

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 210.000: THE ADMINISTRATION OF MEDICATIONS IN PUBLIC AND NON-PUBLIC SCHOOLS

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210.001: Purpose

The purpose of 105 CMR 210.000 is to provide minimum standards for the safe and proper storage and administration of medications to students in the Commonwealth's public and non-public primary and secondary schools. 105 CMR 210.000 permits school nurses to delegate responsibility for administration of medications to trained, nursing-supervised unlicensed school personnel, provided the school district or non-public school registers with the Department of Public Health. The aim of 105 CMR 210.000 is to ensure that students requiring medication administration during regular school activities will be able to attend school and to ensure that medications are safely administered and stored in schools. 105 CMR 210.000 encourages collaboration between caregivers, health care providers, and the school in this effort.

210.002: Definitions

As used in 105 CMR 210.000, the following words, unless the context clearly requires otherwise, shall have the following meanings:

Administration of Medication means the direct application of a medication by inhalation, ingestion, or by any other means to the body of a person.

Caregiver means a parent or guardian of a student.

Controlled Substance shall have the meaning as defined in M.G.L. c. 94C, § 1.

Cumulative Health Record means the collection of an individual student's medical documentation relevant to the health of the student maintained by a school or school district which may include historical and ongoing medications, applicable diagnosis information, allergies and other relevant medical conditions, immunization records, health screenings, health office visits notes, and contact information for the student's health care providers. The records may be maintained in a paper or electronic format or a combination of both.

Delegation shall have the meaning as defined in 244 CMR 10.01: *Definitions*. The delegating nurse must provide adequate supervision of all nursing activities delegated to unlicensed persons. Delegation is the most common model under which unlicensed school personnel can administer medications in schools.

Department means the Massachusetts Department of Public Health.

Drug shall have the meaning as defined in M.G.L. c. 94C, § 1.

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Emergency Rescue Medication means a schedule II-VI medication which is administered in the event of an allergic reaction, hypoglycemia, apparent opioid overdose, asthma or other loss of consciousness and/or acute respiratory event, in order to prevent imminent death or serious injury or illness. Examples may include, but are not limited to:

- (1) epinephrine in an FDA-approved, pre-dosed auto-injector or FDA-approved, pre-dosed forms that are administered through the mucous membranes of the nose, digestive tract, or lungs;
- (2) opioid antagonists in an FDA-approved, pre-dosed auto-injector or FDA-approved, pre-dosed forms that are administered through the mucous membranes of the nose, digestive tract, or lungs;
- (3) glucagon in an FDA-approved, pre-dosed auto-injector or FDA-approved, pre-dosed forms that are administered through the mucous membranes of the nose, digestive tract, or lungs;
- (4) atropine, pralidoxime chloride or other designated nerve agent antidotes that are in an FDA-approved, pre-dosed form;
- (5) rescue inhalers; and
- (6) other medications in FDA-approved, pre-dosed forms that are administered through the mucous membranes of the nose, digestive tract, or lungs.

Investigational New Drug means any medication with an approved investigational new drug (IND) application on file with the Food and Drug Administration (FDA) which is being scientifically tested and clinically evaluated to determine its efficacy, safety and side effects and which has not yet received FDA approval.

Licensed Practical Nurse means an individual who is a graduate of an approved practical nursing program, and who is currently licensed as a practical nurse pursuant to M.G.L. c. 112.

Licensed Prescriber means a health care provider who is legally authorized to prescribe medication pursuant to M.G.L. c. 94C and applicable federal laws and regulations.

Medical Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory for use as outlined in 21 U.S.C. § 321.

Medication means any controlled substance in schedules II-VI or FDA-approved over-the-counter medication with a drug fact sheet.

Medication Program Manager means a School Nurse that has assumed responsibility for a school or district medication program by registering with the Department of Public Health.

Parenteral Medication means any medication administered in a manner other than by the digestive tract or topical application, as by intravenous, intramuscular, subcutaneous, or intradermal injection.

Physician means a doctor of medicine or osteopathy licensed to practice medicine in Massachusetts or in another state.

Pro re nata (abbreviated p.r.n.) means "as needed."

Regular School Activities means all instructional/academic activities, as well as all activities organized or sanctioned by the school including, but not limited to, day and overnight field trips, school-provided transportation, interscholastic sporting events, after school or extracurricular clubs or organizations, and proms or other social events organized as part of the instructional/academic portion of the school.

School Nurse means a nurse practicing in a school setting, who is:

- (1) a graduate of an approved school for professional nursing;
- (2) currently licensed as a Registered Nurse pursuant to M.G.L. c. 112; and
- (3) appointed by a School Committee or a Board of Health in accordance with M.G.L. c. 71, §§ 53, 53A, and 53B or, in the case of a non-public school, by the governing body.

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School Physician means a physician appointed by a School Committee or Board of Health in accordance with M.G.L. c. 71, §§ 53, 53A, and 53B or, in the case of a non-public school, by the governing body.

Self-administration shall have the meaning as defined in 105 CMR 700.001: *Definitions*.

Self-carry means storage of limited quantities of medications including, as appropriate, multi-dose medications on a student's person, at the discretion of the school nurse, as outlined in 105 CMR 210.006.

Supervision means guidance by a qualified school nurse, provided through any communication medium, to accomplish a task, with initial direction and instruction concerning the task and periodic inspection and oversight of activities related to the task.

Unlicensed School Personnel means any individual employed by or through contract with the school committee or in the case of a non-public school, by the governing body, who does not hold a healthcare license in Massachusetts that authorizes the licensee to administer medications.

210.003: Policies Governing the Administration of Medications in Schools

(A) The School Committee or governing body, consulting with the Board of Health where appropriate, shall adopt policies and procedures governing the administration of medications and self-administration of medications within the school system, following development of a proposal by the medication program manager, in consultation with the school physician. Review and revision of such policies and procedures shall occur as needed but at least every two years. At a minimum, these policies shall include:

- (1) designation of a medication program manager as supervisor of the medication administration program in a school;
- (2) documentation of the administration of medications;
- (3) response to a medication emergency;
- (4) storage of medications;
- (5) reporting and documentation of medication errors;
- (6) dissemination of information to caregivers. Such information shall include an outline of a school's medication policies and shall be available to caregivers upon request;
- (7) procedures for resolving questions between the school and a caregiver regarding administration of medications. Such procedures shall provide for and encourage the participation of the caregiver. Existing procedures for resolution of differences may be used whenever appropriate.

(B) The School Committee or governing body shall submit these policies and procedures to the Department of Public Health upon request.

(C) All schools/districts where medication is stored or where medication administration is delegated to unlicensed school personnel must obtain a Massachusetts Controlled Substances Registration by registering with the Department of Public Health. At minimum, schools/districts may accomplish this by registering for emergency medication training.

(D) Schools/districts are not authorized to make use of 105 CMR 700.003(C) for the administration of emergency rescue medications during regular school activities.

(E) Schools/districts that hold a Massachusetts Controlled Substances Registration may purchase stock prescription medications not prescribed to an individual as permitted by the Drug Control Program.

210.004: Policies Regarding Delegation of Medication Administration

(A) The School Committee, Board of Health, or governing body may develop a policy that allows the school nurse to delegate responsibility to unlicensed school personnel for medication administration.

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- (1) For the purpose of administering emergency medication to an individual student, including parenteral administration of medication pursuant to 105 CMR 210.004(A)(4), the school nurse may identify individual unlicensed school personnel who may be trained pursuant to 105 CMR 210.007 or 105 CMR 210.010, in the case of epinephrine, or 105 CMR 210.011, in the case of an emergency rescue opioid antagonist. Said unlicensed school personnel shall be listed on the medication administration plan developed in accordance with 105 CMR 210.005(E) and receive education in the administration of emergency medication to a specific student.
- (2) An individual selected by the school nurse may be authorized to administer medication if they meet the following criteria:
 - (a) demonstrates sound judgment;
 - (b) is able to read and write in the language in which the medication order is written;
 - (c) is able to communicate with the school nurse orally and in writing;
 - (d) is able to communicate with the student receiving the medication or has ready access to an interpreter when needed;
 - (e) is able to meet the requirements of 105 CMR 210.000 and follow nursing supervision;
 - (f) is able to respect and protect the student's confidentiality; and
 - (g) has completed an approved training program pursuant to 105 CMR 210.007 or completed an approved training program pursuant to 105 CMR 210.010 in the case of epinephrine.
- (3) A school nurse shall be on duty while medications are being administered by designated unlicensed school personnel, and be available should consultation be required. The consultation may be in person or virtual (telephonic or web-based).
- (4) Parenteral medications may not be delegated or administered by training, with the exception of epinephrine or injectable glucagon in an FDA-approved, pre-dosed autoinjector administered in accordance with the restrictions outlined in 105 CMR 210.000.
- (5) With the exception of emergency rescue medications, which may be administered under the delegation model according to the student's emergency medication plan without a separate nursing assessment, medications to be administered pursuant to p.r.n. orders may be administered by authorized unlicensed school personnel after an assessment by or consultation with the school nurse for each dose.
- (6) Neither prescription medication nor over-the-counter medications can be administered by delegation by unlicensed school personnel without student-specific medication orders from a licensed prescriber.
- (7) The name of the unlicensed school personnel administering medication by delegation must be identified in the student health record.

210.005: Responsibilities of the School Nurse Regarding Medication Administration

- (A) The medication program manager, in consultation with the school physician and the School Wellness/Health Advisory Committee, if established pursuant to 105 CMR 215.000: *Standards for School Wellness Advisory Committees*, shall develop policies and procedures consistent with 105 CMR 210.000 for approval by the School Committee or governing body, in consultation with the Board of Health where appropriate.
- (B) The medication program manager shall have responsibility for the development and management of the medication administration program. Such responsibility shall be delineated in policies and procedures adopted by the School Committee or governing body, in consultation with the Board of Health where appropriate.
- (C) The school nurse, in consultation with the school physician, shall have final decision-making authority with respect to delegating and training on administration of medications to unlicensed school personnel consistent with the requirements established in this regulation and in Board of Registration in Nursing regulations, 244 CMR 3.00: *Registered Nurse and Licensed Practical Nurse*.

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(D) Medication Orders.

(1) The school nurse shall ensure that there is a proper medication order from a licensed prescriber which is renewed at the beginning of each academic year and as clinically necessary. A telephone order or an order for any change in medication shall be received only by the school nurse. Any verbal order must be followed by a written or electronic order within three school days. Whenever possible, the medication order shall be obtained, and the medication administration plan specified in 105 CMR 210.005(E) shall be developed before the student enters or re-enters school.

(a) In accordance with standard medical practice, a medication order from a licensed prescriber shall contain:

1. the student's name;
2. the name and signature of the licensed prescriber and business and emergency phone numbers;
3. the name, route and dosage of medication;
4. the frequency and time of medication administration;
5. the date of the order;
6. a diagnosis and any other medical condition(s) requiring medication, if not a violation of confidentiality or if not contrary to the request of a caregiver or student to keep confidential;
7. specific directions for administration.

(b) Every effort shall be made to obtain from the licensed prescriber the following additional information, as appropriate:

1. any student-specific side effects, contraindications and adverse reactions to be observed;
2. any other medications being taken by the student;
3. the date of return visit, if applicable.

(2) Special Medication Situations.

(a) For short-term medications, *i.e.*, those requiring administration for ten school days or fewer, the pharmacy-labelled container may be used in lieu of a licensed prescriber's order. If the school nurse has a question, they may request a licensed prescriber's order.

(b) For "over-the-counter" medications, *i.e.*, non-prescription medications, the school nurse shall follow the Board of Registration in Nursing's Advisory Ruling 92-05: *Medication Administration of Over the Counter Drugs*.

(c) For medications administered under a standing order, the school nurse shall follow the Board of Registration in Nursing's Advisory Ruling 9324: *Accepting, Verifying, Transcribing and Implementing Medication Orders*. Unlicensed school personnel can only administer a medication under a standing order that is specific to an individual patient (with the exception of an emergency rescue opioid antagonist) and under the delegation model.

(d) Investigational new drugs may be administered in the schools with:

1. a written order by a licensed prescriber;
2. written consent of the caregiver; and
3. a pharmacy-labelled container for dispensing. If there is a question, the school nurse may seek consultation and/or approval from the school physician to administer the medication in a school setting.

(3) The school nurse shall ensure that there is a written authorization by the caregiver which contains:

- (a) the caregiver's printed name and signature and phone number;
- (b) a list of all medications the student is currently receiving, if not a violation of confidentiality or contrary to the request of the caregiver or student that such medication not be documented;
- (c) approval to have the school nurse or unlicensed school personnel designated by the school nurse administer the medication;
- (d) persons to be notified in case of a medication emergency if the caregiver is unavailable.

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(E) Medication Administration Plan: The school nurse, in collaboration with the caregiver whenever possible, shall establish a medication administration plan for each student receiving a medication. Whenever possible, a student who understands the issues of medication administration shall be involved in the decision-making process and their preferences respected to the maximum extent possible. If appropriate, the medication administration plan shall be referenced in any other health or educational plan developed pursuant to St. 1972, c. 766 the Massachusetts Special Education Law (Individual Education Plan under Chapter 766) or federal laws, such as the Individuals with Disabilities Education Act (IDEA) or Section 504 of the Rehabilitation Act of 1973.

(1) Prior to the initial administration of the medication, the school nurse shall assess the student's health status and develop a medication administration plan which includes:

- (a) the name of the student;
- (b) a medication order from a licensed prescriber, which meets the requirements of 105 CMR 210.005(D)(1);
- (c) the signed authorization of the caregiver, which meets the requirements of 105 CMR 210.005(D)(3);
- (d) any known allergies to food or medications;
- (e) the diagnosis, unless a violation of confidentiality or the caregiver or student requests that it not be documented;
- (f) any possible side effects, adverse reactions or contraindications;
- (g) the quantity of medication to be received by the school from the caregiver;
- (h) the required storage conditions;
- (i) the duration of the medication order;
- (j) the designation of unlicensed school personnel, if any, who will administer the medication to the student in the absence of the school nurse, and plans for back-up if the designated personnel are unavailable;
- (k) plans, if any, for teaching self-administration of the medication;
- (l) with caregiver permission, other persons, including teachers, to be notified of medication administration and possible adverse effects of the medication;
- (m) when appropriate, the location where the administration of the medication will take place;
- (n) a plan for monitoring the effects of the medication;
- (o) the school nurse has final decision-making authority for the provision of medication administration in the case of field trips and other short-term special school events, which may include nursing staffing, delegation of medication administration, or a combination of nursing staffing and delegation of medication administration.

(F) Developing Procedures for Administration of Medications.

(1) The medication program manager shall develop procedures for the administration of medications which shall include the following:

- (a) A procedure to ensure the positive identification of the student who receives the medication;
- (b) A system for documentation and record-keeping which meets the requirements of 105 CMR 210.009.

(2) The medication program manager shall develop a system of documenting observations by the school nurse or unlicensed school personnel and communicating significant observations relating to medication effectiveness and adverse reactions or other harmful effects to the student's caregiver and/or licensed prescriber;

(3) The medication program manager shall develop and implement procedures regarding receipt and safe storage of medications in accordance with 105 CMR 210.008;

(4) The medication program manager shall develop procedures for responding to medication emergencies, *i.e.*, any reaction or condition related to administration of medication which poses an immediate threat to the health or well-being of the student. This includes maintaining a list of persons, with their phone numbers, to be contacted as appropriate, in addition to the caregiver, school nurse, licensed prescriber and other persons designated in the medication administration plan. Such persons may include other unlicensed school personnel, the school physician, clinic or emergency room staff, ambulance services and the local poison control center;

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(5) The medication program manager shall develop procedures and forms for documenting and reporting medication errors. The procedures shall specify persons to be notified in addition to the caregiver and school nurse, including the licensed prescriber or school physician if there is a question of potential harm to the student. A medication error includes any failure to administer medication as prescribed for a particular student, including failure to administer the medication:

- (a) within appropriate time frames;
- (b) in the correct dosage;
- (c) in accordance with accepted practice; and
- (d) to the correct student.

(6) The medication program manager shall develop procedures to review reports of medication errors and take necessary steps to ensure appropriate medication administration in the future.

(G) Delegation/Supervision. When a School Committee or governing body, in consultation with the Board of Health where appropriate, has registered with the Department of Public Health and authorized unlicensed school personnel to administer medications, such personnel shall be under the supervision of the school nurse for the purposes of 105 CMR 210.000. The School Committee or governing body, in consultation with the Board of Health where appropriate, shall provide assurance that sufficient school nurse(s) are available to provide proper supervision of unlicensed school personnel. Responsibilities for supervision, at a minimum, shall include the following:

(1) After consultation with the principal or administrator responsible for a given school, the school nurse shall select, train and supervise the specific individuals who may administer medications. When necessary to protect student health and safety, the school nurse may rescind such selection.

(2) The number of unlicensed school personnel to whom responsibility for medication administration may be delegated is to be determined by:

- (a) the number of unlicensed school personnel the school nurse can adequately supervise, as determined by the school nurse; and
- (b) the number of unlicensed school personnel necessary, in the school nurse's judgment, to ensure that the medications are properly administered to each student.

(3) The school nurse shall support and assist persons who have completed the training specified in 105 CMR 210.007 to prepare for and implement their responsibilities related to the administration of medication.

(4) The first time that an unlicensed school personnel administers medication, the delegating school nurse shall provide supervision at the work site. In extenuating circumstances, as determined by the school nurse, the skills competency for p.r.n. emergency rescue medications administered through inhalation or through the mucous membranes of the nose, digestive tract, or lungs (such as inhalers and nasal preparations of glucagon and diazepam) or, in the case of injectable glucagon, an FDA-approved, pre-dosed autoinjector, may be demonstrated without administration of the medication to the student. When a p.r.n. emergency rescue medication is administered, the medication plan shall address notification of the local emergency medical services system, followed by notification of the student's caregiver.

(5) The degree of supervision required for each student shall be determined by the school nurse after an evaluation of the appropriate factors involved in protecting the student's health including, but not limited to, the following:

- (a) health condition and ability of the student;
- (b) the extent of training and capability of the unlicensed school personnel to whom the medication administration is delegated;
- (c) the type of medication; and
- (d) the proximity and availability of the school nurse to the unlicensed school personnel who is performing the medication administration.

(6) For the individual student, the school nurse shall:

- (a) determine whether or not it is medically safe and appropriate to delegate medication administration;
- (b) administer the first dose of the medication, if:
 - 1. there is reason to believe there is a risk to the student as indicated by the health assessment; or

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2. the student has not previously received this medication in any setting. In extenuating circumstances, as determined by the school nurse, p.r.n. emergency rescue medications administered through inhalation or through the mucous membranes of the nose, digestive tract, or lungs (such as inhalers and nasal preparations of glucagon and diazepam) or, in the case of injectable glucagon, an FDA-approved, pre-dosed autoinjector, are not required to be administered previously. When a p.r.n. emergency rescue medication is administered, the medication plan shall address notification of the local emergency medical services system, followed by notification of the student's caregiver;
 - (c) review the initial orders, possible side effects, adverse reactions and other pertinent information with the unlicensed school personnel to whom medication administration has been delegated;
 - (d) provide supervision and consultation as needed to ensure that the student is receiving the medication appropriately. Supervision and consultation may include record review, on-site observation and/or assessment;
 - (e) review all documentation pertaining to the delegation of medication administration on a weekly basis or more often if necessary.
- (H) In accordance with standard nursing practice, the school nurse may refuse to administer or allow to be administered any medication which, based on their individual assessment and professional judgment, has the potential to be harmful, dangerous or inappropriate. In these cases, the caregiver and licensed prescriber shall be notified immediately by the school nurse.
- (I) For the purposes of 105 CMR 210.000, a Licensed Practical Nurse may not delegate the administration of medications to unlicensed school personnel.
- (J) The school nurse shall have access to current, peer-reviewed medication references.

210.006: Self-administration and Self-carry of Medications

Consistent with school policy, the school nurse may permit self-carry and self-administration of medication by a student provided that the following requirements are met:

- (1) the student, school nurse and caregiver, where appropriate, enter into an agreement which specifies the conditions under which medication may be self-administered, which may include the conditions under which a student may self-carry medication for the purpose of administration by another, or whether the medication being self-administered is being taken or applied by the student themselves or with an FDA-approved medical device;
- (2) the school nurse, as appropriate, develops a medication administration plan pursuant to 105 CMR 210.005(E) which contains only those elements necessary to ensure safe self-administration of medication;
- (3) the school nurse evaluates the student's health status and abilities and deems self-administration safe and appropriate. As necessary, the school nurse shall observe initial self-administration of the medication;
- (4) the school nurse is reasonably assured that the student is able to identify the appropriate medication, knows the frequency and time of day for which the medication is ordered, and follows the school self-administration protocols;
- (5) there is written authorization from the student's caregiver that the student may self-administer medication, unless the student has consented to treatment under M.G.L. c. 112, § 12F or other authority permitting the student to consent to medical treatment without caregiver permission;
- (6) if requested by the school nurse, the licensed prescriber provides a written order for self-administration;
- (7) the school nurse establishes a plan for the safe storage of self-administered medication and, as necessary, consults with teachers, the student and caregiver, if appropriate, to determine a safe place for storing the medication for the individual student, while providing for accessibility if the student's health needs require it. This may include self-carry of the medication and this information shall be included in the medication administration plan. In the case of an inhaler or other preventive or emergency medication, whenever possible, a backup supply of the medication shall be kept in the health room or a second readily available location;

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- (8) the school nurse develops and implements a plan to monitor the student's self-administration, based on the student's abilities and health status. Monitoring may include teaching the student the correct way of taking the medication, and notifying the caregiver or licensed prescriber of any side effects, variation from the plan, or the student's refusal or failure to take the medication;
- (9) with caregiver and student permission, if required by law, as appropriate, the school nurse may inform appropriate teachers and administrators that the student is self-administering and/or self-carrying a medication.

210.007: Training of Unlicensed School Personnel Responsible for Administering Medications

- (A) Any unlicensed school personnel administering medication must be properly trained and supervised by a school nurse.
- (B) Training shall be provided under the direction of the school nurse.
- (C) At a minimum, the training program shall include content standards and a test of competency developed and approved by the Department of Public Health in consultation with the Board of Registration in Nursing and practicing school nurses.
- (D) Personnel designated to administer medications shall be provided with the names and locations of unlicensed school personnel who have documented certification in cardiopulmonary resuscitation. Schools should make every effort to have a minimum of two school staff members with documented certification in cardiopulmonary resuscitation present in each school building throughout the day.
- (E) The school nurse shall document the training and evidence of competency of unlicensed school personnel designated to assume the responsibility for medication administration.
- (F) The school nurse shall provide a training review and informational update at least annually for those unlicensed school personnel authorized to administer medications.
- (G) The requirements for training specific to the administration of epinephrine and the administration of an emergency rescue opioid antagonist by unlicensed school personnel are outlined in 105 CMR 210.010 and 105 CMR 210.011 respectively.

210.008: Handling, Storage and Disposal of Medications

- (A) A caregiver or caregiver-designated responsible adult shall deliver all medications to be administered by school personnel or to be taken by self-administering students, if required by the self-administration agreement 105 CMR 210.006, to the school nurse or other person designated and trained by the school nurse to receive medication.
 - (1) The medication must be in a pharmacy or manufacturer labelled container specific to that medication.
 - (2) The school nurse or other trained person receiving the medication shall document the quantity of the medication delivered.
 - (3) In extenuating circumstances, as determined by the school nurse, the medication may be delivered by other persons or a licensed pharmacy; provided, however, that the school nurse is notified in advance by the caregiver of the arrangement and the quantity of medication being delivered to the school.
- (B) All medications shall be stored in their original pharmacy or manufacturer labelled containers and in such manner as to render them safe and effective.

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- (C) All medications to be administered by school personnel shall be kept in a securely locked cabinet used exclusively for medications, which is kept locked except when opened to obtain medications. The cabinet shall be substantially constructed and anchored securely to a solid surface. Medications requiring refrigeration shall be stored in either a locked box in a refrigerator or in a locked refrigerator maintained at temperatures between 36°F (2°C) to 46°F (8°C). Medications requiring freezer storage shall be stored in either a locked box in a freezer or in a locked freezer maintained at temperatures between -13°F (-25°C) to 14°F (-10°C).
- (D) Access to stored medications shall be limited to persons authorized to administer medications and to self-medicating students, to the extent permitted by school policy developed pursuant to 105 CMR 210.006(7). Access to keys and knowledge of the location of keys shall be restricted to the maximum extent possible. Students who are self-medicating shall not have access to other students' medications.
- (E) Caregivers may retrieve the medications from the school at any time.
- (F) No more than a 30-school-day supply of the medication for a student shall be stored at the school, with the exception of multidose devices, which may contain more than a 30-day supply.
- (G) Where possible, all unused, discontinued or outdated medications shall be returned to the caregiver and the return appropriately documented. In extenuating circumstances, with caregiver consent when possible, such medications may be destroyed by the school nurse in accordance with any applicable policies of the Massachusetts Department of Public Health, Drug Control Program.

210.009: Documentation and Record-keeping

- (A) Each school where medications are administered by school personnel shall maintain a medication administration record for each student who receives medication during school hours.
 - (1) Such record at a minimum shall include a daily log and a medication administration plan, including the medication order and caregiver authorization.
 - (2) The medication administration plan shall include the information as described in 105 CMR 210.005(E).
 - (3) The daily log shall contain:
 - (a) the dose or amount of medication administered;
 - (b) the date and time of administration or omission of administration, including the reason for omission and action taken post omission;
 - (c) a mechanism for identifying the person administering each dose.
 - (4) The school nurse shall document in the medication administration record significant observations of the medication's effectiveness, as appropriate, and any adverse reactions or other harmful effects, as well as any action taken.
 - (5) All documentation shall be recorded in a manner that prevents alteration or destruction of the record.
 - (6) With the consent of the caregiver, or student where appropriate, the completed medication administration record and records pertinent to self-administration shall be filed in the student's cumulative health record. When the caregiver or student, where appropriate, objects, these records shall be regarded as confidential medical notes and shall be kept confidential, except as provided in 105 CMR 210.000.
- (B) Medication errors, as defined in 105 CMR 210.005(F)(5), shall be documented by the school nurse on the school/district's accident/incident report form and in the student's health record. These reports shall be retained in a location as determined by school policy and made available to the Department of Public Health upon request. All suspected diversion or tampering of drugs shall be reported to the Department of Public Health, Drug Control Program. All medication errors requiring medical care or ongoing assessment shall be reported as instructed to the Department of Public Health.

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(C) The school district shall comply with the Department of Public Health's reporting requirements for medication administration in the schools.

(D) The Department of Public Health may inspect any individual student medication record or record relating to the administration or storage of medications without prior notice to ensure compliance with 105 CMR 210.000.

210.010: Administration of Epinephrine

(A) A public school district or non-public school, as defined by the Massachusetts Department of Elementary and Secondary Education, may register with the Department for the limited purpose of permitting properly trained unlicensed school personnel to administer any available, FDA-approved, pre-dosed form of epinephrine (hereafter, any available, FDA-approved, pre-dosed form of epinephrine will be referred to solely as epinephrine for the purposes of 105 CMR 210.010) in a life-threatening situation during regular school activities when a school nurse is not immediately available, including field trips, provided that the following conditions are met:

(1) the school committee or governing body approves policies developed by the medication program manager governing administration of epinephrine. This approval must be renewed every year;

(2) the school committee or governing body provides an assurance to the Department that the requirements of 105 CMR 210.000 will be met through registration with the Department;

(3) in consultation with the school physician, the medication program manager oversees and has final decision-making authority about the epinephrine program;

(4) the unlicensed school personnel authorized to administer epinephrine are trained and evaluated by the medication program manager, or school nurses designated by this person, in accordance with standards and a curriculum established by the Department.

(a) The medication program manager, or school nurses designated by this person, shall document the training and evaluation of competency.

(b) The medication program manager, or a designee, shall provide a training review and informational update at least twice a year.

(c) The training, at a minimum, shall include:

1. procedures for risk reduction.
2. recognition of the symptoms of a severe allergic reaction;
3. the importance of following the medication administration plan;
4. proper use of the administration device; and
5. requirements for proper storage and security, notification of appropriate persons following administration, and record keeping.

(d) The school shall maintain and make available upon request by caregivers or staff documentation of those unlicensed school personnel authorized and trained to administer epinephrine in an emergency, when the school nurse is not immediately available;

(5) epinephrine given by unlicensed school personnel shall be administered only in accordance with an individualized medication administration plan satisfying the applicable requirements of 105 CMR 210.005(E) and 210.009(A)(6), updated every year, which includes the following:

(a) a diagnosis by a licensed prescriber that the student is at risk of a life-threatening allergic reaction and a medication order containing proper dosage and indications for administration of epinephrine;

(b) written authorization by a caregiver;

(c) phone number for the caregiver, as well as the names(s) and phone number(s) of any other person(s) to be notified if the caregiver is unavailable;

(d) identification of places where the epinephrine is to be stored, following consideration of the need for storage:

1. at one or more places where the student may be most at risk;
2. in such a manner as to allow rapid access by authorized persons, including possession by the student when appropriate; and
3. in a place accessible only to authorized persons. The storage location(s) should be secure, but not locked during those times when epinephrine is most likely to be administered, as determined by the school nurse;

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- (e) documentation of the unlicensed school personnel who would administer the epinephrine to the student in a life-threatening situation when a school nurse is not immediately available;
 - (f) a plan for comprehensive risk reduction for the student, including preventing exposure to specific allergens; and
 - (g) an assessment of the student's readiness for self-administration and training, as appropriate.
- (6) when epinephrine is administered, there shall be immediate notification of the local emergency medical services system (generally 911), followed by notification of the student's caregiver. If epinephrine is administered by unlicensed school personnel, the school nurse, and other individuals as warranted and deemed appropriate by the school nurse, must also be notified;
- (7) there shall be procedures, in accordance with any standards established by the Department, for:
- (a) developing the medication administration plan;
 - (b) developing general policies for the proper storage of medication, including limiting access to persons authorized to administer the medication and returning unused or outdated medication to a caregiver whenever possible;
 - (c) recording receipt and return of medication by the school nurse;
 - (d) documenting the date and time of administration;
 - (e) notifying appropriate parties of administration and documenting such notification;
 - (f) reporting medication errors in accordance with 105 CMR 210.005(F)(5);
 - (g) reviewing any incident involving administration of epinephrine to determine the adequacy of the response and to consider ways of reducing risks for the particular student and the student body in general;
 - (h) planning and working with the emergency medical system to ensure the fastest possible response;
 - (i) disposing properly of used or expired epinephrine administration devices;
 - (j) submitting the Department of Public Health Epinephrine Administration Report to the Department of Public Health each time epinephrine is administered to a student or staff, in accordance with 105 CMR 210.009(C); and
 - (k) permitting the Department of Public Health to inspect any record related to the administration of epinephrine without prior notice, to ensure compliance with 105 CMR 210.010.

(B) Epinephrine may be administered in accordance with 105 CMR 210.000 in before and after school programs offered or provided by a school, such as athletic programs, special school events and school-sponsored programs on weekends, provided that the public school district or non-public school is registered with the Department pursuant to 105 CMR 210.010(A) and meets the requirements set forth in 105 CMR 210.010(B).

- (1) Epinephrine may be administered in such before and after school programs and special events, to students attending the school where the epinephrine is to be administered, provided that the following requirements in 105 CMR 210.010(B)(1)(a) through (d) are met:
- (a) school committee or governing body approves, in the policy developed in accordance with 105 CMR 210.010(A)(1), administration of epinephrine in such programs. The policy shall identify the school official(s), along with a school nurse for each school designated by the medication program manager, responsible for determining which before and after school programs and special events are to be covered by the policy;
 - (b) the designated school nurse approves administration of epinephrine in that program and selects the properly trained person(s) to administer the epinephrine;
 - (c) the school complies with the requirements of 105 CMR 210.010(A), including immediate notification of emergency medical services following administration of epinephrine, but need not comply with the requirement of 105 CMR 210.004(A)(3); and
 - (d) the program is not licensed by another state or municipal agency, in which case the regulations promulgated by that agency will apply.

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(2) Epinephrine may be administered in such before and after school programs and special events to students from another school or school district if approved in the school policy developed pursuant to 105 CMR 210.010(A)(1) and in accordance with the requirements in 105 CMR 210.010(B)(2)(a) through (d).

(a) The school complies with the requirements of 105 CMR 210.010(A) and 210.010(B)(1), including immediate notification of emergency medical services following administration of epinephrine, except as provided in 105 CMR 210.010(B)(2)(d).

(b) In the event the student is accompanied by unlicensed school personnel from the sending school, such personnel, whenever possible, shall assume responsibility for ensuring that the epinephrine is brought, properly stored and administered as necessary, in accordance with the medication administration plan developed by the sending school in accordance with 105 CMR 210.010(A)(5).

(c) In the event the student is not accompanied by unlicensed school personnel from the sending school or such personnel are not trained in the administration of epinephrine, the receiving school may, at its discretion, assume responsibility for administering epinephrine, provided that:

1. the designated school nurse in the receiving school is provided with adequate prior notice of the request, which is at the discretion of the designated school nurse in the receiving school;
2. as appropriate the designated school nurse selects properly trained person(s) to administer the epinephrine; and
3. the student provides the epinephrine to be administered.

(d) If the receiving school assumes responsibility for administering epinephrine, whenever possible, the sending school may, with proper consent, provide the designated school nurse in the receiving school with copy of the medication administration plan developed in accordance with 105 CMR 210.005(E). The medication administration plan shall be provided to the receiving school nurse prior to the event, if possible, or on the day of the event. If no medication administration plan is provided, the student at a minimum shall provide to the designated school nurse in the receiving school:

1. written authorization and emergency phone numbers from a caregiver;
2. a copy of a medication order from a licensed provider; and
3. any specific indications or instructions for administration.

(C) Administration and storage of epinephrine shall be governed solely by 105 CMR 210.010.

210.011: Administration of Emergency Rescue Opioid Antagonist

(A) A public school district or non-public school, as defined by the Massachusetts Department of Elementary and Secondary Education, may register with the Department for the limited purpose of permitting properly trained unlicensed school personnel to administer any available, FDA-approved, pre-dosed form of an emergency rescue opioid antagonist (hereafter, any available, FDA-approved, pre-dosed form of an emergency rescue opioid antagonist will be referred to solely as an emergency rescue opioid antagonist for the purposes of 105 CMR 210.011) in a life-threatening situation during regular school activities when a school nurse is not immediately available, including field trips, provided that the following conditions are met:

- (1) the school committee or governing body approves policies developed by the medication program manager governing administration of an emergency rescue opioid antagonist. This approval must be renewed every year;
- (2) the school committee or governing body provides an assurance to the Department that the requirements of 105 CMR 210.000 will be met through registration with the Department;
- (3) in consultation with the school physician, the medication program manager oversees and has final decision-making authority about the emergency rescue opioid antagonist program;
- (4) the unlicensed school personnel authorized to administer an emergency rescue opioid antagonist are trained by the school nurse, or a training provider designated by the school nurse, in accordance with standards established by the Department;

(a) the training, at a minimum, shall include:

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1. recognition of the symptoms of an opioid overdose; and
 2. proper use of the administration method.
 - (b) the medication program manager, or school nurses designated by this person, shall document the training and evaluation of competency.
 - (c) the school shall maintain and make available upon request by caregivers or staff documentation of those unlicensed school personnel authorized and trained to administer an emergency rescue opioid antagonist when the school nurse is not immediately available.
 - (5) when an emergency rescue opioid antagonist is administered:
 - (a) there shall be immediate notification of the local emergency medical services system (generally 911), followed by notification of a student's caregiver as appropriate, the school nurse, and other individuals as warranted and deemed appropriate by the school nurse; and
 - (b) the medication program manager will report the administration of an emergency rescue opioid antagonist to the Department of Public Health as directed each time an emergency rescue opioid antagonist is administered during regular school activities, in accordance with 105 CMR 210.009(C).
 - (6) all school staff, regardless of licensure, should follow a medication order for the administration of an emergency rescue opioid antagonist; and
 - (7) identification of places where the opioid antagonist is to be stored, following consideration of the need for storage:
 - (a) at one or more places students and visitors are most likely to be located;
 - (b) in such a manner as to allow rapid access by trained persons, including possession by the student when appropriate; and
 - (c) in a place that minimizes risk of unintended use. The storage location(s) should be secure but not locked.
- (B) Any individual, including unlicensed school personnel, may carry and administer an emergency rescue opioid antagonist on school grounds or at school events, as permitted by the statewide standing order and within M.G.L. c. 94C, §§ 19(d) and 34A(e).
- (C) Administration and storage of an emergency rescue opioid antagonist in schools shall be governed by 105 CMR 210.011.

210.015: Waiver of Requirements Imposed on Entities Administering Medications under 105 CMR 210.000

- (A) The Commissioner may issue a waiver of one or more of the requirements imposed through 105 CMR 210.000 upon a finding that:
- (1) compliance would cause undue hardship to the public school district or non-public school;
 - (2) the public school district or non-public school's noncompliance does not jeopardize the health or safety of individuals or the public;
 - (3) the public school district or non-public school is in substantial compliance with the spirit of the regulations and has instituted compensating measures that are acceptable to the Commissioner; and
 - (4) the public school district or non-public schools provides to the Commissioner, or their designee, written documentation supporting its request for a waiver.

210.017: Inspection

- (A) Inspections. The Department may visit a school storing or administering medications and may request documentation from such school to determine compliance with state law and regulations.
- (B) Statement of Deficiencies. After an inspection conducted pursuant to 105 CMR 210.017(A) in which any violation of law or regulation is observed, the Department shall prepare a deficiency statement, a copy of which shall be sent to the medication program manager, the school principal or headmaster, and the district superintendent.

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(C) Plans of Correction. A school that has received a deficiency statement pursuant to 105 CMR 210.017(B) shall submit to the Department a written plan of correction of each violation cited in the deficiency statement within 30 business days after the deficiency statement is sent. Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with the relevant section of law or regulation will be achieved. The timetable and compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. A plan of correction which does not meet the requirements of the relevant section of law or regulation shall be considered unacceptable by the Department and returned to the school storing or administering medications under 105 CMR 210.000 for correction and resubmission.

(D) Inspections pursuant to 105 CMR 210.017 may be conducted in conjunction with relevant licensure authorities or other law enforcement agencies.

210.019: Severability

If any provision of 105 CMR 210.000 is declared invalid or unenforceable, the other provisions shall not be affected thereby, but shall continue in full force and effect.

REGULATORY AUTHORITY

105 CMR 210.000: M.G.L. c. 94C, § 7(g); c. 71, § 54B.