by the applicant. These records shall include monitoring that is required by clause (b) of subparagraph (ii) of paragraph (4) of subdivision (d) of this section for the administration of parenteral conscious (moderate) sedation; and

(c) provide current documentation of completion of a course in advanced cardiac life support (ACLS) from a department approved course sponsor, or its equivalent as determined by the department.

(iii) Dental parenteral conscious (moderate) sedation for patients 12 years old and younger:

(a) if the applicant has ever had any patients with irreversible morbidity or mortality due to the sedation provided by him or her, the applicant must provide an explanation of the incident(s) to the department for review, in a form prescribed by the department. Depending on the circumstances, the department may require remediation before a dental parenteral conscious (moderate) sedation for patients 12 years old and younger certificate will be issued;

(b) have a certificate to provide parenteral conscious (moderate) sedation for, at least, the 3 years immediately preceding the applicant's submission of his or her application to the department for review;

(c) provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered parenteral conscious (moderate) sedation (via the intravenous route) in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the department for review with no patients having had irreversible morbidity or mortality due to the sedation provided by the applicant. These records shall include monitoring that is required by clause (b) of subparagraph (ii), of paragraph (4) of subdivision (d) of this section for the administration of parenteral conscious (moderate) sedation;

(d) provide current documentation of completion of a course in advanced cardiac life support (ACLS) from a department approved sponsor, or its equivalent as determined by the department; and

(e) provide current documentation of completion of a course in pediatric advanced life support (PALS) from a department approved sponsor, or its equivalent as determined by the department.

(iv) Dental enteral conscious (moderate) sedation for patients 13 years old and older:

(a) if the applicant has ever had any patients with irreversible morbidity or mortality due to the sedation provided by him or her, the applicant must provide an explanation of the incident(s) to the department for review, in a form prescribed by the department. Depending on the circumstances, the department may require remediation before a dental enteral conscious (moderate) sedation for patients 13 years old and older certificate will be issued;

(b) provide 20 anesthesia records of patients that the applicant has administered enteral conscious (moderate) sedation in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the department for review, in a form prescribed by the department. These records shall include monitoring that is required by clause (b) of subparagraph (ii) of paragraph (4) of subdivision (d) of this section for the administration of enteral conscious (moderate) sedation; and

(c) provide current documentation of completion of a course in advanced cardiac life support (ACLS) from a department approved course sponsor, or its equivalent as determined by the department.

(v) Dental enteral conscious (moderate) sedation for patients 12 years old and younger:

(a) if the applicant has ever had any patients with irreversible morbidity or mortality due to the sedation provided by him or her, the applicant must provide an explanation of the incident(s) to the department for review, in a form prescribed by the department. Depending on the circumstances, the department may require remediation

before a dental enteral conscious (moderate) sedation certificate for patients 12 years old and younger will be issued;

(b) have a certificate to provide enteral conscious (moderate) sedation for at least the 3 years immediately preceding the applicant's submission of his or her application to the department for review;

(c) provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered enteral conscious (moderate) sedation in the licensed jurisdiction, within the three years immediately preceding the applicant's submission of his or her application to the department for review. These records shall include monitoring that is required by clause (b) of subparagraph (ii) of paragraph (4) of subdivision (d) of this section for the administration of enteral conscious (moderate) sedation;

(d) provide current documentation of completion of a course in advanced cardiac life support (ACLS) from a department approved sponsor, or its equivalent as determined by the department; and

(e) provide current documentation of completion of a course in pediatric advanced life support (PALS) from a department approved sponsor, or its equivalent as determined by the department.

(3) Renewal of certification. A licensed dentist shall meet the educational and training requirements of this paragraph for the renewal of certification.

(i) For the renewal of certificates in dental general anesthesia, [which authorizes the licensed dentist to employ conscious sedation (enteral or parenteral route with or without inhalation), deep sedation, and general anesthesia; and for the renewal of certificates in dental parenteral conscious sedation, which authorizes the licensed

dentist to employ conscious sedation (enteral or parenteral route with or without inhalation agents),] a licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation attesting to this fact[.];

(b) a course in pediatric advanced life support (PALS), or its equivalent as determined by the department and have current documentation of course completion attesting to the fact if the dentist with the general anesthesia certificate is providing conscious (moderate) sedation, deep sedation or general anesthesia to patients 12 years old or younger; and

(c) an additional twelve clock hours of education (exclusive of the ACLS and PALS requirements contained in clauses (a) and (b), respectively, of this subparagraph) in anesthesia/sedation techniques approved by an acceptable accrediting body and the department, including but not limited to, coursework in medications and recognition and management of complications and emergencies including rescue from deeper levels of sedation as may occur in both the pediatric and adult patient populations.

(ii) For the renewal of certificates in dental [enteral conscious sedation, which authorizes the licensed dentist to employ conscious sedation (enteral route only with or without inhalation agents)], parenteral conscious (moderate) sedation for patients 12 years old and younger, and dental enteral conscious (moderate) sedation for patients 12 years old and younger, the licensed dentist shall successfully complete:

(a) a course in [basic] advanced cardiac life support ([BLS] ACLS), or its equivalent as determined by the department, and have current documentation attesting to this fact; and

(b) a course in pediatric advanced life support (PALS), or its equivalent as determined by the department and have current documentation of course completion attesting to this fact; and

(c) an additional [six] twelve clock hours of education (exclusive of the ACLS and PALS requirements contained in clauses (a) and (b), respectively, of this subparagraph) in anesthesia/sedation techniques, approved by an acceptable accrediting body and the department, including but not limited to, coursework in medications and recognition and management of complications and emergencies including rescue from deeper levels of sedation as may occur in both the pediatric and adult patient populations.

(iii) For the renewal of certificates in dental parenteral and enteral conscious (moderate) sedation for patients 13 years old and older the licensed dentist shall successfully complete:

(a) a course in advanced cardiac life support (ACLS), or its equivalent as determined by the department, and have current documentation attesting to this fact; and

(b) an additional twelve clock hours of education (exclusive of the ACLS requirement contained in clause (a) of this subparagraph) in anesthesia/sedation techniques, approved by an acceptable accrediting body and acceptable to and previously approved by the department, including but not limited to, coursework in medications and recognition and management of complications and emergencies, including rescue from deeper levels of sedation as may occur in both the pediatric and adult patient populations.

(iv) The coursework required to be completed for the renewal of certification may be creditable toward meeting the dentist's continuing education requirement, provided that it meets all requirements of section 61.15 of this Part.

4. Subdivision (d) of section 61.10 of the Regulations of the Commissioner of Education is amended, effective July 1, 2017, as follows:

(d) Practice requirements. All licensed dentists who administer conscious (moderate) sedation or deep sedation or general anesthesia shall meet the practice requirements of this subdivision.

(1) A licensed dentist who employs conscious (moderate) sedation using [a] an enteral or parenteral route with or without inhalation agents or deep sedation or general anesthesia shall have current documentation of course completion in advanced cardiac life support (ACLS), or its equivalent as determined by the department. A licensed dentist who employs conscious (moderate) sedation using an enteral or parenteral route with or without inhalation agents, [but who does not employ conscious sedation using the parenteral route with or without inhalation agents or deep sedation or general anesthesia, shall have current documentation of course completion in basic life support (BLS), or its equivalent as determined by the department, except that a licensed dentist who has obtained a waiver of the educational and training requirements for the initial certificate to employ enteral conscious sedation with or without inhalation agents, pursuant to clause (c)(1)(3)(b) of this section, shall not be required to have current documentation of course completion in basic life support (BLS), or its equivalent as determined by the department, until one year after initial certification] or deep sedation or general anesthesia to patients 12 years old or younger shall have current documentation in pediatric advanced life support (PALS), or its equivalent as determined by the department.

(2) A licensed dentist shall not administer conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents) or deep sedation or general anesthesia to more than one patient at a time except when supervising no more than

two dental students or residents at one time in a teaching institution. A licensed dentist, a licensed physician, a registered professional nurse, or a licensed practical nurse shall personally monitor recovery from conscious (moderate) sedation or deep sedation or general anesthesia.

(3) A licensed dentist who uses conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents) or deep sedation or general anesthesia for a patient shall be responsible for all aspects of the procedure including pre-operative preparation and evaluation, life support procedures, monitoring, recovery, discharge, and recordkeeping. [The following parameters shall be monitored: vital signs, including blood pressure, pulse, and oxygen saturation, which oxygen saturation shall be continuously monitored by the use of a pulse oximeter or an equivalent device, except that oxygen saturation shall not be required to be monitored in cases in which conscious sedation using an enteral route, with or without inhalation agents, is employed and the patient's conduct prohibits the monitoring of oxygen saturation. Ventilation shall be evaluated by observation and/or auscultation. A licensed dentist who uses parenteral conscious sedation or deep sedation or general anesthesia shall also continuously monitor the electrical activity of the heart. A device capable of measuring body temperature shall be readily available during the administration of deep sedation or general anesthesia. When agents implicated in precipitating malignant hyperthermia are utilized, continual monitoring of body temperature shall be performed.]

(4) At a minimum, the following practice requirements shall be followed:

(i) Deep sedation or general anesthesia:

(a) Pre-operative preparation:

(1) A written and oral medical history shall be obtained;

(2) Consultation with the patient's physician, as appropriate, for patients ASA III (a patient with severe systemic disease, according to the American Society of Anesthesiologists [ASA] patient physical status classification system) or greater;

(3) Pre-operative instructions shall be given to the patient, parent, escort, guardian or caregiver;

(4) Preoperative dietary restrictions shall be considered based on the anesthetic/sedative technique planned;

(5) The patient, parent, guardian or care giver shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed anesthesia/sedation shall be obtained;

(6) A focused physical evaluation shall be performed as deemed appropriate;

(7) Baseline vital signs shall be obtained unless the patient's behavior prohibits such determination and in any such case, this fact shall be noted in the time-oriented anesthesia record;

(8) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure shall be completed; and

(9) An intravenous line, which is secured throughout the procedure, shall be established. If, due to lack of patient cooperation, the intravenous line cannot be maintained throughout the procedure, the inability to maintain such shall be documented in the anesthesia record.

(b) Monitoring:

(1) Oxygenation:

(i) Color of mucosa, skin or blood shall be continually evaluated; and

(ii) Oxygen saturation shall be evaluated continuously by pulse oximetry.

(2) Ventilation:

(i) Intubated patient: end-tidal CO₂ shall be continuously monitored and evaluated;

(ii) Non-intubated patient: breath sounds via auscultation and/or end-tidal CO₂ shall be continuously monitored and evaluated;

(iii) Respiration rate shall be continually monitored and evaluated; and

(iv) When agents implicated in precipitating malignant hyperthermia are utilized, end-tidal CO₂ shall be continuously monitored and evaluated.

(3) Circulation:

(i) The dentist shall continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry; and

(ii) The dentist shall continually evaluate blood pressure.

(4) Temperature:

(i) A device capable of measuring body temperature shall be readily available during the administration of deep sedation or general anesthesia; and

(ii) When agents implicated in precipitating malignant hyperthermia are utilized, continuous monitoring of body temperature shall be performed.

(ii) Conscious (moderate) sedation:

(a) Pre-operative preparation:

(1) A written and oral medical history shall be obtained;

(2) Consultation with the patient's physician, as appropriate, for patients ASA III (a patient with severe systemic disease, according to the American Society of Anesthesiologists [ASA] patient physical status classification system) or greater;

(3) Pre-operative instructions shall be given to the patient, parent, escort, guardian or caregiver;

(4) Preoperative dietary restrictions shall be considered based on the anesthetic/sedative technique planned;

(5) The patient, parent, guardian or care giver shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed anesthesia/sedation shall be obtained;

(6) A focused physical evaluation shall be performed as deemed appropriate;

(7) Baseline vital signs shall be obtained unless the patient's behavior prohibits such determination and in any such case, this fact shall be noted in the time-oriented anesthesia record;

(8) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure shall be completed; and

(9) An intravenous line, which is secured throughout the procedure, shall be established when parenteral sedation is being administered by way of an intravenous route. If, due to lack of patient cooperation, the intravenous line cannot be maintained throughout the procedure, the inability to maintain such shall be documented on the anesthesia record.

(b) Monitoring:

(1) Consciousness:

(i) Level of consciousness (e.g., responsiveness to verbal command) shall be continually assessed.

(2) Oxygenation:

(i) Color of mucosa, skin or blood shall be continually evaluated; and

(ii) Oxygen saturation shall be evaluated continuously by pulse oximetry.

(3) Ventilation:

(i) The dentist shall observe chest excursions continually; and

(ii) The dentist shall monitor ventilation by auscultation of breath sounds, monitoring end-tidal CO₂ or by verbal communication with the patient.

(4) Circulation:

(i) The dentist shall continually evaluate blood pressure and heart rate (unless the patient is unable to tolerate the monitoring and this is noted in the time-oriented anesthesia record);

(ii) During the administration of dental conscious (moderate) enteral sedation, continuous evaluation of ECG shall be done when there is a finding of cardiovascular disease that warrants such monitoring; and

(iii) During the administration of dental conscious (moderate) parenteral sedation, the dentist shall continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry

(5) The recovery and discharge of the patient is the responsibility of any of the following: the licensed dentist providing the anesthesia/sedation management for that patient, another licensed dentist with a anesthesia/sedation certificate permitting him or her to provide the same level of anesthesia/sedation administered to the patient treated or a licensed physician with the appropriate anesthesia training. Prior to discharge, the patient shall meet the following discharge criteria, which shall be documented in the patient's chart:

(i) Alert and responsive;

(ii) Patient can maintain and support his or her airway without intervention;

(iii) Vital signs, including oxygenation on room air, are within acceptable limits;

(iv) Patient is ambulatory with assistance;

(v) Responsible adult escort is present to escort the patient from the office;

(vi) Written and verbal instructions are given to patient and responsible adult escort. These instructions shall include a way for the patient/guardian to communicate with the anesthesia provider or provider of dental care in case of an emergency or adverse reaction; and

(vii) Prior to discharge, evaluation of the patient's pain and post-operative nausea and vomiting (PONV) shall be done. The results of these assessments and management shall be documented in the patient's chart.

[4](6) Every facility at which conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents) or deep sedation or general anesthesia is employed in the practice of dentistry shall be equipped and staffed in a manner appropriate for the administration and monitoring of anesthetic drugs or agents and for the treatment of emergencies which may arise. Each facility shall be constructed to permit ready access by emergency equipment. A protocol for handling emergencies, including transport to an emergency facility, shall be posted in each treatment and recovery area. [A defibrillator shall be immediately accessible at each facility in which conscious sedation using a parenteral route with or without inhalation agents, or deep sedation, or general anesthesia is employed]. All dental facilities shall have an automatic external defibrillator (AED) or other defibrillator at the facility.

[5](7) [Beginning on or after January 1, 2002, the requirements of this paragraph shall be applicable.] Personnel requirements:

(i) During the administration of deep sedation or general anesthesia, a minimum of three individuals shall be present in the operatory. Such individuals shall include a licensed dentist or licensed physician qualified to administer the deep sedation or general anesthesia, who shall be in charge of the administration of the anesthesia care; and two additional individuals, who have current documentation that they have

successfully completed a course in basic life support (BLS), or its equivalent as determined by the department.

(ii) During the administration of conscious (moderate) sedation using the enteral or parenteral route with or without inhalation agents, a minimum of two individuals shall be present in the operatory. Such individuals shall include a licensed dentist or licensed physician qualified to administer the conscious (moderate) sedation, who shall be in charge of the administration of the anesthesia care; and one additional individual, who has current documentation that he or she has successfully completed a course in basic life support (BLS) or its equivalent as determined by the department.

[(6) Specific dietary instructions shall be provided to the patient for whom conscious sedation or deep sedation or general anesthesia has been or will be employed, based on the techniques used and the patient's physical state.

(7) Appropriate oral or written instructions shall be provided to the patient and/or the patient's guardian, based on the techniques used and the patient's physical state.]

(8) Recordkeeping. Licensed dentists who hold certification pursuant to this section shall maintain the records prescribed in this paragraph, which shall be available for review by the department, upon request.

(i) The licensed dentist shall maintain records on the administration of conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents), deep sedation, or general anesthesia, in accordance with the requirements of paragraph (3) of subdivision (a) of section 29.2[(a)(3)] of this Title, which shall include but not be limited to:

(a) a medical history of the patient and appropriate informed consent for administration of conscious (moderate) sedation (enteral or parenteral route with or

without inhalation agents), deep sedation, or general anesthesia, prior to the performance of any procedure;

[(b) time oriented anesthetic records, based on the level of anesthesia administered, that reflect pre-operative, intra-operative, and pre-discharge monitoring of blood pressure, pulse, and oxygen saturation, except that records of oxygen saturation shall not be required when conscious sedation using an enteral route, with or without inhalation agents, is employed and the patient's conduct prohibits the monitoring of oxygen saturation, in which case the record shall document this fact.]

(b) written or documented verbal consultations with licensed physicians that are obtained prior to, during, or 24 hours following the administration of conscious (moderate) sedation, deep sedation or general anesthesia;

[(c) drugs and dosage of these drugs used prior, during and post procedure, including inhalation agents and persons present during the administration of the drugs.]

(c) time-oriented anesthesia records, based on the level of anesthesia administered, that indicate:

(1) Date of treatment;

(2) Demographic information:

(i) patient's name;

(ii) age, height, and weight;

(iii) Nothing by mouth (NPO) status;

(iv) medical conditions;

(v) allergies;

(vi) medications;

(vii) diagnosis; and

(viii) treatment proposed/performed.

(3) Pre-treatment evaluation/examination:

(i) results of a focused examination and airway evaluation; and

(ii) ASA (American Society of Anesthesiologists [ASA] patient physical status classification system) status.

(4) clinical care:

(i) all enteral, parenteral and inhalation agents administered;

(ii) dosage of these drugs according to the time administered preoperatively, intraoperatively and during the in-office recovery phase;

(iii) type and placement of intravenous access;

(iv) type and total amount of intravenous fluids administered;

(v) type of advanced airway management used;

(vi) all types of monitoring used;

(vii) the physiologic findings of pre-operative (base-line findings), intra-operative, and pre-discharge monitoring including but not limited to:

(A) blood pressure;

(B) heart rate;

(C) respiratory rate;

(D) end tidal CO₂ (ETCO₂);

(E) temperature and ECG rhythm if monitored;

(F) oxygen saturation, except that records of oxygen saturation and blood pressure shall not be required when conscious (moderate) sedation using an enteral route, with or without inhalation agents, is employed and the patient's conduct prohibits the monitoring of oxygen saturation and blood pressure, in which case the record shall document this fact; and

(G) if a physiologic parameter cannot be monitored, the reason should be reflected on the anesthesia record;

(viii) the time of placement and removal of a throat pack or throat drape when used;

(ix) persons present in the treatment room who are providing care or assisting during the procedure;

(x) name of the individual holding an anesthesia certificate responsible for recovery and discharge; and

(xi) any irreversible morbidity that occurs during the treatment and in-office recovery period.

(ii) The licensed dentist shall maintain current documentation of successful course completion in [basic life support (BLS)] pediatric advanced life support (PALS) or advanced cardiac life support (ACLS), or their equivalent, as required for the anesthesia certificate held, and current documentation of course completion in basic life support (BLS), or its equivalent, required to be held by individuals present in the operatory during the administration of anesthesia pursuant to the requirements of paragraph ([5] 7) of this subdivision, for six years from the date of completion of the coursework. In addition, a licensed dentist who completes [six] twelve clock hours of education in anesthesia/sedation techniques for the renewal of a certification to administer conscious (moderate) enteral sedation, conscious (moderate) parenteral sedation, deep sedation or general anesthesia [employ conscious sedation using an enteral route only with or without inhalation agents,] shall be required to maintain records documenting completion of such course work for six years from the completion of the coursework. The records shall include the number of clock hours completed, the sponsor's name and any identifying number, and the date and location of the program. If any of the

coursework is being used by the licensed dentist to meet his or her continuing education requirement, as prescribed in section 61.15 of this Part, such records shall be maintained in accordance with the requirements of subdivision (f) of section 61.15[f] of this Part.

(9) The dentist administering conscious (moderate) sedation, deep sedation or general anesthesia is responsible for anesthetic/sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of conscious (moderate) sedation, deep sedation or general anesthesia and provision of the equipment, drugs and protocols for patient rescue.

([9]10) Mortality or irreversible morbidity occurring during or within 48 hours following, or otherwise related to, the administration of conscious (moderate) sedation or deep sedation or general anesthesia administered pursuant to this section shall be reported, in writing, by the certificate holder to the department within 30 days of the occurrence. This report shall include, but not be limited to the following: the name and license number of the dentist with the anesthesia certificate, as well as that of the operating dentist, if he or she was not providing the anesthesia; the names and titles of office staff present on the date of the incident; name and date of birth of the patient; if the patient is a minor, the name of the parent or guardian must also be included; date of the incident; type of anesthesia administered; and the facts and circumstances surrounding the incident.

8 NYCRR §61.10

ASSESSMENT OF PUBLIC COMMENT

Since the publication of a Notice of Proposed Rule Making in the March 9, 2016 State Register, the State Education Department received the following comments:

1. COMMENT:

An association of dental surgeons submitted several comments in support of clarifying the term conscious sedation to mean moderate sedation, requiring certificate holders to have prerequisite educational coursework of at least 60 hours, requiring 12 hours of anesthesia related continuing education for permit renewal, requiring ACLS at every certificate level and PALS for pediatric sedation, reporting mortality or irreversible morbidity to SED within two days, and strengthening dentists' responsibility for patient discharge.

The association of dental surgeons feels strongly that end-tidal CO2 monitoring should be required for all anesthetized patients, not just intubated ones as required by the proposal. The association does not agree that training in pediatric sedation should automatically qualify a certificate holder to perform adult sedation. The certificate should additionally require the necessary live adult cases (10 or 20) as a prerequisite. The association would like to see route of administration removed from certificate categories and they be solely based upon a level of sedation. The proposal should require a consult with the patient's physician for all ASA III class sedated patients. Any consult with the patient's physician should be left to the discretion of the dentist as stated in the ADA Anesthesia Guidelines. The association would like to see hours for ACLS/PALS courses count toward the 12 hours of continuing education necessary for renewal.

DEPARTMENT RESPONSE:

Due to the inconsistent efficacy of end-titration CO₂ monitoring with an open airway, the Department determined that the anesthesia provider should have the discretion of using auscultation or end-titration CO₂ monitoring for the purpose of monitoring ventilation during the administration of deep sedation or general anesthesia. During the administration of conscious (moderate) sedation, it was determined that the dentist must monitor ventilation by auscultation of breath sounds, monitoring end-titration CO₂ or by verbal communication with the patient.

Most pediatric residencies involve the treatment of developmentally delayed patients, including adult patients. Many pediatric dentists continue to treat such patients into adulthood. The Department agrees with the commenter that adults and children present with different medical circumstances. Therefore, the Department has revised proposed section 61.10(c)(1) to require applicants for the certificates in parenteral and enteral conscious (moderate) sedation for patients 12 years old or younger to successfully complete a clinical experience involving the use of parental/enteral conscious (moderate) sedation by the respective routes on no fewer than 15 live dental patients who must be 12 years or younger and five live dental patients who must be 13 years old or older. Section 61.10(c)(2)(iii)(c) has also been revised to require applicants for certification through endorsement for the certificate in dental parenteral conscious (moderate) sedation for patients 12 years old and younger to provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered parenteral conscious (moderate) sedation (via the intravenous route) in the licensed jurisdiction. It is required that the anesthesia cases in these records be within the three years immediately preceding the applicant's submission of his or her application to the Department for

review with no patients having had irreversible morbidity or mortality due to the sedation provided by the applicant. This replaces the current 20 anesthesia records of patients 12 years old and younger. Additionally, section 61.10(c)(2)(v)(c) has been revised to require applications for certification through endorsement for the certificate in dental enteral conscious (moderate) sedation for patients 12 years old and younger to provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, that the applicant has administered enteral conscious (moderate) sedation in the licensed jurisdiction. It is required that the anesthesia cases in these records be within the three years immediately preceding the applicant's submission of his or her application to the Department for review. These revisions will help ensure the safety of patients 13 years and older, who are treated by licensed dentists seeking one or both of these certificates because it will require such dentists to submit clinical experience in successfully treating patients in this age group with the type of anesthesia they are seeking an certification in.

The Department does not feel that level of administration adequately protects the public. If the anesthesia certificates were issued via level, everyone with a certificate would have to be trained in both enteral and parenteral techniques. It is the opinion of the Department that the education process of teaching parenteral techniques, which includes the intravenous (IV) route of administration, is more extensive than the oral technique. This is due to the time it takes the student/resident to learn how to place an IV, titrate medications (this is not done with oral sedation) and so on. Many dentists want the option of providing sedation for their patients but do not want the additional training and liability which comes with administering parenteral sedation. This is evidenced by the 837 enteral certificates the Department has issued as of April 2016 compared to the 291 parenteral certificates which have been issued.

The Department has revised section 61.10(d)(4)(i)(a)(2) and 61.10(d)(4)(ii)(a)(2) to clarify that one of the practice requirements for deep sedation or general anesthesia and conscious (moderate) sedation pre-operative preparation is consultation with the patient's physician, as appropriate, instead of requiring such consultation in all instances, for patients ASA III (a patient with severe systemic disease, according to the American Association of Anesthesiologists patient physical status classification system) or greater.

With respect to the commenter's request that ACLS/PALS courses count toward the 12 hours of continuing education necessary for certificate renewal, it is the Department's position that requiring an additional 12 clock hours of education, exclusive of the ACLS/PALS requirements, furthers public protection because of the additional coursework licensed dentists will be required to take in order to renew their anesthesia certification(s). Sections 61.10(c)(3)(i)(c), 61.10(c)(3)(ii)(c), and 61.10(c)(3)(iii)(b) have also been revised to clarify that ACLS/PALS courses cannot be used to satisfy the 12 hours of continuing education necessary for certificate renewal. However, ACLS/PALS may be used toward the 60 continuing education hours required for triennial registration.

Section 61.10(d)(4)(i)(a)(7) and 61.10(d)(4)(ii)(a)(7) have been revised to add the requirement that, in deep sedation or general anesthesia and conscious (moderate) sedation pre-operative preparation, when a patient's baseline vital signs cannot be obtained because the patient's behavior prohibits it, this fact must be noted in the time-oriented anesthesia record.

2. COMMENT:

One commenter stated that any effort to make sedation dentistry unreasonably difficult to provide to patients will in the long run cause a lot more harm to patients who are too fearful to come to the dentist.

DEPARTMENT RESPONSE:

It is the Department's position that the proposed amendment to section 61.10 does not make the requirements for dental anesthesia certification and dental anesthesia administration "unreasonably difficult." The proposed amendment conforms the regulations to the current practice of dental anesthesia administration and improves the protection of the public, which should assist in alleviating some of the anxiety of dental patients.

3. COMMENT:

One commenter submitted several comments raising concerns about requiring ACLS or PALS for all levels of anesthesia. To improve patient safety, two things need to change: (1) increase airway management training at all levels; and (2) require a separate operator, with a general anesthesia permit to administer medications and monitor the unconscious dental patient. Most patients only require anxiolysis or conscious sedation for oral surgery, root canals and other dental procedures, which is "perfectly safe." Some patients want to be "out cold" and others are "unmanageable unless unconscious." This small percent of patients creates the most risk and there needs to be a cost effective way to have them treated in the hospital setting under general anesthesia or in an office with a dedicated anesthesia team and recovery process.

The commenter supports improving patient safety by prioritizing airway management.

DEPARTMENT RESPONSE:

The Department notes ACLS and PALS are specific courses which train healthcare providers how to react in specific situations. The course content includes, but is not limited to, CPR and use of the automated external defibrillators (AEDs),

physiology, ventilation, pharmacology and airway management. The initial coursework in each of these courses ranges from 10-14 hours. Dentists who treat patients 12 and younger must take both ACLS and PALS in order to qualify for a certificate. The airway management course is 5 hours. It is the opinion of the Department, based on research, that most of the information in the 5 hour airway course will be covered in the 10-14 hours of ACLS and PALS courses.

Additionally, the Department's Office of Professional Discipline's records do not contain evidence that would support the argument that any of the reported morbidity or mortality cases would have had different outcomes if a separate provider was administering the anesthesia at the time of the incident.

4. COMMENT:

An association of anesthesiologists submitted a comment recommending that the administration of general anesthesia for children two years old and younger be permitted only in an accredited hospital or an accredited ambulatory care setting.

DEPARTMENT RESPONSE:

The Department has not received any morbidity or mortality reports in children less than 2 years old, who have been administered general anesthesia in the course of dental treatment. The patients in this age group account for a very small portion of dental anesthesia which is administered each year. The lack of reports may, at least in part, be due to the fact that such patients are already being treated in an accredited hospital or an accredited ambulatory care center.

5. COMMENT:

One commenter suggested that the regulation should be summarized for each type of certificate holder separately, so Dentists can understand and comply with the regulations. Moderate sedation should be compared with light sedation (anxiolysis).

Any patient provided a sedative drug along with Nitrous Oxide should be monitored with a pulse oximeter. It is unclear whether the regulation defines this as anxiolysis or moderate sedation, however this level of sedation should require training and a certificate. Capnography or monitoring breath sounds via auscultation results in better control and monitoring of the patient. Capnography is well documented as the standard for monitoring an intubated patient undergoing general anesthesia. There are some who feel that monitoring breath sounds in a moderately sedated patient is more accurate and provides a faster reaction time. Types of monitoring required should be clearly explained for each type of certificate and level of sedation.

The commenter further suggests requiring the American Heart Association's course on airway management (or equivalent) instead of ACLS.

DEPARTMENT RESPONSE:

The Department intends to provide a summary of the certificate requirements for each dental anesthesia certificate in guidance. The Department does not regulate minimal sedation or anxiolysis. Thus, the suggested comparison is unwarranted. The proposed regulation explains the type of ventilation monitoring that is required for each level/type of sedation. If the Department determines that there is a need for additional information regarding the type of ventilation monitoring that is required for each level/type of sedation, it may consider providing such additional information through guidance.

ACLS and PALS are specific courses which train healthcare providers how to react in specific situations. The course content includes, but, is not limited to, CPR and use of the AEDs, physiology, ventilation, pharmacology and airway management. The initial coursework in each of these courses ranges from 10-14 hours. Dentists who treat patients 12 and younger must take both ACLS and PALS in order to qualify for a

certificate. The airway management course is 5 hours. It is the opinion of the Department that most of the information in the 5 hour airway course will be covered in the 10-14 hours of ACLS and PALS courses.