

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Health Facilities and Emergency Medical Services Division**

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 24 - MEDICATION

ADMINISTRATION REGULATIONS

6 CCR 1011-1 Chapter 24

ADOPTED BY THE BOARD OF HEALTH ON APRIL 17, 2017. EFFECTIVE JULY 1, 2017

SECTION 1 – STATUTORY AUTHORITY AND APPLICABILITY

- 1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103 and 25-1.5-301 through 25-1.5-303, C.R.S.
- 1.2 Any licensed facility that administers medications to persons under its care shall comply with all applicable federal and state statutes and regulations, including but not limited to this Chapter 24.
- 1.3 Any facility, as defined herein, which administers medications to persons under its care but is not licensed by the Department may be required to comply with this Chapter 24 as a condition of operating its facility if so directed by its authorizing state agency.

SECTION 2 – DEFINITIONS

- 2.1 "Administration" means assisting a person in the ingestion, application, inhalation, or, using universal precautions, rectal or vaginal insertion of medication, including prescription drugs, according to the legibly written or printed directions of the attending physician or other authorized practitioner or as written on the prescription label and making a written record thereof with regard to each medication administered, including the time and the amount taken, but "administration" does not include judgment, evaluation, or assessments or the injections of medication, the monitoring of medication, or the self-administration of medication, including prescription drugs and including the self-injection of medication by the resident.

"Administration" also means ingestion through gastrostomy tubes or naso-gastric tubes, if administered by a person authorized pursuant to section 25.5-10-204(2)(j) and 27-10.5-103(2)(i), C.R.S., as part of residential or day program services provided through service agencies approved by the Department of Health Care Policy and Financing and supervised by a licensed physician or nurse.
- 2.2 "Approved training entity" means an agency, association, facility, individual, institution or organization that is approved by the Department to provide medication administration students with a suitable classroom and clinical experience.
- 2.3 "Approval" means recognition that a medication administration training program meets the standards established by the Department.
- 2.4 "Authorized practitioner" means the attending physician or other individual authorized by law to prescribe treatment, medication or medical devices who holds a current unrestricted license to practice and is acting within the scope of such authority.
- 2.5 "Classroom" means that portion of the training program in which medication administration students receive instruction in the principles that form the basis for safe medication administration and conform to the requirements of this Chapter 24. The classroom portion of the training program may be conducted either electronically or in person.

- 2.6 "Competency evaluation" means either:
- (A) The examination offered by an approved training entity that must be taken and passed as a condition of becoming a qualified medication administration person, or
 - (B) The written and clinical examination administered by the Department before July 1, 2017.
- 2.7 "Controlled substance" means any medication that is regulated and classified by the Controlled Substances Act at 21 U.S.C. §812 as being schedule II through V.
- 2.8 "Course content" means the classroom and skills practice that the training entity is required to deliver as a condition of Department approval.
- 2.49 "Department" means the Department of Public Health and Environment.
- 2.210 "Facility" for purposes of this Chapter means:
- (A) Correctional facilities under the supervision of the Executive Director of the Department of Corrections;
 - (B) Juvenile facilities operated by or under contract with the Department of Human Services, as set forth in section 19-2-401, et seq., C.R.S.;
 - (C) Assisted living residences as defined in section 25-27-102(1.3), C.R.S.;
 - (D) Adult foster care facilities provided for in section 26-2-122.3, C.R.S.;
 - (E) Alternate care facilities provided for in section 25.5-6-303(3), C.R.S.;
 - (F) Residential child care facilities for children as defined in section 26-6-102(8), C.R.S.;
 - (G) Secure residential treatment centers as defined in section 26-6-102(9), C.R.S.;
 - (H) Facilities that provide treatment for persons with mental illness as defined in section 27-65-102(7), C.R.S, except for those facilities which are publicly or privately licensed hospitals;
 - (I) All services funded through and regulated by the Department of Health Care Policy and Financing pursuant to Article 6 of Title 25.5, C.R.S., in support of persons with intellectual and developmental disabilities; and
 - (J) Adult day care facilities providing services in support of persons as defined in section 25.5-6-303(1), C.R.S.
- 2.11 "Medication administration training program" (hereinafter referred to as "training program") means a course of study that is approved by the Department that meets the requirements of this Chapter.
- 2.312 "Medication reminder box" means a container that is compartmentalized and designed to hold medications for distribution according to a time element such as day, week, or portions thereof.
- 2.13 "Monitoring" means

- (A) Reminding the resident to take medication(s) at the time ordered by the authorized practitioner;
 - (B) Handing a resident a container or package of medication that was lawfully labeled previously by an authorized practitioner for the individual resident;
 - (C) Visual observation of the resident to ensure compliance;
 - (D) Making a written record of the resident's compliance with regard to each medication, including the time taken; and
 - (E) Notifying the authorized practitioner if the resident refuses or is unable to comply with the practitioner's instructions regarding the medication.
- 2.14 "Nurse" means an individual who holds a current unrestricted license to practice pursuant to Article 38 of Title 12, C.R.S., and is acting within the scope of such authority.
- 2.15 "Qualified manager" means a person who:
- (A) Is the owner or operator of the facility or a supervisor designated by the owner or operator of the facility for the purpose of implementing sections 25-1.5-303, C.R.S., and
 - (B) Has completed training in the administration of medication pursuant to section 25-1.5-303, C.R.S., or is a licensed nurse, licensed physician, or licensed pharmacist in the State of Colorado.
- 2.16 "Program coordinator" means the individual designated by an approved training entity who acts as liaison to the Department and is responsible for transmitting the names of students who have passed the training entity's competency examination, applicable fees and course content updates.
- 2.17 "Qualified instructor" means a nurse, pharmacist, physician or physician assistant with an active, unrestricted Colorado license.
- 2.18 "Qualified medication administration person" or "QMAP" means an individual who passed a competency evaluation administered by the Department before July 1, 2017, or passed a competency evaluation administered by an approved training entity on or after July 1, 2017 and whose name appears on the Department's list of persons who have passed the requisite competency evaluation.
- 2.19 "Self-administration" means the ability of a person to take medication independently without any assistance from another person.
- 2.20 "Skills practice" means that portion of the training program where students in a simulated care setting practice medication administration skills and application of classroom principles under the direct supervision of qualified instructors. The skills practice portion of the training program shall be conducted in person and not electronically.

SECTION 3 – FACILITY RESPONSIBILITIES

- 3.1 Each facility shall ensure that there is a qualified medication administration person onsite any time medication is administered, including when medication is administered pro re nata (PRN) or "as needed."

- 3.2 Each owner, operator or supervisor of a facility that employs a person who is not licensed to administer medications shall conduct a criminal background check on each employee prior to employment or promotion to a position in which he or she has access to medications.
- 3.3 Each facility shall establish, follow and maintain a written policy and procedure concerning criminal background checks required by section 3.2. Such policy and procedure shall include, at a minimum:
- (A) Criteria for the investigation and evaluation of any criminal offenses revealed by the background check, and
 - (B) Criteria for monitoring any person hired with a criminal offense history.
- 3.4 A facility shall require each qualified medication administration person or qualified manager, as a condition of employment or promotion to a position where the individual has access to medications, to sign a disclosure statement under penalty of perjury stating that he or she has never had a professional license to practice nursing, medicine, or pharmacy revoked in Colorado or any other state for reasons directly related to the administration of medications.
- 3.5 A facility that employs or contracts with a person who is not licensed to administer medications shall verify that the person's name is included on the Department's list of qualified medication administration persons.
- 3.6 The operator or administrator of each facility that hires a qualified medication administration person shall provide such person with on-the-job training that focuses on the unique needs of the facility.
- 3.7 A facility shall ensure that each qualified medication administration person hired on or after July 1, 2017, is adequately supervised until he or she has successfully completed the training.
- 3.8 The facility shall retain documentation of compliance with sections 3.2 through 3.7.

SECTION 4 - PROCEDURES FOR TRAINING ENTITY APPROVAL

- 4.1 Any agency, association, facility, individual, institution or organization desiring to become an approved training entity shall:
- (A) Submit an application and all required attachments concerning its medication administration training program in the form and manner required by the Department, and
 - (B) Designate a program coordinator who shall be responsible for compliance with this Chapter.
- 4.2 A training entity shall not enroll students in a medication administration training program until it has received approval from the Department. Students attending and completing a non-approved program are not eligible for inclusion on the Department's public list of individuals who have passed the QMAP competency evaluation and a facility shall not allow such individual to administer medications.

SECTION 5 - TRAINING PROGRAM ADMISSIONS

- 5.1 The approved training entity shall ensure that all applicants wishing to enroll in a training program to become a medication administration person provide proof of being at least eighteen (18) years of age.

- 5.2 The approved training entity shall provide each applicant, prior to enrollment, with a written statement regarding the basic reading, writing and math skills that an applicant is expected to possess in order to successfully complete the course.

SECTION 6 – TRAINING PROGRAM COURSE CONTENT

- 6.1 The course content shall be developed, implemented and managed by the training entity and approved by the Department.
- (A) Each approved training entity shall, prior to implementation, promptly provide the Department with information concerning any anticipated changes that significantly alter the approved course content or competency evaluation.
- 6.2 The course content shall contain the required items specified by the Department and contained in this Chapter.
- 6.3 Classroom and skills practice in the required content must be completed before students proceed to the competency examination.
- 6.4 Classroom and skills practice shall be taught and overseen by a qualified instructor.
- 6.5 The competency evaluation shall include written and practical skills testing and be administered by a qualified instructor who shall document each student's success with the competencies.
- (A) The written portion of the competency evaluation shall cover, at a minimum, all the required curriculum content set forth in section 6.7 of this Chapter.
- (B) The practical skills portion of the competency evaluation shall assess, at a minimum, whether each student is capable of safe, sanitary and accurate medication administration from preparation to allowable routes of administration and documentation.
- 6.6 Approved training entities shall retain student competency evaluation records for a minimum of three years.
- 6.7 The course content shall include classroom and skills practice in all of the following areas:
- (A) The principles of administering medications that include, at a minimum:
- (1) The scope of service of a qualified medication administration person including, but not limited to:
- (a) Authorized settings and requirements,
 - (b) Medication restrictions,
 - (c) Roles, responsibilities and cautions,
 - (d) Seven rights of medication administration,
 - (e) Routes and forms of acceptable medication administration,
 - (f) Reading, understanding and validating medication orders, and
 - (g) Expiration and refill dates.

- (2) The uses and forms of drugs including but not limited to:
 - (a) The purpose of prescribed medications.
 - (b) Controlled substance classification and accountability.
 - (c) Medication effects including therapeutic, side, and adverse effects.
 - (d) When, where and how to properly navigate appropriate medication reference resources.
 - (3) Medication administration records (MARs) including, but not limited to:
 - (a) Medication timing options (specified vs. time window), and
 - (b) Rules and practice for documenting administration of medication to resident or client.
 - (4) Communication and interpersonal skills for addressing unique needs and behaviors of individuals who are elderly, have impaired physical capacity, impaired cognitive ability, behavioral issues, dementia and/or Alzheimer's.
 - (5) Infection control.
 - (6) Safety and emergency procedures
 - (7) Drug diversion awareness.
 - (8) Preventing and reporting abuse, neglect and misappropriation of resident or client property.
- (B) Medication administration procedures including, but not limited to:
- (1) Administering, monitoring and self-administration,
 - (2) Administering PRN medications in accordance with scope of practice,
 - (3) Standards, precautions and safe practice,
 - (4) Preparing or altering medication for administration in accordance with manufacturer's instructions and authorized practitioner's orders,
 - (5) Counting, administering and documenting controlled substances,
 - (6) Proper documentation of medication administration,
 - (7) Determining, documenting and reporting medication errors,
 - (8) Medication storage and disposal, and
 - (9) Filling and administration of medication reminder boxes and day/trip packs.

SECTION 7 – MEDICATION ADMINISTRATION PRACTICE STANDARDS

- 7.1 Prescription and non-prescription medications shall be administered by qualified medication administration persons only upon written order of an authorized practitioner. Such orders shall be current for all medications.
- (A) New orders from an authorized practitioner shall be obtained and followed whenever a resident or client returns to the facility after an inpatient hospitalization.
- 7.2 Non-prescription medications shall be labeled with the recipient's full name.
- 7.3 No resident or client shall be allowed to take another's medication and staff shall not give medication to anyone other than the resident or client for whom it was ordered.
- 7.4 Qualified medication administration persons shall not administer medication through a gastrostomy tube or administer insulin unless specifically authorized to do so pursuant to rules adopted by the Department of Health Care Policy and Financing or the Department of Human Services.
- 7.5 A qualified medication administration person shall not administer epinephrine injections unless the QMAP:
- (A) Has been directed to do so by a 911 emergency call operator as an urgent first aid measure, or
- (B) Has completed an anaphylaxis training program conducted by a nationally recognized organization and is authorized to use an epinephrine injector pursuant to section 25-47-103, C.R.S.
- 7.6 The contents of any medication container having either no label or an illegible label shall be destroyed immediately.
- 7.7 Medication that has a specific expiration date shall not be administered after that date.
- 7.8 For all medications managed by a facility, there shall be documentation that discontinued, out dated, or expired medications are returned to the resident, client or legal representative with instructions for their proper disposal or promptly disposed of by the facility if the resident, client or legal representative consents.

SECTION 8 – MEDICATION REMINDER BOXES OR SYSTEMS

- 8.1 Residents or clients who self-administer medication may use medication reminder boxes. Facilities using medication reminder boxes for persons who are not self-administering shall have a nurse or qualified medication administration person available to assist with or administer from the medication reminder box.
- 8.2 Only authorized practitioners, nurses or qualified medication administration persons are allowed to assist residents or clients with medication reminder boxes.
- (A) Each qualified medication administration person assisting a resident or client with a medication reminder box shall be familiar with the type and quantity of medication in each compartment of the box.
- 8.3 Each qualified medication administration person assisting with or administering from a medication reminder box shall, immediately after assisting or administering, record the assist or administration on medication administration record forms developed or acquired and maintained by the facility.

- (A) The medication administration record shall contain complete instructions for the administration of each medication.
 - (B) The medication administration record shall contain a specific entry for each medication given that includes the date, time and amount of the medication, and the signature of the person administering the medication.
- 8.4 The facility shall be responsible for administering the correct medications to its residents or clients in a manner consistent with the provisions of section 25-1.5-303, C.R.S.
- 8.5 Medication reminder boxes or systems are allowable only if such containers have been filled and properly labeled by a pharmacist licensed pursuant to Article 42.5 of Title 12, C.R.S., a nurse licensed pursuant to Article 38 of Title 12, C.R.S, a qualified medication administration person, or through the gratuitous care of family members or friends of the resident or client.
- 8.6 The facility shall ensure that a label is attached to each medication reminder box.
- (A) The information on the label shall include the name of the resident or client, each medication, the dosage, the quantity, the route of administration, and the time that each medication is to be administered.
 - (B) The facility shall ensure that each medication reminder box has a corresponding medication administration record where all administrations are documented immediately after administration.
 - (C) If AN authorized practitioner orders a change in any medication for the resident, the facility shall discontinue use of the medication reminder box until it has been properly refilled according to the change ordered.
- 8.7 If any medication in the medication reminder box is not consistent with the labeling, the qualified medication administration person shall not administer the medication to the resident or client and shall immediately notify the proper person as outlined in the policies and procedures of the facility.
- (A) For purposes of this paragraph, the proper person shall be whoever filled the medication reminder box or the authorized practitioner who prescribed the medication(s).
 - (B) Once the problem with the medication(s) is resolved and all medications are correctly assigned to the appropriate compartments of the medication reminder, the qualified medication administration person may resume the administration or assistance to the resident or client from the medication reminder box.
- 8.8 Any medication problem shall be resolved prior to the next administration.
- 8.9 PRN or "as needed" medications of any kind shall not be placed in a medication reminder box. Only medications intended for oral ingestion shall be placed in the medication reminder BOX.
- (A) Medications that require administration according to special instructions, including but not limited to instructions such as "30 minutes or an hour before meals," rather than administered routinely shall not be placed in a medication reminder.
- 8.10 Medications in the medication reminder box shall only be used at the time specified on the box. Medication reminder boxes shall not be filled for more than two weeks at a time.

- 8.11 Any medication reminder “day packs” or individual “trip packs” assembled for administration outside the facility shall comply with the requirements of this section 8.

SECTION 9 – STORAGE OF MEDICATION

- 9.1 All medication shall be stored on-site including medication that is placed in a medication reminder box and filled by staff, a family member or other designated person.
- 9.2 All controlled substances shall be stored under double lock, counted and signed for at the end of every shift in the presence of either two (2) QMAPS or a QMAP and a qualified manager.
- (A) If the above procedure is not possible, the QMAP going off-duty shall count and sign for the controlled substances and the next on-duty QMAP shall verify the count and sign. If the count cannot be verified, the discrepancy shall be immediately reported to the facility administrator.
- 9.3 All prescription and non-prescription medication shall be maintained and stored in a manner that ensures the safety of all residents or clients.
- 9.4 Medication shall not be stored with disinfectants, insecticides, bleaches, household cleaning solutions, or poisons.