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, et seq., 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 XXIV.

SECTION 2 – DEFINITIONS

2.1 "Department" means the Department of Public Health and Environment.

2.2 "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 Human Services pursuant to article 10.5 of Title 27, C.R.S., in support of persons with 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.
2.3 "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.

2.4 "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 section 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.

2.5 "Qualified medication administration staff member" or "QMAP" means a person who has passed the department's competency evaluation and:

(A) Is trained and employed by a facility on a full or part-time basis to provide direct care service including medication administration to the facility's residents, or

(B) Is utilized by a facility on a contractual, full or part-time basis to provide direct care services including medication administration to the facility's residents.

(1) The term qualified medication administration staff member does not apply to intermittent, temporary or pool staffing services provided by agencies offering such services.

2.6 "Self-administration" means the ability of a person to take medication independently without any assistance from another person.

SECTION 3 – GENERAL PROVISIONS

3.1 The facility shall ensure that there is a qualified medication administration staff member onsite any time medication is administered, including when medication is administered "as needed" or "PRN."

3.2 The facility shall maintain payment or other documentation verifying the employment status of each qualified medication administration staff member.

(A) If the qualified medication administration staff member is a contract employee, documentation shall consist of the employment contract and include the following:

(1) The name of the specific person who is trained in medication administration and will be providing those services;

(2) Verification that the person's direct care and medication administration services will only be provided to the residents of the licensed facility; and

(3) Verification that the facility is paying for this person's services.

3.3 The department shall maintain a list on its web site of all qualified medication administration staff members who have passed the competency evaluation.

3.4 Every unlicensed person who is a "qualified manager" shall pass the competency evaluation approved by the department pertaining to the administration of medications at least once every four years.
3.5 The facility shall report to the department if a QMAP or qualified manager engages in a pattern of deficient medication administration practice or administers medication contrary to a physician’s order or these rules that either causes or has the potential to cause harm to the recipient. Such report shall be made no later than the next business day after the occurrence or no later than the next business day after the facility becomes aware of the occurrence.

SECTION 4 – POLICIES AND PROCEDURES

4.1 All licensed facilities shall maintain and follow written policies and procedures for the administration of medication that are consistent with the regimen taught in the medication administration course.

4.2 Pursuant to section 25-1.5-302(8), C.R.S., each facility that employs a person who is not licensed to administer medications shall conduct a drug-related criminal background check on each person prior to employment.

   (A) All licensed facilities shall establish, follow and maintain a written policy and procedure concerning drug-related criminal background checks. Such policy and procedure shall include, at a minimum:
       (1) Criteria for the investigation and evaluation of any drug-related offenses revealed by the background check;
       (2) Criteria for monitoring any person hired with prior drug-related offenses; and
       (3) Sufficient record keeping to document compliance with items (1) and (2).

4.3 Facility operators and administrators shall require each unlicensed person who administers medication in the facility to pass the competency evaluation developed or approved by the department pursuant to section 25-1.5-302(2), C.R.S., as a condition of employment in that facility at least once every five years. QMAPs who have not retested in the five years prior to January 1, 2010, shall do so as soon as practicable, but no later than January 1, 2012.

   (A) Facility operators and administrators shall document each unlicensed person’s satisfactory completion of on-the-job training and passage of the competency evaluation in his or her permanent personnel file.

   (B) If an existing QMAP does not successfully complete the competency evaluation within the time limits established in this section 4.3, the facility shall immediately cancel that individual’s medication administration responsibility and so notify the department.

SECTION 5 – ADMINISTRATION OF MEDICATION

5.1 The term “administration” of medication does not include judgment, evaluation, assessment or monitoring of medication.

5.2 Prescription and non-prescription medications shall be administered only by qualified medication administration staff members and only upon written order of a licensed physician or other licensed authorized practitioner. Such orders shall be current for all medications.

   (A) New orders from either a physician, physician’s assistant or advance practice nurse with prescriptive authority shall be obtained and followed whenever a patient or resident returns to the facility after an inpatient hospitalization.

5.3 Non-prescription medications shall be labeled with resident's full name.
5.4 No resident shall be allowed to take another's medication nor shall staff be allowed to give one resident's medication to another resident.

5.5 Unless otherwise authorized by statute, qualified medication administration staff members shall not:

(A) Administer medication through a gastrostomy tube, or

(B) Prepare, draw up or administer medication in a syringe for injection into the bloodstream or skin, including insulin pens.

5.6 The contents of any medication container having no label or with an illegible label shall be destroyed immediately.

5.7 Medication that has a specific expiration date shall not be administered after that date.

5.8 Each facility shall document the disposal of discontinued, out-dated, or expired medications.

SECTION 6 – MEDICATION REMINDER BOXES OR SYSTEMS

6.1 Residents who self-administer medication may use medication reminder boxes. Facilities using medication reminder boxes for persons who are not self-administering shall have a QMAP available to assist with or administer from the medication reminder box.

6.2 Only QMAPs may assist residents with medication reminder boxes.

(A) Each QMAP assisting a resident with a medication reminder box shall be familiar with the type and quantity of medication in each compartment of the box.

6.3 Each QMAP assisting with or administering from a medication reminder box shall, immediately after assisting or administering, record the assist or administration on medication 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.

6.4 The facility shall be responsible for administering the correct medications to its residents in a manner consistent with the provisions of section 25-1.5-303, C.R.S.

6.5 A licensed pharmacist shall prepare medications for each medication reminder box in a registered prescription drug outlet or other outlet and in accordance with sections 12-22-121(4) and 12-22-123, C.R.S.

(A) If a physician or other authorized practitioner orders a change in any medication for the resident, the facility shall discontinue use of the medication reminder until the pharmacist has refilled it according to the change ordered.
6.6 If a licensed nurse or QMAP fills the medication reminder box or a family member or friend gratuitously fills it, the facility shall ensure that a label is attached to the box. If the medication reminder box has a labeling system, such labeling system may be used.

(A) The information on the label shall include the name of the resident, 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 record where all administrations are documented immediately after administration. If a physician or other authorized practitioner orders a change in any medication for the resident, the facility shall discontinue use of the medication reminder box until the nurse, QMAP designated by the qualified manager, family member or friend has refilled the box according to the change ordered.

6.7 If any medication in the medication reminder box is not consistent with the labeling, administration or assistance to the resident shall not proceed and the qualified medication administration staff member 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 resident's physician or other licensed 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 staff member may resume the administration or assistance to the resident from the medication reminder box.

6.8 Any medication problem shall be resolved prior to the next administration.

6.9 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.

(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.

6.10 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.

6.11 Any medication reminder "day packs" or individual "trip packs" assembled for administration outside the facility shall comply with the requirements of this section 6.

SECTION 7 – STORAGE OF MEDICATIONS

7.1 All medication shall be stored on-site including medication that is placed in a medication reminder box and filled by staff, family member or other designated person.
7.2 All controlled substances as defined in section 12-22-303, C.R.S., 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.

7.3 All prescription and non-prescription medication shall be maintained and stored in a manner that ensures the safety of all residents.

7.4 Medication shall not be stored with disinfectants, insecticides, bleaches, household cleaning solutions, or poisons.

SECTION 8 – CONTRACT INSTRUCTORS

8.1 The medication administration curriculum may be taught by a person who contracts with the department or is otherwise approved by the department to teach an approved curriculum and holds a valid license in good standing as a physician, nurse, pharmacist or physician assistant.

8.2 All private contractors shall provide the department with a list of all persons who have taken the contractor’s approved training sessions and/or have passed the competency evaluation. Said list shall be provided to the department within fifteen (15) days of the training session or evaluation.

(A) Such contractors shall also provide the department with any other pertinent information reasonably requested by the department pursuant to its authority under this Chapter.

SECTION 9 – DEPARTMENT OVERSIGHT

9.1 Each QMAP and qualified manager shall 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.

(A) Any misrepresentation or falsification of an individual’s disclosure shall constitute good cause for the department to rescind that individual’s medication administration authority.

(B) Each QMAP and qualified manager shall notify the department within ten (10) days of any change in the information previously disclosed.

9.2 If the department determines, after an investigation, that a QMAP or qualified manager has engaged in a pattern of deficient medication administration practice or has administered medication contrary to a physician’s order or these rules that either causes or has the potential to cause harm to the recipient, the department shall rescind that individual’s medication administration authority until the individual undergoes retraining, retesting, and successfully passes the competency examination.

9.3 Compliance with this Chapter XXIV is a condition of licensure for any facility licensed by the department that administers medications to persons under its care. Failure to comply may result in the department taking action against the facility’s license pursuant to 6 CCR 1011-1, Chapter II and section 24-4-104, C.R.S.
**Editor’s Notes**

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the All Versions list on the rule’s current version page. To view versions effective on or after 05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap 04 or 6 CCR 1011-1 Chap 18.

**History**

Chapter 24 entire rule eff. 12/30/2009.

Chapter 24 Sections 2.2 – 2.6, 4.2 eff. 06/30/2011.