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] druginduced 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) <u>dental parenteral conscious (moderate) sedation for patients 12 years old and younger, which authorizes a licensed dentist to employ conscious (moderate) sedation</u>

 (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 <u>dental</u> general anesthesia; [and] <u>dental</u> parenteral <u>conscious</u> sedation and [to administer] <u>dental</u> [parenteral] <u>enteral conscious</u> sedation [for parenteral conscious sedation] only which were issued prior to January 1, [2001] <u>2018</u> 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.] <u>submit an application to the department for renewal of his or her certificate pursuant to the applicable requirements set forth in this section:</u>
- [(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] <u>advanced cardiac</u> life support ([BLS] <u>ACLS</u>), 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 <u>basic life support</u> (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 quardian, 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 <u>anesthesia/</u>sedation techniques for the renewal of a certification to <u>administer conscious</u> (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 <u>subdivision (f) of section 61.15[f]</u> 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.